

# **Current and (Potential) Future Effects of the Affordable Care Act on HIV Prevention**

Abigail H. Viall<sup>1</sup> · Eugene McCray<sup>1</sup> · Jonathan Mermin<sup>2</sup> · Pascale Wortley<sup>1</sup>

Published online: 19 February 2016 © Springer Science+Business Media New York (outside the USA) 2016

Abstract Recent advances in science, program, and policy could better position the nation to achieve its vision of the USA as a place where new HIV infections are rare. Among these developments, passage of the Patient Protection and Affordable Care Act (ACA) in 2010 may prove particularly important, as the health system transformations it has launched offer a supportive foundation for realizing the potential of other advances, both within and beyond the clinical arena. This article summarizes opportunities to expand access to high-impact HIV prevention interventions under the ACA, examines whether available evidence indicates that these opportunities are being realized, and considers potential challenges to further gains for HIV prevention in an era of health reform. This article also highlights the new roles that HIV prevention programs and providers may assume in a health system no longer defined by fragmentation among public health, medical care, and community service providers.

Keywords Affordable Care Act  $\cdot$  HIV  $\cdot$  Prevention  $\cdot$  HIV prevention  $\cdot$  Health care  $\cdot$  Health insurance  $\cdot$  Public health  $\cdot$  Review

This article is part of the Topical Collection on The Science of Prevention

Abigail H. Viall bzv3@cdc.gov

### Introduction

HIV prevention in the USA is experiencing a renaissance. Scientific advances have expanded the breadth of interventions and strategies available and have improved the precision and effectiveness with which they are deployed. Concurrently, the Patient Protection and Affordable Care Act (ACA) is driving changes in the financial and operational architecture of the US health system to improve the availability and accessibility of needed services, as well as the value realized by individuals and populations through their delivery. The confluence of these events has encouraged HIV prevention stakeholders to not only articulate visions (e.g., an "AIDS-Free" generation) that might have seemed untenable a decade ago but also chart a course toward their realization. Reaching the envisioned endpoints within the ambitious timelines set by the National HIV/AIDS Strategy (NHAS) will depend on the ability of HIV programs and providers to successfully capitalize on new structural and policy opportunities created by the ACA to advance HIV prevention through and beyond healthcare [1••].

As many of the ACA's provisions did not go into full effect until 2014, its ultimate ramifications for HIV prevention remain to be determined. In this article, we articulate some core provisions of the ACA and the potential opportunities they present for advancing HIV prevention goals both within and beyond the boundaries of the health care system (see Table 1). We also review the evidence currently available to suggest whether, in fact, anticipated gains are materializing, and we explore potential contributors and impediments to their emergence. Finally, we outline a vision for a transformed prevention landscape—one characterized by closer



<sup>&</sup>lt;sup>1</sup> Division of HIV/AIDS Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC), 1600 Clifton Road NE, Atlanta 30329, GA, USA

<sup>&</sup>lt;sup>2</sup> National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC), Atlanta, GA, USA

Table 1 Notable provisions in the Affordable Care Act: what they do and why they may matter for HIV prevention

