

## World AIDS Day — December 1, 2015

World AIDS Day, observed on December 1, draws attention to the current status of the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) epidemic worldwide. This year's theme is World AIDS 2015: The Time to Act is Now.

The first cases of AIDS were reported more than 30 years ago, in the June 5, 1981 issue of *MMWR*. At the end of 2014, approximately 36.9 million persons worldwide were living with HIV infection (1). Although AIDS-related deaths have decreased by 42% since 2004, an estimated 1.2 million persons died from AIDS in 2014 (1).

Global efforts, including the U.S. President's Emergency Plan for AIDS Relief (in which CDC is a principal agency), have resulted in approximately 13.5 million persons in low- and middle-income countries receiving antiretroviral therapy (ART) for HIV infection in 2014 (2). Globally, approximately 15 million persons are on ART (1). An estimated 1.2 million persons in the United States and Puerto Rico are living with HIV infection (3) and approximately 50,000 persons become infected with HIV each year (4).

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## Lower Levels of Antiretroviral Therapy Enrollment Among Men with HIV Compared with Women — 12 Countries, 2002–2013

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Equitable access to antiretroviral therapy (ART) for men and women with human immunodeficiency virus (HIV) infection is a principle endorsed by most countries and funding bodies, including the U.S. President's Emergency Plan for AIDS (acquired immunodeficiency syndrome) Relief (PEPFAR) (1). To evaluate gender equity in ART access among adults (defined for this report as persons aged  $\geq 15$  years), 765,087 adult ART patient medical records from 12 countries in five geographic regions\* were analyzed to estimate the ratio of women to men among new ART enrollees for each calendar year during 2002–2013. This annual ratio was compared with estimates from the Joint United Nations Programme on HIV/AIDS (UNAIDS)<sup>†</sup> of the ratio of HIV-infected adult women to men in the general population. In all 10 African countries and Haiti, the most recent estimates of the ratio of adult women to men among new ART enrollees significantly exceeded the UNAIDS

estimates for the female-to-male ratio among HIV-infected adults by 23%–83%. In six African countries and Haiti, the ratio of women to men among new adult ART enrollees increased more sharply over time than the estimated UNAIDS female-to-male ratio among adults with HIV in the general population. Increased ART coverage among men is needed to decrease their morbidity and mortality and to reduce HIV incidence among their sexual partners. Reaching more men with HIV testing and linkage-to-care services and adoption of test-and-treat ART eligibility guidelines (i.e., regular testing of adults, and offering treatment to all infected persons with ART, regardless of CD4 cell test results) could reduce gender inequity in ART coverage.

Three approaches to sampling and analysis were employed in the 12 studied countries (Table). In Botswana, Haiti, Mozambique, and Namibia, where large, centralized, electronic ART patient monitoring systems are employed, all available data from 2002–2013 were analyzed. In each of these countries, 67%–100% of all ART patients and 58%–100% of all ART facilities were captured in the electronic system. In Côte d'Ivoire, Nigeria, Swaziland, Vietnam, and Zimbabwe, nationally representative samples of ART facilities were selected, with probability of selection proportional to size. In Tanzania, Uganda, and Zambia, health facilities were purposively selected by investigators to represent the range of ART facilities in each country and ensure that the study remained feasible. Among the eight sample-based surveys, a sample frame of study-eligible ART patients was created at each selected facility, and simple

\* *East Africa*: Tanzania, Uganda; *Southern Africa*: Botswana, Mozambique, Namibia, Swaziland, Zambia, Zimbabwe; *West Africa*: Côte d'Ivoire, Nigeria; *Caribbean*: Haiti; *Southeast Asia*: Vietnam.

<sup>†</sup> Additional information available at <http://aidsinfo.unaids.org/>.

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TABLE. Study designs for antiretroviral therapy (ART) cohort evaluations — 12 countries, 2002–2013

Region	Country	Assessment year	Stage 1: selection of study sites				Stage 2: selection of study patients							
			No. clinics	No. study-eligible clinics*	No. adult clinic enrollees	Estimated no. study-eligible adult ART enrollees at study-eligible clinics	Site sampling technique	No. clinics selected	Age at ART initiation (yrs)	ART enrollment years	Patient sampling technique at selected study clinics	Planned sample size*	No. eligible medical records analyzed	Dates of data collection
East Africa	Tanzania	2007	210	85	41,920	37,728	Purposive	6	≥18	2004–2009	SRS	1,500	1,457 <sup>†</sup>	04–07/2010
	Uganda	2007	286	114	45,946	41,351	Purposive	6	≥18	2004–2009	SRS	1,500	1,466 <sup>‡</sup>	04–07/2010
Southern Africa	Botswana	2014	302	176	247,856	217,082	Census	176	≥15	2002–2013	Census	217,082	217,082	10/2013
	Mozambique	2014	288	170	456,055	306,335	Census	170	≥15	2004–2013	Census	306,335	306,335	04/2014
	Namibia	2013	213	213	140,224	138,054	Census	213	≥15	2003–2012	Census	138,054	138,053 <sup>¶</sup>	12/2013
	Swaziland	2009	31	31	50,767	50,767	PPS	16	≥15	2004–2010	SRS	2,500	2,510	11/2011–02/2012
	Zambia	2007	322	129	65,383	58,845	Purposive	6	≥18	2004–2009	SRS	1,500	1,214 <sup>**</sup>	04–07/2010
	Zimbabwe	2008	104	70	103,806	93,811	PPS	40	≥15	2007–2009	SRS	4,000	3,896 <sup>††</sup>	01–06/2010
West Africa	Côte d'Ivoire	2007	124	78	36,943	36,110	PPS	34	≥15	2004–2007	SRS	4,000	3,682	11/2009–03/2010
	Nigeria <sup>§§</sup>	2009	178	139	168,335	167,438	PPS	35	≥15	2004–2011	SRS	3,500	3,496	12/2012–08/2013
Caribbean	Haiti	2013	149	149	52,120	78,317	Census	149	≥15	2002–2013	Census	78,317	78,317	04/2014
Southeast Asia	Vietnam	2009	173	120	28,090	25,000	PPS	30	≥15	2005–2009	SRS	7,587	7,579 <sup>¶¶</sup>	01–06/2010
<b>Total</b>			<b>2,380</b>	<b>1,474</b>	<b>1,385,325</b>	<b>1,250,838</b>		<b>881</b>				<b>765,875</b>	<b>765,087</b>	

**Abbreviations:** PPS = probability-proportional-to-size; SRS = simple random sampling.

\* To keep sample-based studies feasible, in Côte d'Ivoire, Nigeria, Vietnam, and Zimbabwe, only facilities with ≥50 adults on ART were eligible for sampling, whereas in Tanzania, Uganda, and Zambia only facilities that had enrolled ≥300 adults on ART were eligible.

<sup>†</sup> In Tanzania, record of one patient was excluded from 1,458 sampled because of missing age data at ART initiation.

<sup>‡</sup> In Uganda, records of six patients were excluded from 1,472 sampled because of missing age data at ART initiation.

<sup>¶</sup> In Namibia, among those adults enrolled on ART during 2003–2012, one patient with missing gender information was excluded from analysis.

<sup>\*\*</sup> In Zambia, 243 of 1,457 records sampled were excluded because of noncompliance with simple random sampling procedures at one site.

<sup>††</sup> In Zimbabwe, 23 selected patients with either missing gender (n = 12) or missing outcome (n = 11) were excluded from analysis.

<sup>§§</sup> In Nigeria, implicit stratification was used in the sampling approach.

<sup>¶¶</sup> In Vietnam, among observations from 7,587 records sampled, four were excluded because of lack of gender information and four because of lack of outcome date.

random sampling was used to select the sample of records. Eligibility criteria included initiation of ART ≥6 months before data abstraction, during 2002–2013, and at age ≥15 years. Data were abstracted from ART records onto standardized abstraction forms by trained study personnel.

For each of the 12 countries, the ratio of women to men who were newly enrolled in ART during 2002–2013 was compared with the current ratio of women to men among cumulative ART patients who were alive on ART by the end of each calendar year and with UNAIDS estimates of the ratio of women to men among adults living with HIV for each calendar year. To assess a country's ART program accessibility to women with HIV compared with men with HIV, the percent difference between the most recently available female-to-male new ART enrollee ratio and the UNAIDS estimate of the ratio of women to men among persons with HIV in the general population for the same calendar year was calculated. Data were analyzed using statistical software, and study design was controlled for during analyses.

