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Estimated coverage to address financial barriers to HIV preexposure prophylaxis among persons with indications for its use, United States, 2015

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Abstract

Background—An estimated 1.2 million American adults engage in sexual and drug use behaviors that place them at significant risk of acquiring HIV infection. Engagement in health care for the provision of daily oral antiretroviral medication as preexposure prophylaxis (PrEP), when clinically indicated, could substantially reduce the number of new HIV infections in these persons. However, resources to cover the financial cost of PrEP care is an anticipated barrier for many of the populations with high numbers of new HIV infections.

Methods—Using nationally representative data, we estimated the current national met and unmet need for financial assistance with covering the cost of PrEP medication, clinical visits, and laboratory costs among adults with indications for its use, overall and by transmission risk population.

Results—This study found that, of the 1.2 million adults estimated to have indications for PrEP use, <1% (~7,300) are in need of financial assistance for both PrEP medication and clinical care, at an estimated annual cost of $89 million. An additional 7% (~86,300) are in need of financial assistance only for PrEP clinical care at an estimated annual cost of $119 million.

Conclusion—This information on PrEP care costs, insurance coverage, and unmet financial need among persons in key HIV transmission risk subpopulations can inform policy makers at all levels as they consider how to address remaining financial barriers to the use of PrEP and accommodate any changes in eligibility for various insurance and financial assistance programs that may occur in coming years.

Keywords

HIV prevention; preexposure prophylaxis; PrEP implementation; health care financing; insurance

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Introduction

The Centers for Disease Control and Prevention (CDC) estimates that 1.2 million persons in the United States have sexual or injection behaviors that place them at substantial risk of acquiring HIV infection.[1] These adults would benefit from the use of daily oral antiretroviral prophylaxis (PrEP) which has been proven both safe and highly effective in reducing HIV infections for gay, bisexual and other men who have sex with men (MSM), heterosexually active females and males (HET), and persons who inject drugs not prescribed to them (PWID). The FDA approved PrEP as an indication for daily co-formulated tenofovir disoproxil fumarate and emtricitabine (brand name Truvada) in 2012 and CDC issued clinical practice guidelines for PrEP in 2014.[2] The affordability of medication, laboratory testing, and clinical care visits required for the safe prescription and monitoring of PrEP is a critical issue for its access by those who would benefit from its use. PrEP is being implemented in the United States at the same time as changes in the health care insurance landscape resulting from the Patient Protection and Affordable Care Act (ACA) enacted in 2010. Several studies have found that the anticipation of high cost is a barrier to the acceptability of PrEP use as an HIV prevention method.[3,4] However in one study of 30 financially disadvantage PrEP users in Mississippi[5], all had successfully accessed PrEP despite initial perceived concerns about costs. “While many participants noted that they had initially perceived the high cost of PrEP as a potential barrier to use, those barriers were overcome with the industry sponsored medication assistance program, which pays for PrEP for uninsured patients and provides assistance with medication copayments for insured individuals”. The one participant who stopped PrEP because they lost their job and insurance did not know about the medication assistance program. Although anticipated concerns about coverage of PrEP costs have been widely discussed online,[6] no published studies to document the scale of the problem were available so we assessed the extent to which insurance and PrEP assistance plans will meet the anticipated need.

Methods

Population inputs

Data from national population-based surveys were analyzed to estimate the percentages and numbers of persons with indications for PrEP as previously described[1]. Using the same population-based surveys, we estimated the percentages and number of persons with PrEP indications by insurance type and federal poverty level for each of the three major HIV transmission risk populations, MSM, HET, and PWID. Insurance type was categorized hierarchically into private insurance, public insurance, and no health insurance coverage. For MSM and HET, public insurance included Medicare, Medicaid, Medi-Gap, Indian Health Service, SCHIP, military health care (Champus, Champ/VA), state-sponsored health plan, and other government insurance and no health insurance was defined as the absence of private or public insurance or insured by only a single payer.[7,8] For PWID, public insurance included Medicare, Medicaid, Medi-Gap, SCHIP, military health care (Champus, Champ/VA) or other insurance and no health insurance was the absence of private or public insurance.[9] Federal poverty level was categorized into the estimated percentage and number of persons with household federal poverty level less than 500% or greater than or equal to