| Location reference             | What changes  | HIV prevention relevance  |  |  |
|--------------------------------|---|---|--|--|
| Section 1001                   | Requires plans/issuers that offer dependent coverage to make the coverage available until the dependent is 26   | Increased availability and accessibility of<br>health insurance to persons living with<br>or at high risk for acquiring HIV                     |  |  |
| Section 1201                   | Bars health plans and health insurance issuers from imposing any<br>preexisting condition exclusion with respect to such plan or<br>coverage  |   |  |  |
| Sections 1401-1402             | Provides financial assistance in the form of premium tax credits<br>(available on a sliding scale for persons whose household income<br>falls between 100 and 400 % Federal Poverty Level, or FPL) and<br>cost sharing subsidies (for persons who purchase a silver level plan<br>and have household incomes between 100 and 250 % FPL)   | edits<br>d income<br>FPL) and<br>level plan<br>TPL)   |  |  |
| Section 1557                   | Prohibits discrimination in certain health programs and activities<br>on the basis of race, color, national origin, sex, age, or disability   |   |  |  |
| Section 2001                   | Expands Medicaid eligibility to all Americans <65 whose household income falls at or below 138 % FPL  |   |  |  |
| Sections 1001 and 1302(c)      | <ul> <li>Adds annual limits on beneficiary out-of-pocket costs (including<br/>any cost-sharing or coinsurance obligations, but excluding<br/>premiums) for individual and family coverage</li> <li>Removes annual and lifetime limits on plans' coverage for<br/>essential health benefits</li> </ul>   | Increased access to and use of high impact<br>HIV prevention and care services  |  |  |
| Sections 1001, 4105-4106       | Requires (1001, 4104) or incentivizes (4106) coverage of certain<br>preventive services without cost sharing under Medicare,<br>Medicaid, and private health plans  |   |  |  |
| Section 1302(a)                | <ul> <li>Requires nongrandfathered health plans in the individual and<br/>small group markets, as well as alternative benefit plans offered<br/>to Medicaid expansion populations, to cover items and services<br/>in ten benefit categories including the following:</li> <li>Ambulatory patient services</li> <li>Mental health and substance use disorder services</li> <li>Prescription drugs</li> <li>Preventive and wellness services and chronic disease<br/>management</li> </ul> |   |  |  |
| Sections 3301 and 3314         | Gradually eliminates (by 2020) the so-called "donut hole" under<br>Medicare Part D and specifically allows AIDS Drug Assistance<br>Program (ADAP) expenditures for covered Part D drugs to count<br>towards Medicare Part D enrollees' True-Out-Of-Pocket (TrOOP)<br>limits   |   |  |  |
| Section 2703                   | <ul> <li>Creates a new option for state Medicaid programs to establish "health homes" that can coordinate care for Medicaid enrollees who</li> <li>Have 2 or more specified chronic conditions (HIV is among these)</li> <li>Have one chronic condition and are at risk for a second</li> </ul>   | Enhanced healthcare system capacity to<br>deliver high quality, coordinated care to<br>persons living with or at high risk for<br>acquiring HIV |  |  |
| Sections 2701, 3002, 3011-3015 | <ul> <li>Have one serious and persistent mental health condition</li> <li>Institutes new (e.g., Medicaid adult core measure set) and<br/>strengthens existing (e.g., Physician Quality Reporting System)<br/>healthcare quality measurement efforts</li> <li>Calls for creation of a national strategy to improve healthcare<br/>quality and health outcomes</li> </ul>   |   |  |  |
| Section 3021                   | Establishes an Innovation Center within the Centers for Medicare<br>and Medicaid Services and provides funding for the Innovation<br>Center to develop and test innovative health care payment and<br>service delivery models, including patient centered medical<br>homes and accountable care organizations   |   |  |  |
| Section 5601                   | Provides \$11B in new, dedicated funding for community health centers operations and expansions   |   |  |  |

coordination and integration among public health, community, and medical care providers-and the unique roles that public health can play within this emergent health system.

# Prevention *Through* Healthcare Requires Access *to* Healthcare

Access to comprehensive healthcare services in the USA has generally been mediated through affordable health insurance [2]. For many people living with or at high risk for acquiring HIV, such coverage has been unavailable. Data from the Centers for Disease Control and Prevention's (CDC) Medical Monitoring Project show that between 2009 and 2012, almost 18 % people living with HIV (PLWH) who were actively engaged in HIV medical care lacked any form of health insurance [3]. Estimates from Health Resources and Services Administration (HRSA) suggest that almost 27.6 % of those who received services through the Ryan White program in 2012 were uninsured [4]. Because both systems are limited to PLWH who sought healthcare or support services, these estimates are likely to underestimate the percentage of all PLWH who lack health insurance. Moreover, at least 40 % of HIV-infected adults in medical care received health insurance through Medicaid and/or Medicare, programs for which they generally qualified only once their disease was sufficiently advanced that they became eligible for disability benefits under Social Security [3]. Determining insurance coverage among persons at high risk for acquiring HIV is even more difficult, as the estimates will vary according to a host of conceptual (e.g., the definition of "risk" used) and methodological (e.g., the sampling methods employed) factors. Individuals who belong to demographic groups associated with increased risk of HIV acquisition-for example, young adult men, African-Americans, and persons who belong to low-income households-are more likely to be uninsured [5]. The highest risk subpopulations within these broad groups are likely at even greater risk for being uninsured. For example, data collected through CDC's National HIV Behavioral Surveillance (NHBS) system suggest that, among those surveyed, almost 40 % of persons who injected drugs were uninsured in 2012. Among men who have sex with men (MSM) (surveyed in 2011) and high-risk heterosexuals (surveyed in 2013), the proportions uninsured were 30 and 36 %, respectively [6-8].