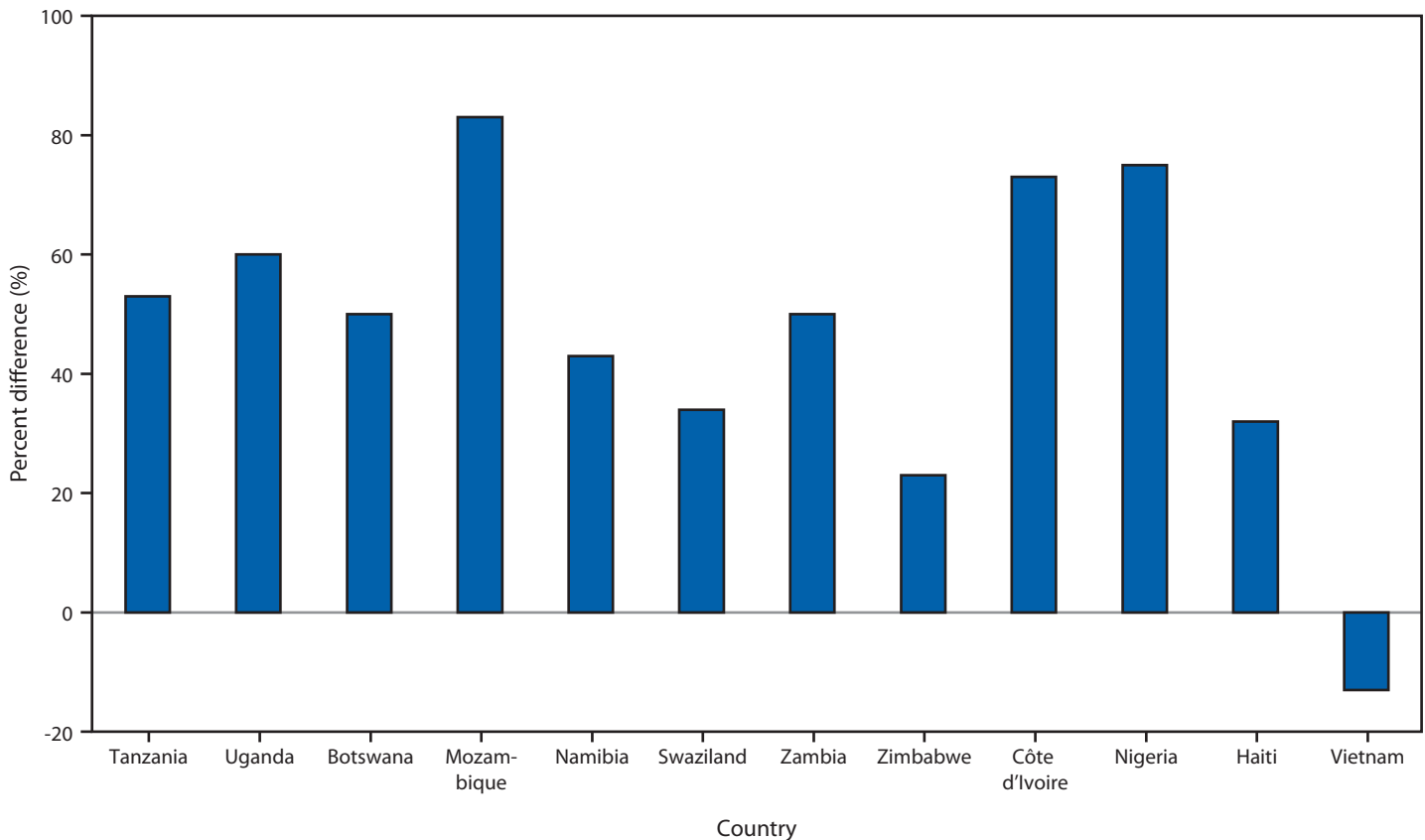
Across the 12 countries, 765,087 adult ART patient records were analyzed. (Graphs of data for all countries are

available online at <http://stacks.cdc.gov/view/cdc/35684>.) In all countries except Vietnam, the most recent estimates of the female-to-male ratio among new ART enrollees, and the ratio of women to men currently enrolled in ART exceeded the UNAIDS female-to-male ratios among persons with HIV. In addition, in seven countries (Botswana, Côte d'Ivoire, Haiti, Nigeria, Mozambique, Swaziland, and Zambia), point estimates of the ratio of female-to-male new ART enrollees increased more sharply over time than did the UNAIDS female-to-male ratios among persons with HIV. The trends in female-to-male ratios of current ART enrollees closely paralleled the new ART enrollee ratio trends.

In east Africa, the most recent female-to-male new ART enrollee ratios were 2.10 in both Tanzania and Uganda for 2009; in contrast, the 2009 UNAIDS female-to-male ratios among adults with HIV were 1.38 and 1.31, respectively. Compared with males, adult females with HIV were approximately 53% and 60% more likely to access ART in Tanzania and Uganda, respectively (Figure).

In southern Africa, the most recent female-to-male new ART enrollee ratios were 1.95 in Botswana (2013); 2.73 in

**FIGURE. Percent difference between female-to-male new antiretroviral therapy enrollee ratios and corresponding UNAIDS ratios of females to males among all persons with HIV, by country\* — 12 countries, 2002–2013**



**Abbreviations:** AIDS = acquired immunodeficiency syndrome; HIV = human immunodeficiency virus; UNAIDS = Joint United Nations Programme on HIV/AIDS.  
\* *East Africa:* Tanzania, Uganda; *Southern Africa:* Botswana, Mozambique, Namibia, Swaziland, Zambia, Zimbabwe; *West Africa:* Côte d'Ivoire, Nigeria; *Caribbean:* Haiti; *Southeast Asia:* Vietnam.

Mozambique (2013); 1.61 in Namibia (2012); 1.91 (95% confidence interval [CI] = 1.70–2.13) in Swaziland (2010); 1.57 in Zambia (2009); and 1.76 (95% CI = 1.53–1.99) in Zimbabwe (2009); whereas the corresponding calendar year UNAIDS female-to-male ratios among adults with HIV for these countries were 1.30, 1.49, 1.13, 1.43, 1.05, and 1.43, respectively. Compared with males living with HIV in southern Africa, females living with HIV were 23%–83% more likely to access ART (Figure).

In west Africa, the most recent female-to-male new ART enrollee ratios were 2.21 (95% CI = 1.77–2.64) in Côte d'Ivoire (2007) and 2.34 (95% CI = 1.86–2.83) in Nigeria (2011); the corresponding calendar year UNAIDS female-to-male ratios among adults with HIV were 1.28 and 1.34, respectively. Compared with men, adult women with HIV were about 73% and 75% more likely to access ART in Côte d'Ivoire and Nigeria, respectively.

In Haiti in 2013, the female-to-male new ART enrollee ratio was 1.89, and the UNAIDS female-to-male ratio among persons with HIV was 1.43. Compared with men, adult

women with HIV were 32% more likely to access ART in 2013. Finally, in Vietnam in 2009, the female-to-male new ART enrollee ratio was 0.34 (95% CI = 0.27–0.41), which was similar to the UNAIDS female-to-male ratio among persons with HIV (0.39).

## Discussion

This analysis of 765,087 adult ART patient records from 12 countries is the most up-to-date and comprehensive assessment of disproportionate ART enrollment among adult women with HIV compared with men, in resource-limited settings (2). In 10 African countries and Haiti (countries with generalized HIV epidemics) women with HIV were more likely to access ART than men with HIV. In addition, in six African countries and Haiti, gender-related disparities in ART coverage appear to be increasing over time. The adult ART program sex distribution was largely reflective of the UNAIDS female-to-male ratio among persons with HIV in only one country, Vietnam.



Higher ART coverage among adult women with HIV in the African countries and Haiti could occur for a number of potential reasons. First, HIV testing and counseling is a part of routine antenatal care, which provides an early entry point to ART for women with HIV. Second, ART eligibility criteria are currently more inclusive for adult women with HIV than men because, to prevent mother-to-child transmission (PMTCT) for pregnant women with HIV, all 12 countries except Nigeria<sup>§</sup> have adopted guidelines recommending universal, lifelong ART, regardless of the results of the CD4 cell count test (referred to as PMTCT Option B+). Third, differences between men and women in health-seeking behavior might also play a role, with men considered more likely to delay access to health care for reasons that include stigma, male norms that discourage admitting ill health, and employment responsibilities, which might involve within-country and cross-border migration (3).

In many of the countries studied, gender inequity in ART coverage appears to be increasing. At the patient level, the recent initiation of PMTCT B+ might explain recent disproportionate accelerations in ART coverage among women in some countries (e.g., Mozambique initiated PMTCT B+ in 2013). However, at governance- and funder-levels, lack of initiatives to address gender inequities in ART coverage might result from tacitly holding men responsible for failing to access ART services, rather than assigning responsibility for improving male ART coverage to global health programs (4). Recent data show that men's health is often considered a lower priority than women's health in global health programs (5). However, this prioritization is not based on disease burden as estimated using disability-adjusted life years: HIV and the other nine top contributors to global disability-adjusted life years are more burdensome in men than in women (5).

Of the 12 countries studied, only Vietnam had female-to-male new ART enrollee ratios similar to UNAIDS female-to-male ratios among persons with HIV. A possible explanation is that Vietnam has a concentrated epidemic, affecting predominantly male persons who inject drugs, and therefore, from the beginning, the ART program in Vietnam has been focused on addressing the disease within this population (6). In Vietnam, men with HIV commonly access ART through routine HIV testing and counseling at needle and syringe exchange programs and methadone maintenance therapy clinics (6). In contrast, women with HIV primarily access HIV testing and linkage to ART via outreach activities to female sex workers, and through routine HIV testing at antenatal care clinics; this coverage was low in 2005, but is increasing (6,7). Continued monitoring of Vietnam's ART program gender ratios is warranted, as women account for increasing proportions of new HIV infections (6).

<sup>§</sup> Additional information available at <http://www.hivpolicywatch.org/>.

## Summary

### What is already known on this topic?

Equitable access to antiretroviral therapy (ART) for human immunodeficiency virus (HIV)-infected men and women is a principle endorsed by most countries and funding bodies, including the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).

### What is added by this report?

To evaluate gender equity in ART access, 765,087 adult ART patient medical records from 12 countries were analyzed to estimate the female-to-male new ART enrollee ratio for each calendar year during 2002–2013. This annual ratio was compared with corresponding Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates of adult female-to-male ratios among all persons with HIV. In all 10 African countries and Haiti, the most recent estimate of the ratio of women to men newly enrolled in ART significantly exceeded the UNAIDS estimate of the ratio of women to men among persons with HIV by 23%–83%.

### What are the implications for public health practice?

Reaching more men with HIV testing and linkage-to-care services and adoption of test-and-treat ART-eligibility guidelines could reduce gender inequity in ART coverage. Government- and donor-level policy and management shifts, including endorsement of male-health-focused strategies, performance-based financing that provides incentives to reach both men and women, and gender disaggregation of HIV treatment cohort data are also needed. Prioritizing increased ART coverage among men with HIV could decrease male morbidity and mortality and reduce HIV incidence among sexual partners.

The findings in this report are subject to at least four limitations. First, UNAIDS estimates of female-to-male ratios among all persons with HIV are derived from epidemic models with inherent uncertainty, limiting the ability to make statistical comparisons between UNAIDS-derived and cohort-derived ratios. Second, cohort data varied in size and generalizability. Third, this study analyzed average female-to-male ratios for adults; future analyses to examine effect modification across adult age groups are needed. Finally, this analysis did not evaluate gender ratios among persons being tested for HIV or linking to care, which would help explain observed ratios among ART enrollees.