500%. The National Health and Examination Survey (NHANES) and National Survey of Family Growth (NSFG) already produce a calculated variable allowing federal poverty level to be grouped by both our definitions[7,8]. The National Survey on Drug Use and Health (NSDUH) does not report federal poverty level by the percentage ranges we defined. So to obtain estimates for PWID, we recalculated federal poverty level based on the U.S. Census Bureau's *Poverty Thresholds for 2013 by Size of Family and Number of Related Children Under 18 Years*, using the weighted average threshold since NSDUH does not include the number of children and size of family unit in their public release dataset.[10] Lastly, the percentage of uninsured persons ineligible for coverage due to immigration status, and uninsured persons in the coverage gap, were based on the Kaiser Family Foundation report, 'The Uninsured: A Primary'.[11]

Cost inputs

The costs of PrEP medication, clinical visits, and laboratory costs were identified from various sources. The Red Book was used to identify the 2016 average wholesale price for a 30 day supply of Truvada.[12] The estimated 340B pricing is equal to 51% of the average wholesale price.[13] The costs of clinical visits for the first year on PrEP were based on estimates reported by the American Medical Association for specified visit CPT billing codes.[14] Lastly, laboratory costs for tests recommended for the first year a person is taking PrEP were based on the Health Care Blue Book[15] and personal communication on Federally Qualified Health Center (FQHC) cost for 4th generation HIV test through a major commercial laboratory (Table 1).

Estimating persons with PrEP indications in need of assistance for all PrEP medication and care or PrEP care only

Figure 1 illustrates the logic of the analysis used to identify persons in need of financial assistance for PrEP care. For each transmission risk group, the health insurance status was identified as described above. For persons who had private or public insurance, based on reports from recent observational studies, we assumed that 1% of persons may have coverage for PrEP denied by their insurance and were therefore in need of assistance (2a). For persons who were uninsured, we then estimated that 15% of persons were undocumented (2b) and 10% of persons were living in a state that did not expand Medicaid coverage (2c).[11] These persons were not eligible for traditional Medicaid or ACA marketplace subsidies (in the coverage gap) and therefore in need of assistance. For persons who had private or public insurance coverage, we estimated the percentage and number who had insurance coverage that did cover PrEP care; these persons were not considered in need of assistance (3a). For persons who were uninsured, we estimated the percentage and number who were documented and not in the coverage gap, these persons were not considered in need of assistance (3b).

Of those identified as in need of assistance, some persons could obtain medication at no cost through the Medication Assistance Program (MAP) offered by Gilead Sciences to uninsured US residents whose household federal poverty level was less than 500%. By insurance coverage, we estimated the percentage of persons that had a federal poverty level less than 500% and identified those persons as in need of financial assistance for the cost of clinical

visits and laboratory tests (PrEP care) if they obtained medication through Gilead's MAP (4a). Those with a federal poverty level greater than or equal to 500% were not eligible for Gilead's MAP and therefore in need of financial assistance for the costs of medication, clinical visits, and laboratory tests (i.e., all PrEP medication and care) (4b).

Costs for medication, clinical visits and laboratory costs were calculated by transmission risk population when recommendations varied by group. Laboratory costs varied by transmission category and sex and included four HIV antibody tests, one 4th generation HIV test, 2 basic metabolic panels, 1 pregnancy test (females only), 1 hepatitis B serology test, 5 syphilis tests for MSM and 2 syphilis tests for the other transmission risk groups, and 15 nucleic acid amplification tests for gonorrhea and chlamydia (NAAT GC/CT) for MSM and 2 for the other transmission risk groups per year (Table 1b).

Based on the estimated number of persons by transmission risk category in need of financial assistance for all PrEP medication and care or for PrEP care but not medication, we estimated the cost per transmission risk group and the estimated total number of persons and cost if a payor of last resort program were to pay for medication, clinical visits, or laboratory tests among persons with indications for PrEP use who were uninsured or whose insurers denied coverage for PrEP.

Sensitivity analyses estimating the effect of varying two key inputs were conducted. The first sensitivity analysis accounted for the variability in the estimated number of persons with indications for PrEP by transmission risk group. We estimated lower and upper bound inputs by calculating the midpoint between the point estimate (Table 1) and the 95% confidence intervals; i.e., [point estimate – ((point estimate – lower 95% confidence interval)/2)].[1] The second sensitivity analysis accounted for the variability in the estimated percentage of persons in households with federal poverty level less than 500% by insurance coverage. Again, we estimated the lower and upper bound inputs by calculating the midpoint between the point estimate and the associated 95% confidence intervals (not reported).