The ACA introduces a number of policy changes intended to address systemic gaps that leave millions of Americans without insurance, or with insurance that offers inadequate access to critical services and incomplete protection from high medical expenses. Specifically, the law bars coverage denials or premium rate setting on the basis of preexisting conditions (e.g., HIV infection), extends dependent coverage to the age of 26, ends annual and lifetime caps on coverage for the essential health benefits (EHB), creates the Health Insurance Marketplace (or "exchange") through which individuals can compare health plans and purchase health insurance, provides advance premium tax credits to individuals with incomes between 100 and 400 % of the Federal Poverty Limit (FPL) and cost sharing reductions for those in the 100 to 250 % of FPL range, and expands Medicaid eligibility (at states' discretion) to all individuals whose household incomes fall at or below 138 % FPL [9•, 10••].

Recent analyses of data from the National Health Interview Survey (NHIS) and the Gallup-Healthways Well-Being Index suggest substantial gains in coverage across major demographic categories, particularly racial and ethnic minorities and young adults, during the ACA's first year of full implementation [11, 12•]. In keeping with the law's emphasis on making insurance more affordable, individuals whose household incomes fall below 250 % FPL seem to account for a sizeable share of these gains [10]. According to the Center for Medicaid and CHIP Services, between October 2013 and May 2015, over 12.8 million additional individuals had enrolled in Medicaid and CHIP [13]. And, enrollment data reported by the independent state exchanges and the federally facilitated marketplace, Healthcare.gov, suggest that of the 9.9 million individuals who selected an insurance plan from an exchange and paid their first month's premium as of June 2015, 84 % were eligible for federal subsidies in the form of premium tax credits and financial assistance with outof-pocket costs, such as deductibles, copayments, and coinsurance [14].

Given the combination of traditionally low rates of insurance coverage and high rates of poverty and near-poverty among people at risk for or living with HIV, it seems reasonable to expect that these groups will realize some of the coverage gains reflected in the aforementioned national trends. To date, there appears to be at least some data that support this supposition. Published projections suggest that between 70, 000 and 200,000, PLWH could newly gain coverage under the ACA if all states expanded Medicaid [15, 16]. Anecdotal data suggest that many PLWH have taken advantage of this opportunity in the first 2 years since the full provisions of the ACA went into effect. An analysis that compared prescription drug data for more than 1 million individuals newly enrolled in plans offered through the Health Insurance Marketplace with that of a matched cohort of one million individuals who received coverage through their employers found that Marketplace enrollees had significantly higher odds (OR = 3.7) of using specialty drugs generally used to treat HIV; the authors interpret this finding as potentially indicative that PLWH are experiencing meaningful coverage gains under the ACA [17]. And, recently published from CDC show that, among MSM who participated in the most recent NHBS data collection cycles, the percentage who reported being uninsured dropped from 31 % in 2011 to 21 % in 2014 [18]. Monitoring the extent to which these early signals represent meaningful gains in insurance coverage among people living with or at high risk for acquiring HIV will be a critical part of efforts to ensure the ACA's benefits are fully and equally realized across all populations.