Increasing ART coverage among men with HIV would reduce morbidity and mortality in this group and contribute to reducing HIV incidence among their sex partners (8), including adolescent girls and young women, a priority population for PEPFAR.<sup>¶</sup> Strategic program changes needed to reach more HIV-infected men with ART include identification of routine HIV testing systems, similar to HIV testing and counseling for women in antenatal care settings, and adoption of test-and-treat guidelines, which was recommended

<sup>¶</sup> Additional information available at <http://www.pepfar.gov/partnerships/ppp/dreams/index.htm>.

by the World Health Organization for the first time this year (9). Although more data on how to increase HIV testing and linkage to ART among HIV-infected men in resource-limited settings are needed, available evidence suggests a strategic combination of facility- and community-based approaches is required (10). From a program management perspective, ensuring that men are not overlooked in gender-related strategic documents prepared by funders (5), special initiatives to reach men with HIV, performance-based financing that provides incentives to reach both men and women, and tailored program evaluation strategies, including gender disaggregation of HIV treatment cohort data (5), are needed.

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## Scale-up of HIV Viral Load Monitoring — Seven Sub-Saharan African Countries

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To achieve global targets for universal treatment set forth by the Joint United Nations Programme on human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) (UNAIDS), viral load monitoring for HIV-infected persons receiving antiretroviral therapy (ART) must become the standard of care in low- and middle-income countries (LMIC) (1). CDC and other U.S. government agencies, as part of the President's Emergency Plan for AIDS Relief, are supporting multiple countries in sub-Saharan Africa to change from the use of CD4 cell counts for monitoring of clinical response to ART to the use of viral load monitoring, which is the standard of care in developed countries. Viral load monitoring is the preferred method for immunologic monitoring because it enables earlier and more accurate detection of treatment failure before immunologic decline. This report highlights the initial successes and challenges of viral load monitoring in seven countries that have chosen to scale up viral load testing as a national monitoring strategy for patients on ART in response to World Health Organization (WHO) recommendations. Countries initiating viral load scale-up in 2014 observed increases in coverage after scale-up, and countries initiating in 2015 are anticipating similar trends. However, in six of the seven countries, viral load testing coverage in 2015 remained below target levels. Inefficient specimen transport, need for training, delays in procurement and distribution, and limited financial resources to support scale-up hindered progress. Country commitment and effective partnerships are essential to address the financial, operational, technical, and policy challenges of the rising demand for viral load monitoring.

In 2014, UNAIDS launched "90-90-90" goals to increase to 90% by 2020 the proportion of persons living with HIV infection who know their status, the proportion of persons living with HIV infection receiving ART, and the proportion of persons living with HIV infection on ART who have achieved viral suppression (defined as HIV RNA concentration below the threshold needed for detection on a viral load assay) (1). Increasing viral load monitoring for ART patients will require lowering costs associated with viral load testing and improving access in LMIC. A global diagnostic access initiative was launched in 2014 by UNAIDS, which challenged the global community to work with manufacturers to provide reasonably

priced viral load testing, reducing the price of test kits to as low as \$10 per test (2).

By the first quarter in 2015, 15 million persons living with HIV infection were on ART globally (3). Recent results from the Strategic Timing of Anti-Retroviral Treatment trial demonstrated that early treatment reduced morbidity and mortality in persons with HIV infection (4). As a result, a greater demand for early ART initiation and viral load testing exists (4). In sub-Saharan Africa, where 11 million persons living with HIV infection are receiving ART (3), an estimated six million ART patients do not have access to viral load testing (5). Certain countries in sub-Saharan Africa have adopted the 2013 WHO recommendation to use routine viral load testing for monitoring treatment (6). This report highlights the initial successes and challenges of viral load monitoring as a national strategy in seven of these countries.

Côte d'Ivoire, Kenya, Malawi, Namibia, South Africa, Tanzania, and Uganda are in various stages of scaling up viral load monitoring. Routine laboratory and clinical data were collected by the ministries of health and CDC personnel from each country's laboratory database on the total number of ART patients, the total number of viral load tests, the number of viral load tests with laboratory-confirmed viral suppression, and the established target number of viral load tests for 2015 and 2016. In addition, information was collected from the laboratory database on the time from sample collection to return of results to the referring clinic. The directors of the national reference laboratories and CDC laboratory liaisons were asked to report operational challenges and successes to viral load monitoring scale-up. The pre-scale-up period was defined as the year before each government scaled up routine viral load monitoring for their country and the post-scale-up period as the time from scaling up routine viral load monitoring until June 2015.

South Africa initiated viral load monitoring in 2004 and scale-up for routine viral load monitoring in 2014 on the basis of the 2013 WHO HIV treatment recommendations. In Kenya, Malawi, Namibia, and Uganda, the pre-scale-up period was 2013, and the post-scale-up period was 2014–2015. For comparison purposes, the pre-scale-up period for South Africa was defined as 2013 and the post-scale-up period as

2014–2015. For Côte d'Ivoire and Tanzania, the pre–scale-up period was 2014 and the post–scale-up period was 2015. In 2015, the number of ART patients was highest in South Africa (2,951,159) and lowest in Namibia (131,721) (Table 1). In 2015, the number of ART patients with one or more viral load test ranged from 3,687 (Côte d'Ivoire) to 2,119,890 (South Africa). Among countries initiating routine viral load monitoring scale-up in 2014, the proportion of ART patients with viral load tests in the pre– and post–scale-up period increased from 8% to 38% in Kenya, 6% to 11% in Malawi, 54% to 95% in Namibia, and 5% to 10% in Uganda (Table 1). A slight increase was seen in South Africa between the pre– and post–scale-up periods, from 72%–75%. In the countries where routine viral load monitoring scale-up occurred in 2015, the proportion of ART patients with viral load tests was low and unchanged between the pre– and post–scale-up periods in Tanzania (from 2% to 3%) and in Côte d'Ivoire (from 4% to 3%).

In 2015, the proportion of viral load tests with viral suppression in countries initiating routine viral load monitoring scale-up in 2014 was 78% in South Africa, 83% in Kenya, 84% in Malawi, 86% in Namibia, and 94% in Uganda (Table 1). Between the pre– and post–scale-up periods, viral suppression levels increased by 30% in Kenya and 16% in Namibia, and changed little in Malawi, South Africa, and Uganda. In comparison, suppression levels decreased in Tanzania (from 80% to 72%) and in Côte d'Ivoire (from 66% to 53%) in 2015 (Table 1).

During the post–scale-up period, the average time from specimen collection to return of results to the referring clinic varied, from 3 days in South Africa to 31 days in Kenya (Table 1). Turnaround times increased between the pre– and post–scale-up periods in Kenya and Malawi, remained unchanged in South Africa and Côte d'Ivoire, and decreased in Namibia, Tanzania, and Uganda. Laboratory results were returned to clinics using various methods, including short message service printers, laboratory information systems, courier services, email, and use of specimen transport networks to reduce turnaround times.

Difficulties in specimen transport and lack of trained laboratory personnel were among the most common challenges reported in viral load monitoring scale-up (Table 2). Five countries reported success with innovations in laboratory information management systems and use of high-throughput viral load platforms. Four countries reported that strong partnerships and use of specimen referral networks, such as networks for transporting specimens from health facilities to referral laboratories for early infant HIV diagnosis, were integral to success.

The majority of countries did not achieve the targets established by each government for routine viral load monitoring in 2015, highlighting the efforts needed in sub-Saharan Africa to improve viral load monitoring coverage rates to achieve the 90–90–90 objectives. The forecasted viral load testing gap for 2016 could be narrowed in some countries with implementation of strategies, including policies on laboratory

**TABLE 1. Selected treatment and monitoring indicators for viral load (VL) monitoring scale-up during pre– and post–scale-up periods, by country — sub-Saharan Africa, 2013–2015**

Country	VL monitoring periods			Cumulative no. of ART patients		No. of ART patients with ≥1 VL test		ART patients with ≥1 VL test (%)		VL tests with viral suppression (%)*		Turnaround time†		Established target number of VL tests	
	Yr of scale-up	Pre-scale-up	Post-scale-up	Pre-scale-up	Post-scale-up	Pre-scale-up	Post-scale-up	Pre-scale-up	Post-scale-up	Pre-scale-up	Post-scale-up	Pre-scale-up	Post-scale-up	2015	2016
Côte d'Ivoire	2015	2014	2015	129,993	138,365	4,922	3,687	4	3	66	53	10	10	50,000	112,000
Kenya	2014	2013	2014–2015	631,503	798,188	53,012	280,645	8	38	64	83	18	31	1,200,000 <sup>§</sup>	1,393,557
Malawi <sup>¶</sup>	2014	2013	2014–2015	472,865	536,438	28,315**	61,227**	6	11	86	84	18	29	132,275	212,598
Namibia	2014	2013	2014–2015	126,779	131,721	76,716**	138,604**	54	95	74	86	5	4	192,616	206,520
South Africa	2014	2013	2014–2015	2,609,275	2,951,159	1,878,927	2,119,890	72	75	75	78	3	3	3,600,000	3,900,000
Tanzania	2015	2014	2015	600,886	758,344	14,334	22,772	2	3	80	72	10	4	87,589	363,314
Uganda	2014	2013	2014–2015	507,663	757,703	25,000	79,207	5	10	90	94	18	6	250,000	800,000

**Abbreviation:** ART = antiretroviral therapy.

\* The percentage of viral load tests with viral suppression might include multiple tests per patient. In Kenya, the viral load suppression rate for pediatrics is 63% and represents 13% of the cumulative number of ART patients.

† Average time from specimen collection to return of test results to referring facility (days).

§ Might represent more than one viral load test per person.

¶ In the post–scale-up period, viral load testing is conducted every 2 years in Malawi compared with every 6 months and 12 months for other countries.

\*\* The number of viral load tests could not be disaggregated at the individual level for adult and pediatric patients in Malawi and Namibia. Therefore, the proportion of ART patients with one or more viral load test is overestimated for these two countries. In Namibia, pediatric patients account for approximately 10% of all ART patients and receive two viral load tests per year. Because of this, 10% of the number of ART patients with one or more viral load test were assumed to be duplicates and were subtracted from the final value reported.