Results

Our analyses of population-based survey data for 2015 estimates that of adults with PrEP indications, 64% of MSM had private insurance, 11% had public insurance, and 25% were uninsured; 49% and 51% of heterosexual females and heterosexual males respectively had private insurance, 27% and 20% had public insurance, and 24% and 29% were uninsured; while among PWID, 21% had private insurance, 29% had public insurance, and 50% were uninsured (Figure 2). The percentage of adults with PrEP indications living at a federal poverty level <500% varied by transmission risk category and insurance coverage (Table 1).

An estimated 50,800 persons with PrEP indications (Table 2) were undocumented US residents, comprising 15% of the uninsured. An estimated 36% of undocumented persons with PrEP indications were MSM, 34% were heterosexual females, 13% were heterosexual males, and 17% were PWID. An estimated 33,900 persons with PrEP indications were in the coverage gap, comprising 10% of the uninsured.

The estimated number of MSM, heterosexual females, heterosexual males, and PWID with indications for PrEP in need of any financial assistance is shown in Table 2. Based on the analysis algorithm (Figure 1), an estimated 34,200 MSM (7%) are in need of PrEP payment assistance, 30,500 of whom are uninsured. An estimated 32,000 (7%) heterosexual females are in need of PrEP payment assistance, 28,400 of whom are uninsured. An estimated 12,400 heterosexual males (8%) are in need of PrEP payment assistance, 11,300 of whom are uninsured. An estimated 15,000 PWID (13%) are in need of PrEP payment assistance, 14,500 of whom are uninsured.

The estimated number of persons in need of financial assistance for both PrEP medications and associated health care (Table 3) was 2,600 MSM, 3,500 heterosexual females, 100 PWID females, 1000 heterosexual males and 100 PWID males. In all transmission risk group populations, the number in need was <1% of those with indications for PrEP use. At Medicaid reimbursement rates for clinical care and 340B pricing for meds, the estimated annual cost of PrEP medications and care per person was $12,913 for MSM, $11,711 for heterosexual and PWID females, and $11,694 for heterosexual and PWID males.

The estimated number of persons in need of financial assistance for PrEP care alone (for clinical visits and laboratory tests but not PrEP medication), was 31,700 MSM, 28,500 heterosexual females, 7,000 PWID females, 11,400 heterosexual males and 7,000 PWID males. At Medicaid reimbursement rates for clinical care (including laboratory tests), the estimated annual cost of PrEP care per person was $2,143 for MSM, $941 for heterosexual and PWID females, and $924 for heterosexual and PWID males.

The average wholesale price of Truvada was $1,759.73,[16] while the estimated 340B price available to many federally funded clinics was $897.46.[13] Clinical visit costs summed to $422.21 for the first year for all persons with PrEP indications. At FQHC prices (Table 3), the cost of PrEP medication was 89% of costs in the first year of care, labs were 8%, and charges for clinical care visits were 3%.

Across all transmission risk group populations, an estimated 7,300 persons are in need of assistance for both PrEP medication and care, with an estimated annual cost of $88.9 million. In addition, 83,300 persons are in need of assistance for PrEP care only, with an estimated annual cost of $119.0 million. Of the 1.2 million adults with PrEP indications, less than 1% are in need of financial assistance for both PrEP medication and care and 7% are need of assistance for PrEP care only.

Sensitivity analyses found that using the calculated lower and upper bound inputs for the estimated number of persons with PrEP indications as described above, the number of persons in need of financial assistance ranged from 68,900 to 118,300 persons resulting in a range of annual costs of $153.3 million to $262.5 million. Using the calculated lower and upper bound inputs for the estimated percentage of persons in households with federal poverty level less than 500%, the number of persons in need of financial assistance remained the same (93,600) with estimated annual costs ranging from $177.6 million to $243.8 million.

Discussion

To inform ongoing discussions about supporting financial access to PrEP medication and associated health care for persons at substantial risk of HIV acquisition, it is important to have a measure of the extent of coverage already available and the size of the population in need of additional resources. We obtained these estimates by applying nationally representative data on public and private insurance coverage; and for the uninsured, data on household income, and criteria for eligibility for ACA insurance or the pharmaceutical PrEP medication assistance plan to a prior assessment of the number of persons with indications for PrEP use in the United States.[1]

In summary, we found that few persons with indications for PrEP use have an entirely unmet need for financial coverage of medication and/or associated clinical care costs. Of persons estimated to have indications for its use, 75% of MSM, 76% of Het females, 71% of Het males, and 50% of PWID have public or private insurance to cover most PrEP care costs. Of those who are privately insured, an unknown proportion are eligible for medication co-pay assistance (<500% FPL) from Gilead Sciences[17] or the Patient Advocates Foundation (<400% FPL).[18]

An estimated 75% of those who are uninsured are eligible by income for ACA insurance through federal or state exchanges. Of those with no access to private, public, or ACA insurance, 92% are eligible by household income for PrEP medication at no cost through the Gilead Medication Assistance Plan (MAP).[17] These persons will benefit from insurance navigation services to enroll in ACA or other healthcare insurance for which they are eligible, or assistance to enroll in the Gilead MAP if not insurable. In addition, PrEP has been nominated for review by the US Preventive Services Task Force. If it receives an A or B rating as a recommended preventive service, some cost elements may be reduced for those with health insurance.