## Prevention *Through* Healthcare Requires Access to the "*Right*" Healthcare Services

In addition to expanding health insurance coverage, the ACA also introduces a number of insurance benefit design, payment, and delivery system reforms that are intended to push the US health system closer to realizing the "Triple Aims" of better individual care experiences, healthier populations, and lower per capita costs of care [19]. People living with or at risk for acquiring HIV often have myriad healthcare needs and priorities; as a result, HIV-related outcomes are shaped by more than access to those services and supports that typically fall under the rubric of HIV prevention and care. An HIV-prevention optimizing system, then, will be one that provides adequate access not only to the kinds of HIV prevention services that address the medical, social, and structural determinants that lead to poor outcomes among populations at greatest risk.

### Screening and Risk-Based Testing for HIV and Other Diseases with Shared Transmission Pathways

Through HIV testing, individuals who are diagnosed with HIV can be swiftly connected a suite of services that increase the quality and length of their lives and decrease their risk of transmitting HIV to others. Meanwhile, those whose HIV test results are negative but who indicate substantial behavioral risk (e.g., active injection drug use or unprotected anal intercourse) can explore the full range of currently available preventive options—including risk reduction education, condom use, preexposure prophylaxis, and medication-assisted drug treatment—with their providers.

The USA has made important progress toward reducing the proportion of PLWH who remain unaware of their infections [20]. However, to reach the estimated one in eight persons living with HIV who remain unaware of their infections, efforts to implement routine HIV testing must be sustained and expanded [19]. Unfortunately, despite recommendations from CDC and the United States Preventive Services Task Force (USPSTF) that individuals between the ages of 15 and 65 should be tested for HIV at least once in their lifetimes and that those with risk factors should be tested more frequently (at least annually), HIV testing rates remain suboptimal [22, 23]. According to the most recently released estimates from NHIS, less than 40 % of adults reported having ever been tested for HIV [24]. Meanwhile, data from National Survey of Family Growth (NSFG) suggest that, among individuals between the ages of 15 and 44 who report behaviors that increase their risk for acquiring HIV, approximately twothirds were not tested for HIV in the last year [25, 26].

The ACA introduces a requirement for nongrandfathered health plans to cover without cost sharing (1) preventive services that have in effect an "A" or "B" rating from the

USPSTF. (2) immunizations recommended by the Advisory Committee on Immunization Practices, and (3) guidelines for preventive care and screenings for women, infants, and children recognized by HRSA [27...]. Through subsequent rulemaking, the Department of Health and Human Services (DHHS) has further clarified that these coverage requirements are included in its definition of the essential health benefits package and so are applicable to both qualified health plans (QHPs) sold through the Health Insurance Marketplace and Alternative Benefit Plans (ABPs) offered to Medicaid Expansion populations [28, 29]. As a consequence, more Americans-including many persons living with HIV or at increased risk of acquiring it-now have enhanced access to HIV testing, as well as screening and preventive services for other related conditions (e.g., gonorrhea, syphilis, and hepatitis C) that operate as sentinel conditions for behavioral risk and, in some cases, independently increase individual risk for HIV acquisition or transmission (see Table 2).

#### Linkage to, and Retention in, HIV-Related Care

In 2013, only 73 % of persons newly diagnosed with HIV were successfully linked to care within 30 days, and only 54 % of individuals living with diagnosed HIV were retained in care in 2012 [1••]. The consequences of these system failures for both individual and public health are significant: Individuals who do not start antiretroviral therapy quickly or who are not adequately retained in care may experience delayed virologic suppression, higher cumulative viral load burden, poorer immunologic function and overall health, and increased risk of death [30–34]. In a recent analysis of HIV transmissions at each step of the care continuum, individuals diagnosed with HIV but not receiving regular care accounted for 61 % of the HIV transmissions estimated to have occurred in the USA [35•].

The extent to which individuals who do not have HIV, but are at increased risk for acquiring it, are successfully linked to, and continuously able to access, clinical preventive services is unknown. However, it is plausible that the same health system fragmentation responsible for the abovementioned failures in the HIV care continuum also contributes to inconsistent utilization of recommended preventive services such as preexposure prophylaxis, risk reduction counseling, and medication-assisted treatment for substance use disorders, by persons at high risk for acquiring HIV.