**TABLE 2. Common challenges and successes to viral load scale-up in seven countries — sub-Saharan Africa, 2013–2015\***

Challenges/Successes	Côte d'Ivoire	Kenya	Malawi	Namibia	South Africa	Tanzania	Uganda
<b>Challenges</b>							
No operational budget to support scale-up	X	X				X	X
Difficulty transporting samples	X	X	X	X		X	
Delays in commodity procurement and distribution		X	X				X
Inadequate laboratory information systems		X					X
Insufficient trained human resources dedicated for viral load testing	X	X	X			X	X
Equipment breakdown, delay in equipment repair		X					X
Inadequate laboratory and storage space to accommodate sample volume		X					
Insufficient viral load testing results management (record keeping and use of results for patient management in health care facilities)					X		
<b>Successes</b>							
Strong collaboration within MOH programs (e.g., HIV and laboratory) and between MOH and development partners	√	√	√	√	√		
Use of dried blood spots for viral load testing		√	√				√
Use of sample referral networks	√	√	√			√	√
Introduction of high throughput automated platforms	√	√	√		√	√	√
Renovations to improve laboratory infrastructure	√						√
Development of standardized procedures and curriculum	√	√					√
Participation in viral load EQA program	√		√	√			√
Innovations in laboratory information management systems	√	√	√	√			√

**Abbreviations:** EQA = external quality assurance; HIV = human immunodeficiency virus; MOH = ministry of health.

\* Challenges and successes were based on country self-report. If a country did not report a particular challenge or success, the respective box was left blank.

service provision, use of automated high-throughput and polyvalent platforms, introduction of point-of-care viral load technologies, increasing work-flow efficiencies, and improving laboratory infrastructure.

### Discussion

The majority of countries in this report are in early stages of initiating viral load testing as a national monitoring strategy for patients on ART. Five countries reported high levels of viral load suppression, which has been previously reported (7). The increase in viral load testing for Kenya and Namibia was associated with an increase in viral suppression levels; however, minimal change in viral suppression occurred in Malawi, and there was a decrease in viral suppression in Côte d'Ivoire and Tanzania. One possible explanation for increases in viral load suppression following increases in viral load testing is that with scale-up in viral load testing, follow-up of patients is more frequent, which can reinforce ART adherence and lead to an overall improvement in viral load suppression. In other settings where a decrease in viral load suppression was noted, the increase in viral load testing might have overwhelmed constrained resources, leading to a backlog in performing viral load tests, and preventing the timely use of results for patient management, which might ultimately result in a decrease in viral load suppression.

Numerous health system challenges were encountered as viral load monitoring scale-up was initiated, including difficulties

with specimen transport, equipment breakdown, personnel shortages, and weak laboratory information management systems and laboratory infrastructure. Similar challenges have been reported with the expansion of early infant diagnosis of HIV-infected children (8). Furthermore, even in programs with routine viral load monitoring, a substantial proportion of patients with confirmed virologic failure on first-line ART are not being appropriately switched to second-line ART (9). Therefore, as viral load monitoring is being scaled up, management of patient results should also be addressed. Novel approaches are needed, including alternative methods to improve the quality and efficiency of specimen transport, the use of electronic tools for transmission of results, and efficient use of human resources. Continuous quality improvement in laboratory systems is needed to meet the rising demand for viral load testing (10). Workforce development should be optimized through training of health care providers to use viral load results appropriately for patient management. Appropriate use of viral load results is important to the impact of increasing viral load testing. As scale-up progresses, a robust monitoring and evaluation system is needed to determine the effectiveness of viral load monitoring scale-up.

The findings in this report are subject to at least four limitations. First, because it was not possible to disaggregate results by patient and timing of test, the direct impact of viral load monitoring on patient management could not be assessed. Second, lower viral suppression rates observed during the

**Summary****What is already known on this topic?**

The World Health Organization advocates viral load testing to monitor persons with human immunodeficiency virus (HIV) infection receiving antiretroviral therapy (ART) to enable earlier detection of treatment failure. Although viral load monitoring is the standard of care in the developed world, CD4 cell counts and clinical monitoring have been used to monitor ART response in sub-Saharan Africa. Low- and middle-income countries face political, financial, and operational challenges to scaling up viral load testing.

**What is added by this report?**

In seven sub-Saharan African countries, viral load testing as a national monitoring strategy was scaled up during 2014–2015. Difficulties with specimen transport was a common challenge. Strengthening collaborations between ministries of health, HIV programs, laboratory programs, and development partners contributed to success in most countries.

**What are the implications for public health practice?**

Viral load testing in sub-Saharan Africa, with the goal of complete viral load suppression, will improve the health status of persons living with HIV and decrease HIV transmission and the occurrence of HIV drug resistance, and is a necessary step toward the goal of epidemic control of HIV. Training of additional personnel to meet the requirement for skilled human resources and improved sample transport systems are needed.

pre-scale-up period might not be representative of all persons on ART but might reflect targeted testing of persons who were suspected to be failing treatment. Third, the results for pediatric and adult patients might differ; however, pediatric data were unavailable for six of the seven countries. Finally, specific patient information was not collected to inform the findings on the proportion of patients who achieved viral load suppression.

The initial experience of viral load scale-up in these seven sub-Saharan African countries provides evidence that routine viral load monitoring for ART patients in this region can be achieved. Considerable investments will be required to improve laboratory systems for service delivery and strengthen the overall health systems infrastructure. Effective partnerships and substantial financial, operational, technical, and political commitments are needed for successful scale-up. Routine viral load monitoring and usage of results to inform clinical decisions for ART patients in sub-Saharan Africa will lead to substantial improvements in health outcomes moving toward epidemic control of HIV.

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# Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition — United States, 2015

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## Abstract

**Background:** In 2014, approximately 40,000 persons in the United States received a diagnosis of human immunodeficiency virus (HIV) infection. Preexposure prophylaxis (PrEP) with daily oral antiretroviral medication is a new, highly effective intervention that could reduce the number of new HIV infections.

**Methods:** CDC analyzed nationally representative data to estimate the percentages and numbers of persons in the United States, by transmission risk group, with indications for PrEP consistent with the 2014 U.S. Public Health Service's PrEP clinical practice guideline.

**Results:** Approximately 24.7% of sexually active adult men who have sex with men (MSM) (492,000 [95% confidence interval {CI} = 212,000–772,000]), 18.5% of persons who inject drugs (115,000 [CI = 45,000–185,000]), and 0.4% of heterosexually active adults (624,000 [CI = 404,000–846,000]), had substantial risks for acquiring HIV consistent with PrEP indications.

**Conclusions:** Based on current guidelines, many MSM, persons who inject drugs, and heterosexually active adults have indications for PrEP. A higher percentage of MSM and persons who inject drugs have indications for PrEP than heterosexually active adults, consistent with distribution of new HIV diagnoses across these populations.

**Implications for Public Health Practice:** Clinical organizations, health departments, and community-based organizations should raise awareness of PrEP among persons with substantial risk for acquiring HIV infection and their health care providers. These data can be used to inform scale-up and evaluation of PrEP coverage. Increasing delivery of PrEP and other highly effective HIV prevention services could lower the number of new HIV infections occurring in the United States each year.

## Introduction

In 2014, approximately 40,000 persons in the United States received a diagnosis of human immunodeficiency virus (HIV) infection (1). Since 2010, several randomized, placebo-controlled clinical trials have reported that with high medication adherence (measured by detectable blood drug levels), daily oral antiretroviral preexposure prophylaxis (PrEP) reduced new HIV infections by 92% among MSM (2), 90% among heterosexually active men and women in HIV-discordant couples (3), and 73.5% among persons who inject drugs (4). In 2014, CDC published the U.S. Public Health Service's clinical practice guideline for PrEP (5). Since 2014, open-label studies and demonstration projects conducted among MSM in the United States have reported that high adherence is achievable in community-based PrEP delivery, and effectiveness is similar to or better than that in clinical trials (6,7). As a result, the National HIV/AIDS Strategy Updated to 2020 calls for the scale-up of the delivery of PrEP and other highly effective prevention services to reduce new HIV infections (8).

PrEP is a complementary strategy to other effective HIV prevention methods, including early diagnosis and treatment of HIV infection to achieve viral suppression and consistent condom use. A randomized controlled trial demonstrated that antiretroviral treatment reduces HIV transmission to HIV-discordant heterosexual sex partners by 93% (9). PrEP can reduce the risk for HIV infection among HIV-negative persons with sexual or injection exposures from partners who are among the estimated 70% of HIV-infected persons in the United States who are not virally suppressed and are at high risk for transmitting infection (10), including persons with undiagnosed HIV infection, persons with diagnosed infection who are not receiving treatment, and persons receiving treatment who are not virally suppressed. The combined protective effect of treatment and PrEP has recently been demonstrated in an open-label study with HIV-discordant couples in Africa (11). This report estimates the percentages and numbers of adults in the United States with indications for PrEP consistent with the 2014 U.S. Public Health Service's PrEP guideline.

## Methods

Data from national population-based surveys were analyzed to estimate the percentages and numbers of persons with indications for PrEP in each of three transmission-risk populations: MSM, heterosexually active adults, and persons who inject drugs. The prevalence of surveyed behaviors most closely related to those described as indications for PrEP in the 2014 guideline (6) were used to define the size of the target populations (Table 1).

The number of men aged 18–59 years not known to be HIV-positive who reported sex with a man in the past 12 months was derived from National Health and Nutrition Examination Survey (NHANES) data from 2007–2008, 2009–2010, and 2011–2012 combined.\* The number of these MSM reporting sex with two or more men in the past 12 months and any condomless sex or sexually transmitted infections in the past 12 months was used to calculate the percentage of HIV-negative sexually active adult MSM with behavioral indications for PrEP use. This percentage was weighted as recommended for NHANES data using current population estimates† of the population of men aged 18–59 years to yield an estimate of the number of U.S. MSM with indications for PrEP. Estimates of MSM with indications for PrEP did not consider injection risk.