Less than 1% of persons with indications for PrEP are not insured, not eligible for ACA insurance, and ineligible for MAP, resulting in an entirely unmet need for financial assistance for all elements of PrEP care. Many of these persons can receive subsidized care through sliding fee schedules at FQHCs and other safety-net clinics, but will still have problems with drug costs that may be prohibitive. For them, a number of solutions are being considered or have been implemented, including state PrEP assistance plans (payor of last resort plans), some of which cover only the medication[19], and some of which cover only the clinicial visit and lab costs.[20]

In all cases, navigation and linkage to PrEP care services by community workers, social workers, nurses, or others will aid in having more people with indications for its use aware of PrEP and able to access the necessary clinical care to receive it. Equally important, financial benefits navigation for all PrEP patients to ensure that they retain all coverage benefits as their employment status, income, residence, or other life circumstances change will be critical to retention in PrEP care and protective levels of medication adherence. Loss of insurance coverage leading to medication non-adherence has been associated with acquisition of HIV infection in cohorts of PrEP patients.[21]

The national cost of covering PrEP for all persons with indications for its use in need of assistance is significant, an estimated $208 million annually, including both those who need help with clinical care costs only, ($119 million) and those who need help with both medication and clinical care costs ($89 million). For comparison, the FY16 federal budget allocates 19.7 billion dollars for treatment and health care for persons already living with HIV infection, approximately 75% of the domestic funding for HIV.[22] In addition, while there is evidence that PrEP uptake is increasing rapidly in some locations[23-25] particularly among MSM, there are only estimated to be about 80,000 persons who were prescribed PrEP in 2012-2015 nationwide[26] or approximately 6% of the number who we estimate would benefit from its use. At current rates of uptake, it will be some time before all persons in need of financial assistance are attempting to access PrEP services.

Another key concern is that PrEP is not currently accessed equitably in the geographic areas (e.g., the southern US) and subpopulations (e.g., young African American MSM and women) experiencing the most severe disparities in rates of new HIV infections.[27] Given our analysis and the current financial burden in some subpopulations, existing inequities are likely to be exacerbated, especially among undocumented persons who are ineligible for most forms of federally-funded health insurance.

There are several limitations of the analysis that merit consideration. While we are unaware of any insurance, public or private, that has a formal policy not to cover PrEP care, we have used an estimate of 1% non-coverage to allow for the likelihood that we are unaware of the few plans that do not cover it, as well as the unknown proportion of coverage that is declined in error (i.e., despite no formal policy of non-coverage). This may be overestimating the number of insured persons who need financial assistance. There is a complex array of deductibles, co-pay, and coinsurance rates that apply to the range of insurance options depending on the level of plan chosen. Within each level, some plans have deductible limits for medications separate from the limit for all other expenses; some have a deductible for each individual in a family separate from the deductible for the family as a whole. This analysis does not include these potential out-of-pocket costs explicitly, although we do use income to assess eligibility for co-pay/co-insurance assistance and experience to date suggests that residual costs are affordable for most.

There are at least three areas where public health systems can leverage opportunities to support provision of PrEP as a clinical HIV prevention service: 1) linking clinical and community prevention, 2) supporting the development of alternative payment methodologies to cover community-based and clinical prevention services, and 3) using epidemiologic knowledge to ensure access to PrEP for populations at highest risk of HIV acquisition. Public health has a key role in developing and reinforcing systems to provide clinical and community prevention services.[28]

Conclusion

PrEP is an important new tool for HIV prevention and its expanded use is supported by several federal agency efforts, including the National HIV/AIDS Strategy. The FDA-approved use of Truvada for PrEP has been widely available for four years, but many people

who can benefit from PrEP aren't yet being prescribed it. The causes for this are varied, but concern is frequently raised about the costs of the daily medication, and the ongoing periodic clinical visits and laboratory testing recommended by the Public Health Service (PHS) clinical practice guidelines issued by CDC to ensure its safe and effective use. This study found that a small number of patients would not be financially covered for their clinician visits and laboratory tests, and an even smaller number would have no coverage for medication, as well as the clinical costs of PrEP care. If the eligibility for different types of insurance, medication or co-pay assistance programs changes substantially in coming years, it will impact the financial feasibility of scaling up PrEP use to the many who would benefit from its use. This information on PrEP care costs, insurance coverage, and unmet financial need among persons in key HIV transmission risk subpopulations can inform policy makers at all levels as they consider how to begin addressing remaining financial barriers to the use of PrEP in their communities as part of a renewed effort to decrease the number of new HIV infections in the United States.