Through its authorization of and provision of funding support for various new care delivery and payment models and reform efforts, including patient-centered medical homes, accountable care organizations, Medicaid Health Homes, and the State Innovation Model (SIM) initiative, the ACA is pushing the US health system from a model that primarily supports acute care delivery to one that emphasizes patient and

 Table 2
 Cost-sharing under the ACA for important HIV/STI primary prevention services

Services currently subject to ACA requirements for coverage without cost-sharing<sup>a</sup>

| Recommendation source                     | Intervention or service   | Rating <sup>b</sup> | Population(s) addressed   | Date recommendation issued              |
|---|---|---------------------|---|---|
| USPSTF                                    | Alcohol misuse: screening and behavioral counseling                                     | В                   | Adults aged 18 and older  | May 2013                                |
| USPSTF                                    | Interventions in primary care<br>Chlamydia and gonorrhea: screening                     | В                   | Sexually active women age 24 years<br>and younger and in older women<br>who are at increased risk for<br>infection  | September 2014                          |
| USPSTF                                    | Hepatitis B in pregnant women:  | А                   | Pregnant women  | June 2009                               |
| USPSTF                                    | Hepatitis B virus infection:<br>screening 2014  | В                   | Persons at high risk for infection  | May 2014                                |
| USPSTF                                    | Hepatitis C: screening  | В                   | Adults at high risk for infection; one-<br>time screening for HCV infection<br>to adults born between 1945 and<br>1965.                                     | June 2013                               |
| USPSTF                                    | Human immunodeficiency virus<br>(HIV) infection: screening                              | A                   | Adolescents and adults 15–65 years<br>old, regardless of risk; pregnant<br>women; adolescents and adults<br>who are at increased risk,<br>regardless of age | April 2013                              |
| USPSTF                                    | Sexually transmitted infections:<br>behavioral counseling <sup>d</sup>                  | В                   | Sexually active adolescents and for<br>adults who are at increased risk<br>for sexually transmitted infections<br>(STIs).                                   | September 2014                          |
| USPSTF                                    | Syphilis infection in pregnancy:  | А                   | Pregnant women  | May 2009                                |
| USPSTF                                    | Syphilis infection: screening   | А                   | Persons at increased risk for syphilis  | July 2004 <sup>g</sup>                  |
| ACIP                                      | Hepatitis B: vaccination  | Recommended         | Unvaccinated adolescents<br>(<19 years of age); adults at<br>increased risk for HBV   | December 2005;<br>December 2006         |
| Bright Futures, 3rd Edition               | STI screening: gonorrhea and<br>chlamydia   | Recommended         | Sexually active adolescents and young adults, ages 11–21  | 2008                                    |
| Bright Futures, 3rd Edition               | STI screening: syphilis and HIV   | Recommended         | Sexually active adolescents and<br>young adults, ages 11–21, who<br>screen positive for risk  | 2008                                    |
| Bright Futures, 3rd Edition               | Administration of alcohol, drug use screening tool                                      | Recommended         | Adolescents and young adults, ages<br>11–21, who are positive or risk<br>screening questions  | 2008                                    |
| Women's Preventive Services<br>Guidelines | Counseling for sexually transmitted infections  | Recommended         | All sexually active women   | August 2012                             |
| Women's Preventive Services<br>Guidelines | Counseling and screening for HIV  | Recommended         | All sexually active women   | August 2012                             |
| Women's Preventive Services<br>Guidelines | Contraceptive Methods and<br>Counseling <sup>e</sup>                                    | Recommended         | All women with reproductive capacity  | August 2012                             |
| Services not currently subject to         | ACA requirements for coverage witho   | ut cost-snaring     |   |   |
| Recommendation Source <sup>o</sup>        | Intervention or service   | Rating <sup>6</sup> | Population(s) addressed   | Date recommendation issued <sup>b</sup> |
| USPSTF                                    | Alcohol misuse: screening and<br>behavioral counseling<br>interventions in primary care | Ι                   | Adolescents (under 18 years of age) <sup>f</sup>  | May 2013                                |
| USPSTF                                    | Chlamydia and gonorrhea: screening  | Ι                   | Sexually active men   | September 2014                          |
| USPSTF                                    | Drug use, illicit: screening  | Ι                   | Adolescents, adults, and pregnant women   | January 2008                            |
| USPSTF                                    | Genital herpes: screening   | D                   | Adolescents, adults, and pregnant women   | March 2005 <sup>g</sup>                 |
| USPSTF                                    | Syphilis infection: screening   | D                   | Asymptomatic persons, not at increased risk for syphilis  | July 2004 <sup>g</sup>                  |
| USPSTF                                    | Tuberculosis infection: screening   | N/A                 | · · · · · · · · · · · · · · · · · ·   |   |