The number of persons aged ≥18 years who reported in the National Survey on Drug Use and Health (NSDUH) (2013)§ having injected any assessed drug during the past 12 months and used a needle that had previously been used by another person was used to yield an estimate of the number of U.S. persons who inject drugs with indications for PrEP use. The estimate for persons who inject drugs did not consider sexual risk or HIV infection status.

The number of men and women aged 18–59 years not known to be HIV-positive was derived from NHANES data from 2007–2008, 2009–2010, and 2011–2012 combined and was used to calculate the percentage of HIV-negative adults among NHANES respondents. This percentage was weighted, as recommended for NHANES data, using current population estimates of the population of men and women aged 18–59 years to yield an estimate of the number of HIV-negative adults. Next, National Survey of Family Growth data (2011–2013)¶ were analyzed to identify the number of men and women aged 18–44 years who reported sex with two or more opposite sex partners and either of the following: 1) sex with an HIV-infected partner; or 2) any condomless sex in

the last 4 weeks and sex with a high-risk partner in the past 12 months. High-risk partners were defined as persons who inject drugs or (for women) male partners known to also have sex with men (behaviorally bisexual). The percentage of heterosexually active adults aged 18–44 years with behavioral indications for PrEP use in the National Survey of Family Growth was multiplied by the estimated number of HIV-negative adults aged 18–59 years from NHANES to yield an estimate of the number of heterosexually active adults in the United States with indications for PrEP. Estimated heterosexually active adults with indications for PrEP did not consider injection risk. Bisexual men were assessed by indications for both MSM and heterosexually active adults and added to the populations for which PrEP indications were met.

## Results

An estimated 24.7% of MSM (492,000 [95% confidence interval {CI} = 212,000–772,000]) without HIV infection aged 18–59 years who reported sex with a man in the past year have indications for PrEP (Table 2). An estimated 18.5% of persons aged ≥18 years who inject drugs (115,000 [CI = 45,000–185,000]) have indications for PrEP. An estimated 0.4% of heterosexually active adults aged 18–59 years (624,000 [CI = 404,000–846,000]) have indications for PrEP. Among these heterosexually active adults, 157,000 (CI = 62,000–252,000) are men, and 468,000 (CI = 274,000–662,000) are women.\*\* Overall, an estimated 1,232,000 adults (CI = 661,000–1,803,000) have substantial risk for HIV acquisition, for whom PrEP and other effective prevention methods are indicated.

## Conclusions and Comments

Among adult MSM aged 18–59 years in the United States who report sexual activity in the past year, approximately 25% have indications for PrEP to prevent HIV acquisition, compared with approximately 18% of persons who inject drugs and 0.4% of heterosexually active adults. The high percentage of MSM with PrEP indications is consistent with the high number of new HIV infections among MSM. The high percentage of persons who inject drugs with PrEP indications reflects the relatively high percentage who report using a needle after it was used by another injector. The low percentage and high absolute number of heterosexually active adults is a reflection of the large heterosexually active U.S. population and the low rate of new HIV diagnoses in these adults. The actual risk for acquiring HIV infection for each of these transmission risk groups differs based on efficiency of transmission routes and likelihood of exposure to HIV.

\*\* Does not sum to 624,000 because of rounding.

\* Available at <http://www.cdc.gov/nchs/nhanes.htm>; 2007–2008 data includes men aged 20–59 years.

† Available at [http://www.cdc.gov/nchs/data/series/sr\\_02/sr02\\_161.pdf](http://www.cdc.gov/nchs/data/series/sr_02/sr02_161.pdf) and [http://www.cdc.gov/nchs/data/nhanes/analytic\\_guidelines\\_11\\_12.pdf](http://www.cdc.gov/nchs/data/nhanes/analytic_guidelines_11_12.pdf).

§ Available at <http://www.samhsa.gov/data/population-data-nsduh>.

¶ Available at <http://www.cdc.gov/nchs/nsfg.htm>.



**TABLE 1. Indications for preexposure prophylaxis (PrEP) based on the 2014 U.S. Public Health Service guideline and method for estimating the number of persons with indications using national-level surveys, by transmission risk group — United States, 2015**

Transmission risk group	Indications for PrEP in the 2014 guideline	Method to estimate number of persons with indications for PrEP
Men who have sex with men (MSM)*	Adult man Without acute or established HIV infection Any male sex partner in past 6 months Not in a monogamous partnership with a recently tested, HIV-negative man  AND at least one of the following Any anal sex without condoms (receptive or insertive in past 6 months) Any sexually transmitted infection diagnosed or reported in past 6 months Is in an ongoing sexual relationship with an HIV-positive partner	Man aged 18–59 years Not known to be HIV-positive Sex with two or more men in past 12 months  AND at least one of the following Any reported condomless sex in past 12 months Sexually transmitted infection diagnosis in past 12 months HIV status of partners could not be established
Heterosexually active adults†	Adult person Without acute or established HIV infection Any sex with opposite sex partners in past 6 months Not in a monogamous partnership with a recently tested HIV-negative partner  AND at least one of the following <sup>§</sup> Infrequently uses condoms during sex with one or more partners of unknown HIV status who are known to be at substantial risk of HIV infection (person who injects drugs or bisexual male partner) Is in an ongoing sexual relationship with an HIV-positive partner	Man or women aged 18–59 years Not known to be HIV-positive Sex with two or more opposite sex partners in past 12 months  AND at least one of the following Any reported condomless sex in last 4 weeks AND sex with a partner who injects drugs OR, for females, sex with a bisexual male sex partner in past 12 months Sex with partner reported to be HIV-positive
Persons who inject drugs¶	Adult person Without acute or established HIV infection Any injection of drugs not prescribed by a clinician in past 6 months  AND at least one of the following Any sharing of injection or drug preparation equipment in past 6 months Been in a methadone, buprenorphine, or suboxone treatment program in past 6 months Risk of sexual acquisition	Man or women aged ≥18 years HIV status could not be determined Any injection of heroin, methamphetamine, stimulants, or cocaine in past 12 months  AND at least one of the following Reported injecting with a needle used by someone else before them (other drug preparation equipment not included) Medication-based treatment history could not be assessed  Assessed using sexual risk indications above

\* Source: National Health and Nutrition Examination Survey (NHANES).

† Sources: NHANES and National Survey of Family Growth.

§ Behaviorally bisexual men were assessed for both MSM and heterosexual risk indications.

¶ Source: National Survey on Drug Use and Health.

The large percentage of persons at substantial risk for acquiring HIV infection in some transmission risk groups demonstrates a continuing need for access to, and use of, a broad range of high-impact, clinic-based HIV prevention services that includes increased access to PrEP. These services include 1) regular HIV testing for all persons at substantial risk and their sexual or injection partners, and access to early antiretroviral treatment for persons with HIV infection to achieve viral suppression; 2) regular screening and treatment for sexually transmitted infections for persons with sexual risk when indicated, male and female condom access, and brief risk-reduction counseling to promote consistent condom use; and 3) for persons with injection risk, access to medication-assisted treatment or referral for behavioral treatment of addiction, and access to clean injection equipment for those continuing to inject. Delivering PrEP in conjunction with other effective prevention services and associated preventive health care (e.g., hepatitis B vaccination and hepatitis B or C treatment when indicated) can be expected to reduce incident HIV infections and other preventable adverse health consequences for persons at risk.

Impact models indicate that 50% coverage and modest adherence to PrEP by high-risk MSM in the United States could reduce new infections among MSM by 29% over 20 years (12). Impact models of PrEP use by heterosexually active adults in Botswana, where levels of viral suppression among HIV-infected persons equivalent to U.S. National HIV/AIDS Strategy 2020 goals have already been achieved, estimate that PrEP use could reduce new infections by at least 39% over 10 years (13). Early ecologic evidence of the combined effectiveness of expanded treatment and PrEP provision on reducing new HIV infections has been reported in San Francisco (14).

The findings in this report are subject to at least four limitations. First, estimates for MSM are limited to persons aged 18–59 years. Second, estimates for heterosexually active adults applied National Survey of Family Growth data for respondents aged 18–44 years to estimates of HIV-negative adults aged 18–59 years from NHANES, which might overestimate the number of persons with PrEP indications. Third, not all

**TABLE 2. Estimated percentages and numbers of adults with indications for preexposure prophylaxis (PrEP), by transmission risk group — United States, 2015**

Transmission risk group	% with PrEP indications*	Estimated no.	(95% CI)
Men who have sex with men, aged 18–59 yrs <sup>†</sup>	24.7	492,000	(212,000–772,000)
Adults who inject drugs, aged ≥18 yrs <sup>‡</sup>	18.5	115,000	(45,000–185,000)
Heterosexually active adults, aged 18–59 yrs <sup>¶</sup>	0.4	624,000	(404,000–846,000)
Men**	0.2	157,000	(62,000–252,000)
Women	0.6	468,000	(274,000–662,000)
<b>Total</b>	—	<b>1,232,000</b>	<b>(661,000–1,803,000)</b>

**Abbreviation:** CI = confidence interval.

\* Percentage of all estimated persons in each transmission risk group and demographic subset with PrEP indications.

<sup>†</sup> Based on 2007–2012 National Health and Nutrition Examination Survey (NHANES) data, weighted as recommended using current population estimates. Risk factors used to define PrEP indications included two or more male sex partners and at least one of the following: any condomless sex or sexually transmitted infection diagnosis in past 12 months.

<sup>‡</sup> Based on 2013 National Survey on Drug Use and Health. Risk factors used to define PrEP indications included injection of heroin, methamphetamine, stimulants, or cocaine, and injecting with a needle used by someone else before them.

<sup>¶</sup> Based on 2011–2013 National Survey of Family Growth and 2007–2012 NHANES data, weighted as recommended using current population estimates. Risk factors used to define PrEP indications included two or more opposite sex partners and at least one of the following: sex with an HIV-positive partner; or any condomless sex in the last 4 weeks and sex with a male who injects drugs or bisexual male (females only) in last 12 months.