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References

1. Smith DK, Van Handel M, Wolitski RJ, et al. Vital signs: Estimated percentages and numbers of adults with indications for preexposure prophylaxis to prevent HIV acquisition–United States, 2015. Morbidity and Mortality Weekly Report. 2015; 64(46):1291–1295. [PubMed: 26606148]
2. Centers for Disease Control and Prevention. [Accessed May 28, 2014] US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States - 2014: a clinical practice guideline; 2014. p. 1-67.http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf
3. Auerbach JD, Kinsky S, Brown G, Charles V. Knowledge, attitudes, and likelihood of pre-exposure prophylaxis (PrEP) use among US women at risk of acquiring HIV. AIDS Patient Care STDS. 2015; 29(2):102–110. [PubMed: 25513954]
4. Perez-Figueroa RE, Kapadia F, Barton SC, Eddy JA, Halkitis PN. Acceptability of PrEP Uptake Among Racially/Ethnically Diverse Young Men Who Have Sex With Men: The P18 Study. AIDS Educ Prev. 2015; 27(2):112–125. [PubMed: 25915697]
5. Arnold T, Brinkley-Rubinstein L, Chan PA, et al. Social, structural, behavioral and clinical factors influencing retention in Pre-Exposure Prophylaxis (PrEP) care in Mississippi. PloS one. 2017; 12(2):e0172354. [PubMed: 28222118]
6. Project Inform. Financing and Delivery Mechanisms to Increase Pre-Exposure Prophylaxis (PrEP) Access in Populations at High-Risk of HIV Infection. 2011. http://www.projectinform.org/pdf/PrEp%20Financing%20Report.pdf
7. Centers for Disease Control and Prevention. [Accessed November 9, 2016] National Health and Nutriotion Examination Survey. 2015. http://www.cdc.gov/nchs/nhanes/nhanes_questionnaires.htm
8. Centers for Disease Control and Prevention. [Accessed November 9, 2016] National Survey of Family Growth. 2015. http://www.cdc.gov/nchs/nsfg/nsfg_questionnaires.htm
9. Substance Abuse and Mental Health Services Administration. [Accessed November 9, 2016] National Survey on Drug Use and Health. 2015. http://www.samhsa.gov/data/population-data-nsduh