#### Table 2 (continued)

Services currently subject to ACA requirements for coverage without cost-sharing<sup>a</sup>

|   |   |                        | Asymptomatic adults at increased<br>risk for developing active<br>tuberculosis (TB) disease  | Recommendation<br>statement under<br>development |
|---|---|------------------------|--|--|
| Women's Preventive Services<br>Guidelines | Contraceptive methods—male condoms                  | Explicitly not covered | All women with reproductive<br>capacity  | August 2012                                      |
| N/A                                       | Male and female condoms                             | N/A                    | All men who are sexually active  | N/A  |
| N/A                                       | Preexposure prophylaxis (PrEP)                      | N/A                    | All persons at substantial risk for<br>acquiring HIV, as outlined in the<br>US Public Health Service Clinical<br>Practice Guidelines                 | N/A <sup>h</sup>                                 |
| N/A                                       | Nonoccupational post-exposure<br>prophylaxis (nPEP) | N/A                    | Persons with sexual, injection-drug<br>use, and other substantial nonoc-<br>cupational HIV exposure who<br>seek care within 72 h after expo-<br>sure | N/A <sup>h</sup>                                 |

<sup>a</sup> In practice, benefit design features (including use of provider networks), insurer coding requirements, and provider coding and billing practices may all affect whether an individual will be subject to cost sharing requirements

<sup>b</sup> If applicable. For items to which a particular column does not apply, the table indicates this with a not applicable sign, or N/A

<sup>c</sup> These services include those that have not yet been evaluated, those that have been evaluated, but for which evidence has proven insufficient to warrant a positive recommendation, and those for which the relevant panel has issued a positive recommendation *against* their use. Individual insurers and health plans may nonetheless choose to cover some of these services, either with or without cost-sharing. However, this coverage is not required under Section 2713 of the Public Health Service Act, as added by the Affordable Care Act and incorporated into the Employee Retirement Income Security Act of 1974 (ERISA)

<sup>d</sup> While some variance across insurers is likely with respect to how coverage benefits are defined for recommended services, that variance may be substantial in the case of counseling-based preventive services like this one. For guidance, insurers may—but are not required to—look to standards set by CMS as part of its National Coverage Determinations (NCD) process for Medicare. The NCD for high intensity behavioral counseling to prevent STIs (NCD manual section number 210.10) is available at https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=352&ncdver=1&bc=AgAAgAAAAAAAA%3d%3d&

<sup>e</sup> Under the HRSA Women's Preventive Services Guidelines, coverage without cost sharing is available for all FDA-approved contraceptive methods including, but not limited to, barrier methods, hormonal methods, and implanted devices that are prescribed for an eligible woman by her health care provider. However, the guidelines specifically exclude coverage for contraceptive methods that relate to *male* reproductive capacity, including male condoms and vasectomies

<sup>f</sup> At first glance, there seems to be a discrepancy between USPSTF and HRSA Bright Futures recommendations around screening adolescents for alcohol use/misuse. However, a detailed review of the two recommendation sets suggests that, in fact, the USPSTF and Bright Futures positions may not be in conflict. The USPSTF evaluated and found insufficient evidence to recommend formal alcohol misuse screening and (for those who screen positive) behavioral interventions delivered as part of routine care for adolescents between the ages of 12 and 17. Bright Futures only positively recommends formal screening IF an adolescent first answers affirmatively to some basic behavioral questions around alcohol use. In other words, the USPSTF statement is focused on generalized screening, while the Bright Futures' recommendation deals with targeted screening