\*\* The relative standard error for males was 30.09%.

U.S. Public Health Service PrEP guideline indications could be directly matched with variables reported in the surveys analyzed. This might have underestimated the percentages and numbers for some transmission risk groups and overestimated others to an unknown degree. Fourth, an estimate of HIV-discordant monogamous couples could not be calculated using nationally representative data.

State and local health departments, community-based organizations, and health care providers should become informed about the indications for and delivery of PrEP so that it becomes available to persons at substantial risk for HIV acquisition. In a 2015 national survey of health care providers, 34% had not heard of PrEP (DocStyles, unpublished data, 2015). Increasing the number of persons with indications for PrEP who are offered it and providing support services to maintain these persons in PrEP care with high adherence will help reduce the number of new HIV infections.

The U.S. Department of Health and Human Services is supporting a range of programmatic and research efforts to incorporate scale-up of PrEP awareness and access into high-impact HIV prevention services. CDC provides funding and technical assistance to 1) inform the broader community about PrEP and how to access it, 2) identify HIV-uninfected persons with indications for PrEP and link them to PrEP care, 3) address disparities in knowledge of PrEP and access to it, and 4) provide training

and support to clinicians regarding how to effectively provide PrEP with periodic HIV testing and sexually transmitted infection diagnosis and treatment (15). In addition, CDC supports efforts to improve early diagnosis and linkage to and retention in HIV medical care for persons with HIV infection to increase rates of viral suppression. CDC also is working with state and local health departments to develop methods to monitor PrEP coverage among persons for whom it is indicated and to assess the quality of HIV prevention care provided. Evidence of increasing use is available from limited analyses but comprehensive data on uptake of PrEP nationwide are not yet available (16–18). Efforts also are under way to increase the number of persons receiving prescriptions for PrEP medication and associated health care with coverage by most public and private health insurers and to increase access to medication and copay assistance programs (19). Estimating the percentage and size of the populations to be reached can assist health departments scale up PrEP availability and use, inform evaluation of coverage, and assess its contribution to reducing new HIV infections.

A substantial number of MSM, persons who inject drugs, and heterosexually active adults have indications for PrEP. Efforts to increase knowledge of and access to PrEP should accompany efforts to increase early diagnosis and treatment of persons with HIV infection to achieve the prevention benefits of viral suppression. Reducing disparities in access to clinical care for the prevention and treatment of HIV infection can accelerate achieving the National HIV/AIDS Strategy 2020 goal for reducing the number of new HIV infections in the United States.

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### Key Points

- An estimated one in four (492,000; 95% CI: 212,000–772,000) sexually active HIV-negative adult men who have sex with men (MSM) have indications for PrEP consistent with those defined in the 2014 U.S. Public Health Service preexposure prophylaxis (PrEP) clinical practice guideline.
- An estimated one in five (115,000; 95% CI: 45,000–185,000) HIV-negative persons who inject drugs have indications for PrEP.
- An estimated one in 200 (624,000; 95% CI: 404,000–846,000) HIV-negative heterosexually active adults have indications for PrEP.
- An estimated 1,232,000 (95% CI: 661,000–1,803,000) adults in the United States have substantial risk for acquiring human immunodeficiency virus (HIV) infection.
- Persons at substantial risk for HIV infection and their health care providers need to be aware of daily oral PrEP as one of several highly effective HIV prevention methods available to them.
- Reducing the number of new HIV infections in the United States can be accelerated by increasing 1) the number of persons living with HIV infection who receive diagnoses and treatment to achieve viral suppression 2) the number of persons at substantial risk for acquiring HIV infection who use PrEP, and 3) the use of other prevention strategies.
- Additional information is available at <http://www.cdc.gov/vitalsigns>.

# Vital Signs: Increased Medicaid Prescriptions for Preexposure Prophylaxis Against HIV infection — New York, 2012–2015

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On November 24, 2015, this report was posted as an MMWR Early Release on the MMWR website (<http://www.cdc.gov/mmwr>).

## Abstract

**Background:** Approximately 3,000 incident cases of human immunodeficiency virus (HIV) infection occur in New York state each year. Daily HIV preexposure prophylaxis (PrEP) with the oral antiretroviral medication Truvada is a key component of New York's plan to end HIV/acquired immunodeficiency syndrome (AIDS) as an epidemic in the state by 2020.

**Methods:** Prescription data from the New York state Medicaid program from July 2012 through June 2015 were analyzed with an algorithm using medication and diagnoses codes to identify continuous use of Truvada for >30 days, after excluding use for postexposure prophylaxis or treatment of HIV or chronic hepatitis B infection.

**Results:** During July 2012–June 2013, a total of 259 persons filled prescriptions for PrEP in the Medicaid program. During July 2013–June 2014, a total of 303 persons filled prescriptions for PrEP. During July 2014–June 2015, a total of 1,330 persons filled prescriptions for PrEP, a substantial increase over the previous 12 months. Across all periods studied, 1,708 Medicaid recipients filled at least one prescription for PrEP, most of whom were New York City (NYC) residents, male, aged <50 years, and, for those with available data on race, white.

**Conclusions:** PrEP use by Medicaid-insured persons increased substantially in the years following statewide efforts to increase knowledge of PrEP among potential prescribers and candidates for PrEP. Other jurisdictions can follow New York state's example by taking similar steps to remove the financial and knowledge barriers experienced by both potential users and prescribers of PrEP.

**Implications for Public Health Practice:** Although both state and local health department efforts contribute to the availability and use of PrEP, their collaboration enhances the successful implementation of strategies to increase PrEP use. In addition, the decision by the state Medicaid agency to cover PrEP recognizes the long-term benefits of preventing HIV infections.

## Introduction

On June 29, 2014, the Governor of New York detailed a plan to end human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS) as an epidemic in the state. The goal of this initiative is to reduce the annual number of newly diagnosed cases of HIV infection from an estimated 3,000 to 750 by the end of 2020, thereby achieving the first-ever decrease in HIV prevalence in the state. The three major points of this plan are to 1) identify persons with undiagnosed HIV and link them to care, 2) link and retain persons with diagnosed HIV infection in health care to maximize the likelihood of virus suppression so they remain healthy, and to prevent further transmission of the virus, and 3) facilitate access to preexposure prophylaxis (PrEP) for high-risk HIV-negative persons to prevent their becoming infected and transmitting the virus (1). After the Governor's announcement, a task force including representatives from the community, academia, and state and local governments was formed; the task force produced a set

of 37 recommendations and strategies to accomplish the goals of the Ending the AIDS Epidemic initiative (2). This report describes New York state's policy and programmatic efforts to increase the use of PrEP among Medicaid recipients, and to examine changes in the number of recipients filling prescriptions for PrEP during July 2012–June 2015.

In 2009, the New York State Department of Health's (NYSDOH) AIDS Institute staff recognized the potential for PrEP as a biomedical HIV prevention strategy, should the results of clinical trials underway at that time in the United States and internationally demonstrate the efficacy of PrEP to protect against HIV infection, and began to lay the groundwork for implementing PrEP to reduce HIV acquisition among state residents. By 2012, CDC had published information and guidance concerning PrEP (3,4), and the Food and Drug Administration had approved Truvada (a fixed-dose combination of emtricitabine/tenofovir disoproxil fumarate [FTC/TDF]) for daily use by uninfected adults to help protect



against acquiring HIV through high-risk sexual contact. The AIDS Institute then drafted and began to implement a strategic plan (Box) to promote comprehensive and integrated PrEP and related services throughout the state within primary care, HIV care settings, and other settings that serve persons at risk for HIV and sexually transmitted diseases. In January 2014, the AIDS Institute posted its *Guidelines for the Use of Preexposure Prophylaxis (PrEP) to Prevent HIV Transmission* to its clinical guidelines website (5). This was followed in May 2014 by the release of the U.S. Public Health Service's clinical practice guideline for PrEP (6). To ensure that PrEP would be available to high-risk HIV-negative Medicaid recipients, the state's Medicaid program approved coverage of Truvada for PrEP through the program's fee-for-service drug formulary.

As a key component of New York's plan to end HIV/AIDS as an epidemic in the state, expanding access to PrEP among persons at highest risk for HIV infection has the capacity to substantially reduce the number of incident infections. NYSDOH partnered with the New York City Department of Health and Mental Hygiene (NYCDOHMH) in developing elements of the strategic plan. For example, NYCDOHMH developed and distributed a PrEP toolkit for primary care providers, which the state adapted for use in areas outside of NYC. Also, the city and state health departments collaborated on developing an online directory of providers currently offering PrEP, which is publicly available on their respective websites. NYCDOHMH also devoted an issue of its City Health Information series to providing comprehensive health care to men who have sex with men (MSM) (7) and drafted a PrEP provider FAQ sheet (8), both of which are posted on the agency's website, and created a web address to which queries concerning PrEP and postexposure prophylaxis (PEP) can be sent.

## Methods

An algorithm was developed and applied to Medicaid fee-for-service claims and encounter data submitted by Medicaid managed care plans that are housed in the NYSDOH Medicaid data warehouse (Figure). This algorithm included diagnosis and prescription drug coding that was intended to monitor the number of HIV-negative Medicaid recipients who filled prescriptions for Truvada for PrEP, as distinguished from those recipients receiving Truvada for PEP or as treatment of chronic hepatitis B infection. For this report, this algorithm was applied to the Medicaid data warehouse to examine the number of persons enrolled in Medicaid anytime during the 3-year period from July 2012 through June 2015 and who filled at least one prescription for PrEP.

## Key Points

- Human immunodeficiency virus (HIV) infections continue to increase among gay and bisexual men in New York state.
- Daily oral preexposure prophylaxis (PrEP) is a safe and effective intervention to help protect men who have sex with men (MSM) and other HIV-uninfected adults against acquiring HIV through sexual contact, as well as those exposed to HIV through injection drug use.
- This report describes aspects of New York state's Ending the AIDS Epidemic initiative and various strategies to facilitate access to PrEP.
- New York state has experienced some success in facilitating access to PrEP as evidenced by a more than fourfold increase in the number of Medicaid recipients filling at least one prescription for PrEP during July 2012–June 2015.
- This increase has been achieved in large part through implementation of aspects of a strategic plan to increase PrEP use as part of the state's Ending the AIDS Epidemic initiative.
- Other state and local jurisdictions can use New York state's implementation strategies as a model to adopt or adapt to increase PrEP use among their own populations.
- Additional information is available at <http://www.cdc.gov/vitalsigns>.