10. Census Bureau, US. [Accessed July 7, 2016] Poverty Thresholds for 2013 by Size of Family and Number of Related Children Under 18 Years. 2016. https://www.census.gov/data/tables/time-series/demo/income-poverty/historical-poverty-thresholds.html
11. Kaiser Family Foundation. [Accessed July 7, 2016] The Uninsured: A Primer. 2015. http://files.kff.org/attachment/primer-the-uninsured-a-primer-key-facts-about-health-insurance-and-the-uninsured-in-the-era-of-health-reform
12. Truven Health Analytics. [Accessed July 7, 2016] Red Book. 2016. http://micromedex.com/products/product-suites/clinical-knowledge/redbook
13. Congressional Budget Office. [Accessed June 12, 2016] Prices for Brand-Name Drugs Under Selected Federal Programs. 2005. http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/64xx/doc6481/06-16-prescriptdrug.pdf
14. American Medical Association. [Accessed July 7, 2016] CPT Code/Relative Value Search Tool. 2016. https://www.ama-assn.org/practice-management/find-coding-resources
15. CAREOperative. [Accessed July 7, 2016] Healthcare Bluebook. 2016. https://healthcarebluebook.com/page_Default.aspx
16. Panel on Antiretroviral Guidelines for Adults and Adolescents. [Accessed June 12, 2016] Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents Department of Health and Human Services Cost Considerations and Antiretroviral Therapy. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. 2016. https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/459/cost-considerations-and-antiretroviral-therapy
17. Gilead Sciences. Programs are available that may help lower the cost of TRUVADA for PrEP. 2016. https://start.truvada.com/paying-for-truvada
18. Patient Advocate Foundation. Co-Pay Relief. 2016. https://www.copays.org/diseases/hiv-aids-and-prevention
19. Washington State Department of Health. [Accessed 12 June 2016] Pre-Exposure Prophylaxis Drug Assistance Program (PrEP DAP). 2014. http://www.doh.wa.gov/YouandYourFamily/IllnessandDisease/HIVAIDS/HIVCareClientServices/PrEPDAP
20. New York State AIDS Institute. [Accessed June 12, 2016] Pre-Exposure Prophylaxis Assistance Program (PrEP-AP). 2015. https://www.health.ny.gov/diseases/aids/general/resources/adap/prep.htm
21. Marcus JL, Hurley LB, Hare CB, et al. Preexposure Prophylaxis for HIV Prevention in a Large Integrated Health Care System: Adherence, Renal Safety, and Discontinuation. JAIDS Journal of Acquired Immune Deficiency Syndromes. 2016; 73(5):540–546. [PubMed: 27851714]
22. Kaiser Family Foundation. [Accessed June 12, 2016] Fact Sheet: U.S. Federal Funding for HIV/AIDS: Trends Over Time. 2016. http://kff.org/global-health-policy/fact-sheet/u-s-federal-funding-for-hivaids-trends-over-time/
23. Laufer FN, O'Connell DA, Feldman I, Mps, Zucker HA. Vital Signs: Increased Medicaid Prescriptions for Preexposure Prophylaxis Against HIV infection--New York, 2012-2015. MMWR Morb Mortal Wkly Rep. 2015; 64(46):1296–1301. [PubMed: 26606257]
24. Hood JE, Buskin SE, Dombrowski JC, et al. Dramatic increase in preexposure prophylaxis use among MSM in Washington state. AIDS. 2016; 30(3):515–519. [PubMed: 26562845]
25. Chen YH, Snowden JM, McFarland W, Raymond HF. Pre-exposure Prophylaxis (PrEP) Use, Seroadaptation, and Sexual Behavior Among Men Who Have Sex with Men, San Francisco, 2004–2014. AIDS and Behavior. 2016:1–7. [PubMed: 26370101]
26. Mera R, MS., Palmer, B., Mayer, G., Magnuson, D., Rawlings, K. FTC/TDF (Truvada) for HIV Pre-Exposure Prophylaxis (PrEP) Utilization in the United States: 2012-2015. 2016. http://programme.aids2016.org/PAGMaterial/PPT/5404_11614/Mera%20TVD%20PrEP%20utilization%20IAC%202016%20FINAL.pptx
27. Bush S, MD., Rawlings, M., Hawkins, T., McCallister, S., Mera-Giler, R. American Society for Microbiology 2016. Boston, MA: Jun 16-20. 2016 Racial Characteristics of FTC/TDF for Pre-Exposure Prophylaxis Users in the US. 2016

28. O'Connor JC, Gutelius BJ, Girard KE, Drum Hastings D, Longoria L, Kohn MA. Paying for prevention: a critical opportunity for public health. The Journal of law, medicine & ethics : a journal of the American Society of Law, Medicine & Ethics. 2013; 41(1):69–72.