<sup>g</sup> As of October 26, 2015, recommendation statement was in the process of being reviewed and updated

<sup>h</sup> While no recommendations relating to these services have been issued by one of the entities mentioned in the ACA (i.e., USPSTF, ACIP, or HRSA as part of its Bright Futures and Women's Preventive Services Guidelines), guidelines around using these preventive services are available from the US Public Health Service (for PrEP) and the US Department of Health and Human Services (for nPEP). See http://www.cdc.gov/hiv/pdf/ prepguidelines2014.pdf (PrEP) and http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm (nPEP) for details

population engagement, care continuity and coordination, and provider responsibility for health outcomes and population health. As a result of these changes, practices and services that support linkage to and retention in care will become standard practices and default operations, rather than wrap around supplements necessary to ensure people living with or at risk for acquiring HIV have a better chance of successfully navigating the healthcare system. Curr HIV/AIDS Rep (2016) 13:95-106

Biomedical Approaches to Prevention: Preexposure Prophylaxis and Treatment as Prevention

Since the ACA's passage in 2010, the science of biomedical HIV prevention has been revolutionized by a series of landmark studies that conclusively demonstrated that antiretrovirals offer important preventive, as well as therapeutic, benefits. For people living with HIV, immediate initiation of antiretroviral therapies that lead to durable virologic

suppression not only decreases their risk of morbidity and mortality from AIDS-defining and non-AIDS defining conditions; it also reduces their risk for transmitting HIV to uninfected partners by more than 95 % [34, 36, 37•]. For people who are uninfected but at substantial risk for contracting HIV, several large studies have shown that daily oral preexposure prophylaxis (or, PrEP) with an FDA-approved, fixed-dose combination of tenofovir disoproxil fumarate 300 mg and emtricitabine 200 mg, when taken as prescribed, can reduce HIV acquisition risk by more than 90 % [38]. Recent open label PrEP demonstration studies and programs among MSM have also shown that maintaining the requisite high levels of adherence is possible, with high levels of effectiveness [39, 40].

Unfortunately, both antiretroviral treatment and PrEP are reaching far too few people who stand to benefit from them. CDC has estimated that only 30.2 % of the estimated 1.2 million people who are living with HIV in the USA have achieved durable virologic suppression [41]. Even limited to the proportion of PLWH who are aware of their infections, the figure is 41.7 % [41]. CDC also estimates that as many as 1.2 million persons in the USA meet US Public Health Service recommended indicators for PrEP use [42]. Although similar national figures do not exist to quantify the proportion of individuals most likely to benefit from PrEP who have access to this preventive option, published analyses of awareness and utilization rates—particularly among populations, like black MSM, who are disproportionately affected by HIV—suggest considerable room for improvement [43–45].

The provisions of the ACA that are most likely to have an immediate and durable impact on the accessibility of ART and PrEP are those that require all nongrandfathered individual and small group health plans and Medicaid ABPs to cover essential health benefits [28, 29]. In addition to the previously mentioned inclusion of preventive health services, one of the ten categories of services and benefits specified as part of the EHB package is prescription drugs. Unfortunately, and unintentionally, the original implementing regulation did not ensure coverage for some drugs, including many combination therapies used to treat HIV. An analysis of 84 "silver" level qualified health plans offered in 15 states found that, in 2014, single source brand name HIV drugs (i.e., those for which no generic equivalent was available) were covered 81 % of the time, but combination of HIV medicines, such as Truvada, Combivir, and Stribild, was only included in the formularies of reviewed plans 67 % of the time [46].