## Results

The number of Medicaid recipients filling at least one prescription for PrEP increased by 17.0%, from 259 recipients during July 2012–June 2013 to 303 recipients during July 2013–June 2014, and more recently by 338.9%, to 1,330 recipients during July 2014–June 2015 (Table). Across all periods studied, 1,708 Medicaid recipients filled at least one prescription for PrEP, among whom 80.7% reside in NYC and 82.4% are enrolled in Medicaid managed care plans. The proportion of persons filling prescriptions for PrEP who were male increased across the periods studied from 54.8% to 78.0%, although the number who were female more than doubled. Among recipients for whom race was reported, the proportion of Medicaid recipients filling prescriptions for PrEP who were white increased from 34.8% in the earlier period to 65.7% during the most recent period. However, the number of black recipients who filled at least one prescription for PrEP increased by 67.3%.

Recipients aged 18–49 years accounted for 85.8% of Medicaid recipients filling prescriptions for PrEP across all periods reported. Males accounted for 63.6% of these recipients, and among males in this age group for whom race was

**BOX. Selected ongoing and accomplished elements of a strategic plan for preexposure prophylaxis (PrEP) — AIDS Institute, New York State Department of Health (NYSDOH), 2015–2017**

**Scientific groundwork (formulate guidelines, develop supportive services, define target populations, and integrate into existing services)**

- Establish internal biomedical workgroup to coordinate activities.
- Convene a group of clinicians, consumers, and other stakeholders to develop guidance for New York state practitioners regarding evaluating patients for PrEP and initiating and managing patients on PrEP.
- Develop a summary of PrEP guidelines for nonclinical providers.

**Regulatory, policy, financial groundwork (address issues related to financing and integration of PrEP into public health priorities)**

- Implement a PrEP assistance program, modeled on the state's HIV Uninsured Care Program's AIDS Drug Assistance Program Plus initiative, to provide reimbursement for monitoring and care services delivered to uninsured and underinsured persons on PrEP.
- Convene the Ending the AIDS Epidemic initiative task force, which lists expanding access to PrEP to prevent new infections as one of its three major points.

**Stakeholder and infrastructure groundwork (local participation in implementation planning, building public awareness, and physical and human resources infrastructure)**

- Governor appoints 64 members to the Ending the AIDS Epidemic initiative task force to create the Ending the Epidemic Blueprint.
- Training conducted for "PrEP ambassadors" to answer questions about PrEP and nonoccupational postexposure prophylaxis (nPEP) at Gay Pride events throughout the state.
- NYSDOH website redesigned to permit clinicians and consumers easy access to information regarding PrEP and nPEP, such as departmental guidance for prescribers and a question and answer document for consumers.
- Access and adherence to PrEP included as fundable services in future requests for applications for various grant-supported services.
- NYSDOH adapts the PrEP toolkit created by the New York City Department of Health and Mental Hygiene (NYSDOHMH) and distributed it to primary care providers outside New York City.

**Delivering PrEP (coordinating delivery components and ongoing adjustment and adaptation)**

- Directories of PrEP and PEP providers posted to NYSDOH and NYCDOHMH websites.
- Create a toll-free phone service for clinicians with 24/7 coverage to respond to questions about PrEP.
- Enhance contracts for 23 specialized care centers and primary care clinics to hire an on-site PrEP specialist to promote clinic-wide approaches to provide PrEP and PrEP-related services.
- Contract with clinics with high numbers of transgender persons and young men who have sex with men to increase their awareness of PrEP, assess their appropriateness for treatment, and link them to care.
- Conduct PrEP pilot projects in several hospital-based and community-based clinics, including a number of local health department sexually transmitted disease (STD) clinics, to describe and implement those elements needed to identify, recruit, and retain appropriate candidates for PrEP and assist them in adhering to their medications.

**Long-term monitoring (monitoring population-level effects and learning from the implementation process)**

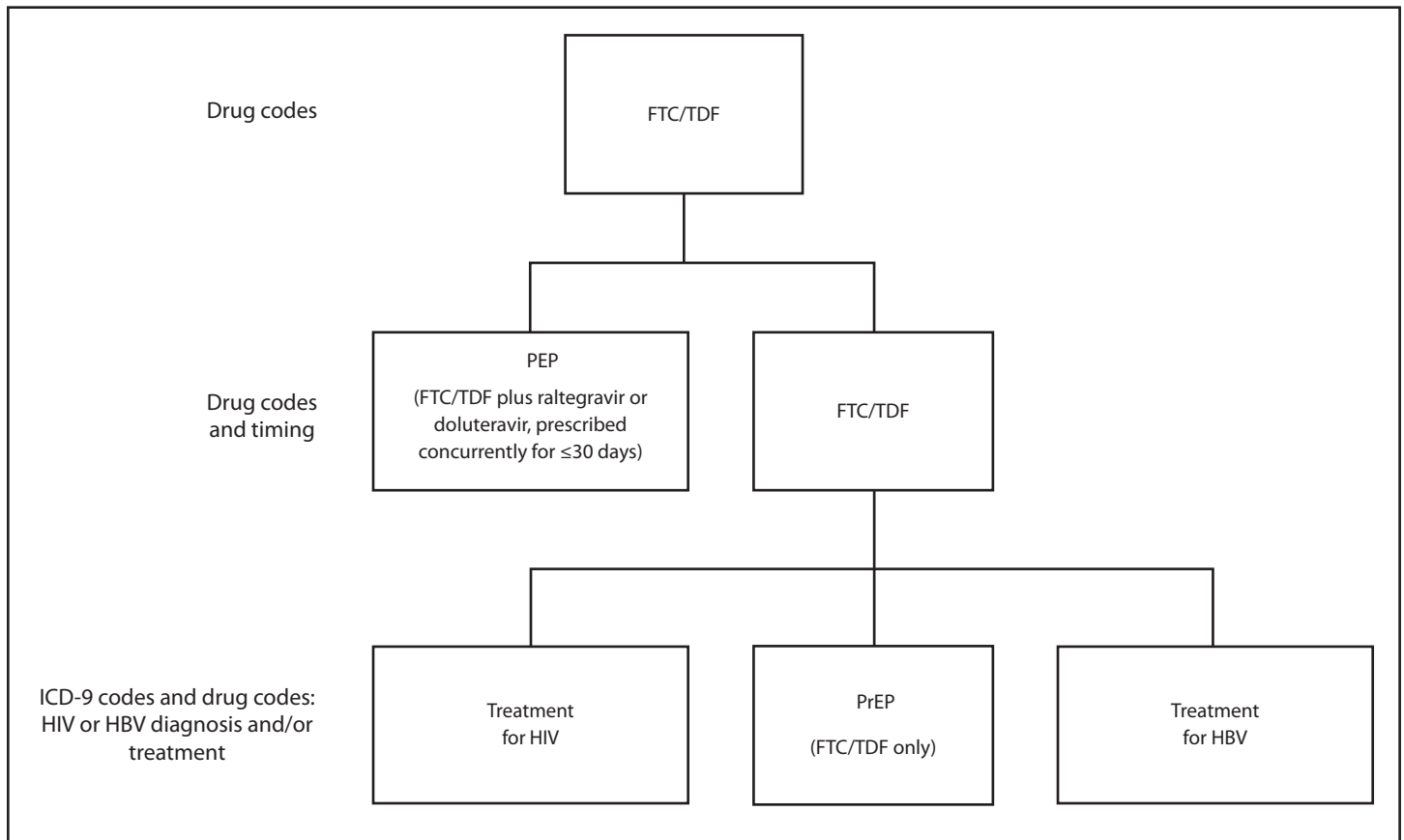
- Require human immunodeficiency virus/STD partner services and disease intervention services staff to include brief PrEP questions and PrEP referrals into their programming.
- Add questions related to PrEP to National HIV Behavioral Surveillance System survey conducted by NYSDOH.
- Periodic analysis of Medicaid data to assess changes in numbers of recipients filling prescriptions for PrEP and nPEP.

reported, 50.5% were white and 22.2% were black. Although males accounted for an increasing proportion of recipients aged 18–49 years using PrEP, the proportion who were black decreased by nearly three quarters, from 59.8% in the early period to 14.9% in the more recent period; however, males accounted for 56.6% of blacks in this age group.

## Conclusion and Comments

New York state experienced substantial increases in the number of HIV-negative Medicaid recipients initiating PrEP after the state's efforts to raise awareness of PrEP among potential users and increase the pool of PrEP prescribers. The

FIGURE. Coding algorithm for extracting Medicaid recipients filling prescriptions for PrEP



**Abbreviations:** FTC = emtricitabine; HBV = hepatitis B virus; ICD-9 = *International Classification of Diseases, Ninth Revision*; PEP = postexposure prophylaxis; PrEP = preexposure prophylaxis; TDF = tenofovir disoproxil fumarate.

state's efforts to provide information to potential users and prescribers included making PrEP-related materials available through the NYSDOH website, training activities, public forums, and other activities focusing on educating potential prescribers and users.

During the 3-year period ending June 30, 2015, the number of Medicaid recipients initiating PrEP in New York state increased more than fourfold. Those recipients initiating PrEP during this period were mostly male, aged <50 years, and, among those for whom data describing race was available, white. Despite the lack of diagnosis coding indicating whether Medicaid recipients filling prescriptions for Truvada are appropriate candidates for PrEP, there is concern that PrEP might not yet be reaching those who are engaging in high-risk behaviors, especially young black MSM (9).