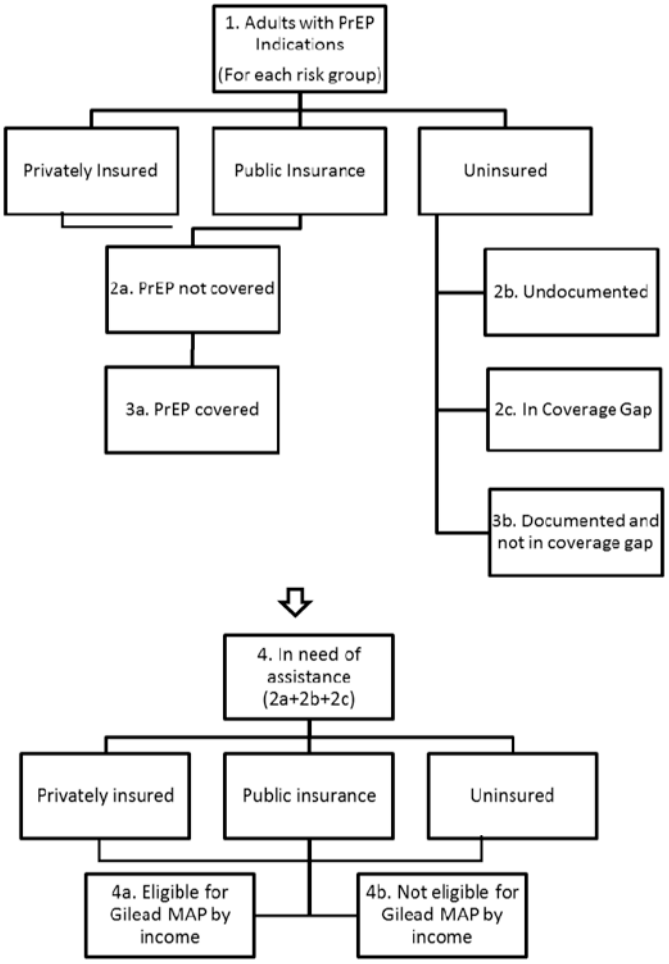

Figure 1.
Diagram of Analysis Algorithm

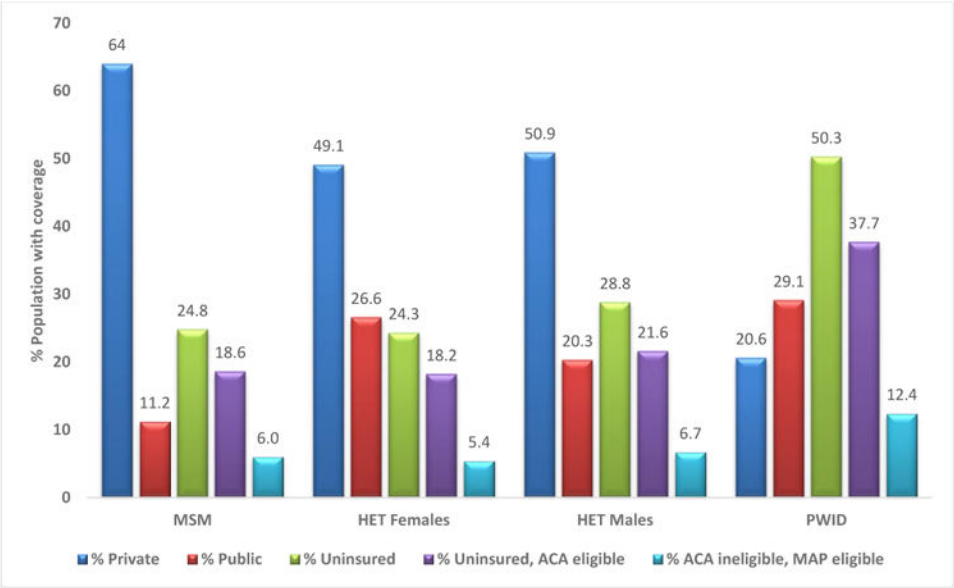

Figure 2.

Coverage Status by Transmission Risk Group, ACA - Affordable Care Act; HET - heterosexually active persons; MAP – Medication Assistance Program; MSM = men who have sex with men; PWID = persons who inject drugs

Table 1

Estimates of insurance status by transmission risk group and PrEP cost estimates

A. Population inputs	**Total**	**MSM**	**HET Females**	**HET Males**	**PWID**
Adults with PrEP indications[1] (N)	1,232,000	492,000	468,000	157,000	115,000
% FPL <500% among privately insured adults[2,3,4]		57.1	83.6	75.7	66.0
% FPL <500% among publicly insured adults[2,3,4]		92.3	99.1	90.6	98.4
% FPL <500% among uninsured adults[2,3,4]		96.2	89.1	92.7	98.9
Uninsured in the coverage gap[5]	10%				
Uninsured ineligible for coverage due to immigration status[5]	15%				
B. Cost Inputs					
Clinician visit costs[7]					
Initial assessment visit (CPT 99204)	$ 166.73				
Initial prescription visit (CPT 99213)	$ 73.30				
Quarterly follow-up visit (CPT 99213)	$ 73.30				
Annual follow-up visit (CPT 99214)	$ 108.88				
Visits for first year, total	$ 422.21				
Clinical laboratory costs					
HIV antibody test (serum) [8]	$ 36.00				
4th generation HIV test (antibody+antigen) [9]	$ 80.00				
Basic metabolic panel (with creatinine, eCrCl) [8]	$ 22.00				
Urine pregnancy test [8]	$ 17.00				
Hepatitis B serology panel (HBsAg, HBsAb) [8]	$ 28.00				
Syphilis serology (RPR, reflex confirmatory tests) [8]	$ 12.00				
NAAT GC/CT (per site sampled, 1 for HET M &F, 3 for MSM)[9]	$ 91.00				
Truvada costs (per 30 day supply)					
Average wholesale price[10]	$ 1,759.73				
Estimated 340B price[11]	$ 897.46				

PrEP – preexposure prophylaxis MSM – men who have sex with men HET – heterosexually active adults PWID – persons who inject drugs FPL – federal poverty level CPT – common procedural terminology eCrCl – estimated creatinine clearance HBsAg – hepatitis B surface antigen HBsAb – hepatitis B surface antibody RPR – rapid plasma reagin GC – gonorrhea NAAT- nucleic acid amplification test CT – chlamydia trachomatis M – male F – female

[1] Smith DK, et al. MMWR 2015

[2] CDC, National Health and Nutrition Examination Survey

[3] CDC, National Survey of Family Growth

[4] SAMHSA, National Survey on Drug Use and Health

[5] Kaiser Family Foundation. The Uninsured: A Primer, 2015

[7] American Medical Association, CPT Relative Value Search Tool

[8] CareOperative, Healthcare Blue Book

[9] Personal communication with a major commercial laboratory

[10] Truven Analytics, Red Book

[11] CBO, Prices for Brand-Name Drugs Under Selected Federal Programs. 2005

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Table 2

Estimated number of adults in need of financial assistance to pay for medication or clinical visits and labs, by HIV transmission category

	Private				Public insurance				Uninsured				Total
	MSM	HET Females	Het Males	PWID	MSM	HET Females	Het Males	PWID	MSM	HET Females	Het Males	PWID	
Adults with PrEP indications	314,880	229,790	79,910	23,690	55,100	124,490	31,870	33,470	122,020	113,720	45,220	57,850	1,232,000
PrEP payment support not available													
Insurance coverage denies payment	3,150	2,300	800	240	550	1,240	320	330	na	na	na	na	8,930
Ineligible for coverage due to immigration status	na	na	na	na	na	na	na	na	18,300	17,060	6,780	8,680	50,820
In Coverage Gap	na	na	na	na	na	na	na	na	12,200	11,370	4,520	5,790	33,880
PrEP payment support available													
Insurance coverage for PrEP	311,730	227,490	79,110	23,450	54,550	123,250	31,550	33,140	na	na	na	na	884,270
Documented and income eligible for marketplace	na	na	na	na	na	na	na	na	91,520	85,290	33,920	43,390	254,120
In need of financial assistance	3,150	2,300	800	240	550	1,240	320	330	30,500	28,430	11,300	14,470	93,630
Eligible for Gilead MAP (income <500% FPL)	1,800	1,920	610	160	510	1,230	290	320	29,340	25,330	10,480	14,310	86,300
Not eligible for Gilead MAP (income ≥500% FPL)	1,350	380	190	80	40	10	30	10	1,160	3,100	820	160	7,330

*All estimates are rounded; totals may not sum due to rounding

PrEP – preexposure prophylaxis MSM –men who have sex with men HET- heterosexually active adults PWID – persons who inject drugs FPL – federal poverty level MAP – medication assistance plan

Table 3

Estimated* cost for medication, clinical visits, and labs for adults in need of financial assistance, by HIV transmission risk category

	Per Person					Population Total (Annual Cost)
	MSM	**HET Females**	**HET Males**	**PWID Females**	**PWID Males**	
# In need of financial assistance to pay for medication, clinical visits, and labs	2,550	3,490	1,040	130	130	7,330
Annual cost of PrEP care at an FQHC (with 340B drug pricing)						
Truvada	$ 10,770	$ 10,770	$ 10,770	$ 10,770	$ 10,770	$ 78,940,780
Clinical visits at Medicaid reimbursement rates	$ 422	$ 422	$ 422	$ 422	$ 422	$ 3,094,800
Lab costs	$ 1,721	$ 519	$ 502	$ 519	$ 502	$ 6,849,480
Total	$ 12,913	$ 11,711	$ 11,694	$ 11,711	$ 11,694	$ 88,885,060
# In need of financial assistance to pay for clinical visits and labs, but not medication	31,650	28,480	11,380	7,400	7,400	83,310
Annual cost of non-medication PrEP care at an FQHC						
Clinical visits at Medicaid reimbursement rates	$ 422	$ 422	$ 422	$ 422	$ 422	$ 36,440,950
Lab costs	$ 1,721	$ 519	$ 502	$ 519	$ 502	$ 82,518,930
Total	$ 2,143	$ 941	$ 924	$ 941	$ 924	$ 118,959,880

* All estimates are rounded; totals may not sum due to rounding

PrEP – preexposure prophylaxis FQHC – federally qualified health center MSM – bisexual and other men who have sex with men HET heterosexually active adults PWID – persons who inject drugs