Although the increase in percentage of Medicaid recipients filling Truvada prescriptions for PrEP during the 3-year period is substantial, the number of persons doing so remains low relative to the number needed to treat in order to achieve the goals of New York state's Ending the AIDS Epidemic

initiative. Although no specific target goal for PrEP coverage has been set, recent modeling studies and other studies have projected reductions in the number of HIV infections from implementation of PrEP (10,11). For example, results from the United Kingdom's PROUD study examining the impact on gay men of using PrEP showed an 86% reduction in HIV infections among MSM receiving PrEP, suggesting that for every 13 persons on PrEP, one HIV infection is averted (11). Although it is still early in the state's Ending the AIDS Epidemic initiative, which includes efforts to facilitate access to PrEP, monitoring the outcomes of the various strategies outlined in this report and others will provide opportunities to assess the impact of the efforts to increase PrEP use as well as inform where and to which populations resources should be most appropriately directed.

The findings in this report are subject to at least three limitations. First, because the analysis was based on administrative billing data, the results must be interpreted with caution. The algorithm derived and the database against which it is applied use combinations of diagnosis and prescription drug

TABLE. Use of preexposure prophylaxis (PrEP) by Medicaid recipients, by selected characteristics — New York state, July 2012–June 2015

Characteristic	Year 1 (July 2012–June 2013)		Year 2 (July 2013–June 2014)		% change (year 1 to 2)	Year 3 (July 2014–June 2015)		% change (year 2 to 3)	All years combined*	
	No. of recipients	(%)	No. of recipients	(%)		No. of recipients	(%)		No. of recipients	(%)
<b>Recipients of PrEP regimen</b>	259	(100.0)	303	(100.0)	+17.0	1,330	(100.0)	+338.9	1,708	(100.0)
<b>Medicaid program</b>										
Fee-for-service	59	(22.8)	58	(19.1)	-1.7	201	(15.1)	+246.6	300	(17.6)
Managed care	200	(77.2)	245	(80.9)	+22.5	1,129	(84.9)	+360.8	1,408	(82.4)
<b>Age group (yrs)<sup>†</sup></b>										
<15	3	(1.2)	3	(1.0)	0.0	15	(1.1)	+400.0	21	(1.2)
15–17	7	(2.7)	11	(3.6)	+57.1	14	(1.1)	+27.3	32	(1.9)
18–24	33	(12.7)	53	(17.5)	+60.6	231	(17.4)	+335.8	294	(17.2)
25–49	168	(64.9)	204	(67.3)	+21.4	938	(70.5)	+359.8	1,171	(68.6)
50–64	45	(17.4)	31	(10.2)	-31.1	129	(9.7)	+316.1	184	(10.8)
≥65	3	(1.2)	1	(0.3)	-66.7	3	(0.2)	+200.0	6	(0.4)
<b>Sex</b>										
Female	117	(45.2)	115	(38.0)	-1.7	292	(22.0)	+153.9	472	(27.6)
Male	142	(54.8)	188	(62.0)	+32.4	1,038	(78.0)	+452.1	1,236	(72.4)
<b>Region</b>										
New York City	224	(86.5)	242	(79.9)	+8.0	1,065	(80.1)	+340.1	1,378	(80.7)
Rest of state (outside of New York City)	35	(13.5)	61	(20.1)	+74.3	265	(19.9)	+334.4	330	(19.3)
<b>Race/Ethnicity</b>										
White, non-Hispanic	77	(29.7)	105	(34.7)	+36.4	574	(43.2)	+446.7	687	(40.2)
Black, non-Hispanic	113	(43.6)	83	(27.4)	-26.5	189	(14.2)	+127.7	336	(19.7)
Asian/Pacific Islander	11	(4.2)	12	(4.0)	+9.1	38	(2.9)	+216.7	50	(2.9)
Native American	1	(0.4)	5	(1.7)	+400.0	7	(0.5)	+40.0	11	(0.6)
Hispanic	19	(7.3)	25	(8.3)	+31.6	66	(5.0)	+164.0	100	(5.9)
Other/unknown	38	(14.7)	73	(24.1)	+92.1	456	(34.3)	+524.7	524	(30.7)

Source: New York state Medicaid data as of July 2015.

\* The counts for all years represent unique counts across the 3 years and include those persons who were enrolled in Medicaid anytime during the study period.

<sup>†</sup> Ages are calculated at initial Truvada claim for PrEP.

codes typically submitted by medical providers for billing and payment purposes, and the database does not contain information that would permit calculating an estimate of potential candidates for PrEP. Second, the database and the claims and encounter data that constitute it are subject to data submission errors and omissions (notably data describing the race and ethnicity of the recipients and any indication of risk) and lag times between the provision of services and claims submission and adjudication. Finally, although the intent of this analysis is to determine the number of Medicaid recipients on PrEP, the results present the number of recipients filling a prescription for Truvada but not whether those persons are following the PrEP regimen.

Despite these limitations, the findings suggest benefits derived from New York state's efforts to raise the awareness and knowledge of PrEP among persons at risk for HIV infection and the clinicians who care for them and can appropriately prescribe the regimen for their patients. This report focuses on results achieved among the state's Medicaid population, which accounts for one quarter (25.6%) of the state's population (NYSDOH, unpublished data, 2015). In addition, almost 170 practitioners, health centers, and practices throughout the state have listed themselves in NYSDOH's online PrEP/PEP

provider directory ([http://www.health.ny.gov/diseases/aids/general/prep/provider\\_directory.htm](http://www.health.ny.gov/diseases/aids/general/prep/provider_directory.htm)), although PrEP and its related services are more widely available.

New York state's response to the availability of PrEP and PEP as a key strategic component of the state's initiative to end HIV/AIDS as an epidemic in the state is illustrative of its efforts to raise awareness about HIV prevention interventions among clinicians and all persons at high risk for becoming infected or transmitting the virus, regardless of health insurance coverage. Recommendations by the Ending the AIDS Epidemic initiative task force and the elements of the AIDS Institute's PrEP strategic plan reflect perceived and reported needs and barriers concerning PrEP. Other jurisdictions can take similar steps to implement interventions appropriate to their populations at high risk for HIV infection or transmitting the virus that remove the financial and knowledge barriers experienced by potential users and prescribers of PrEP.

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## Errata

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### Vol. 64, No. 43

In the *MMWR* report, “Notes from the Field: Primary Amebic Meningoencephalitis Associated with Hot Spring Exposure During International Travel — Seminole County, Florida, July 2014,” the following acknowledgment should be included: “**Alejandro Jordan-Villegas, Pediatric Infectious Diseases, Florida Hospital for Children, Orlando, Florida.**”

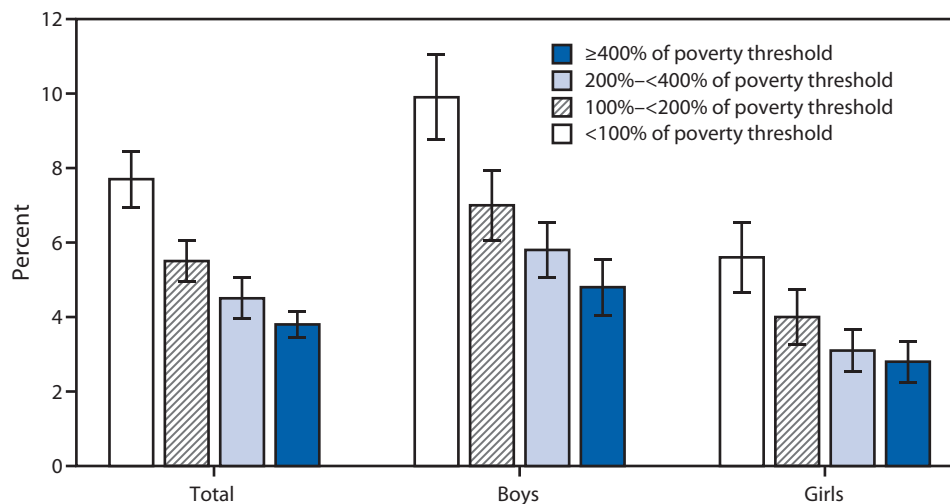
### Vol. 64, No. 45

On page 1278, in the QuickStats, “Percentage of Long-Term Care Services Providers\* That Use Electronic Health Records<sup>†</sup> and Have a Computerized System for Electronic Health Information Exchange,<sup>§</sup> by Provider Sector and Type of Electronic Health Information — United States, 2014,<sup>¶</sup>” the label for the first group of bars should have read, “Electronic health **records.**”

## QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

### Percentage\* of Children and Adolescents Aged 4–17 Years with Serious Emotional or Behavioral Difficulties,<sup>†</sup> by Poverty Status<sup>§</sup> and Sex — National Health Interview Survey, 2011–2014<sup>¶</sup>



\* With 95% confidence intervals indicated with error bars.

<sup>†</sup> Emotional or behavioral difficulties of children were based on parents' responses to the following question: "Overall, do you think that (child) has any difficulties in one or more of the following areas: emotions, concentration, behavior, or being able to get along with other people?" Response options were 1) "no"; 2) "yes, minor difficulties"; 3) "yes, definite difficulties"; and 4) "yes, severe difficulties." Children whose parents responded "yes, definite difficulties" or "yes, severe difficulties" were defined as having serious emotional or behavioral difficulties. These difficulties may be similar to but do not equate with the federal definition of serious emotional disturbance.

<sup>§</sup> Poverty status is based on family income and family size using the annually updated U.S. Census Bureau poverty thresholds. Family income was imputed when missing.

<sup>¶</sup> Estimates are based on household interviews of a sample of the civilian noninstitutionalized U.S. population and are derived from the National Health Interview Survey's Sample Child component.

During 2011–2014 the percentage of children with serious emotional or behavioral difficulties was about twice as high among children living in poor families (<100% of the poverty threshold) compared with children living in the most affluent families (≥400% of the poverty threshold) (7.7% versus 3.8%). This pattern was found for both boys (9.9% versus 4.8%) and girls (5.6% versus 2.8%). At each poverty status level a higher percentage of boys than girls had serious emotional or behavioral difficulties.

**Source:** National Center for Health Statistics, CDC. National Health Interview Survey. Available at <http://www.cdc.gov/nchs/nhis.htm>.

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