Regulators have since recognized the gaps unintentionally present in the initial regulation and have taken corrective action [47•]. For plan years beginning on or after January 1, 2017, entities that issue plans covered by the ACA's EHB requirements must establish a pharmacy and therapeutics (P&T) committee, which will be charged with establishing and managing the plan's drug formulary. Among other things, the P&T committee will be tasked with ensuring that the drug formulary "covers a range of drugs across a broad distribution of therapeutic categories.....[and] provides appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time" [47• (p. 10872)].

These requirements can improve access to the full array of combination ART regimens recommended by the HHS Panel on Antiretroviral Guidelines for Adults and Adolescents, as well as to PrEP when prescribed in accordance with the US Public Health Service's 2014 clinical practice guidelines, *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States*.

# Prevention *Through* Healthcare Must Be Coupled with Prevention *Beyond* Healthcare

Given that the health of both individuals and populations is largely determined by the conditions they confront, and actions they take, outside of their formal interactions with clinical care providers, greater emphasis on integration of public health, community health, and clinical care systems is critical if the USA is to replace the current US system of "sick care" with one that promotes and preserves *health* [48, 49]. The ACA includes several provisions directly aimed at encouraging collaboration and even integration across the traditional boundaries of clinical care, public health, and community services. Integration is increasingly being considered and prioritized as part of the design and operation of various health reform initiatives, as evidenced by changes made to proposal requirements during the second round of funds awarded under Center for Medicare and Medicaid Innovation's SIM initiative [50, 51].

In addition to continuing to provide critical safety net services for individuals unable to benefit from some of the ACA's reforms, such as individuals with incomes below 100 % FPL in states that have not expanded Medicaid, public health, and community partners are uniquely well positioned both to bring *community into* preventive and clinical care (e.g., by helping clinical care providers deliver care that is informed by and responsive to the needs of the communities they serve) and to extend preventive and clinical care *into communities* (e.g., by identifying and helping individuals with chronic conditions reengage in clinical care).

HIV prevention programs and providers have already begun to explore the new roles they may assume in, and the contributions they can make to, a fully integrated system encompassing public health, medical care, and community services and service providers. Health departments are helping to ensure that the healthcare systems in their communities remain nimble and responsive to evolving prevention science and opportunities for impact. New York City, for example, has launched a new outreach campaign that uses public health detailing methods to educate staff in 600 primary care and infectious disease clinics about PrEP and PEP and bolster their capacity to effectively implement practices that increase access to these prevention tools among their patients [52]. Importantly, interactive engagement approaches like detailing represent more than just a mechanism for getting information to clinical providers; they also foster greater bidirectional communication by creating an opportunity for public health staff to collect feedback from clinicians that can inform future health department activities [53].

Health departments are also working with providers and community service organizations to aggregate and make more effective use of available data generated by the delivery system and other sources. For example, under CDC's Data to Care (D2C) initiative, health departments are leveraging HIV surveillance data and other information sources to identify HIV-diagnosed persons who are not in care and reengage them [54•]. D2C creates a platform for real-time (or near realtime) data exchange among providers, payers, public health, and community partners that can provide timely proactive support for linkage to and retention in care, as well as improvements in the quality of care.

Finally, through integrated planning activities, HIV prevention and care service providers are leading efforts to (re)engineer the system as a whole to reduce fragmentation and achieve better outcomes for individuals and communities disproportionately impacted by HIV. In keeping with an emerging vision of health departments as the "chief health strategists" in their communities, those entities bear formal responsibility for developing Integrated HIV Prevention and Care Plans and accompanying Statewide Coordinated Statements of Need [55, 56]. However, successful development and execution of these plans depend on whether the health departments effectively engage with organizations that represent a diverse array of sectors, including clinical care and social services, as well as education, transportation, housing, and local businesses. Integrated planning activities are thus creating a space within which to galvanize community action that goes beyond improving the operations of the health system and also addresses the social determinants of health.

#### Challenges

While the ACA introduces a wealth of new opportunities for HIV prevention in the USA, there are a number of important challenges. First, as of August 2015, 20 states had not yet expanded their Medicaid programs; together, these states accounted for approximately 46 % of new HIV diagnoses in 2013, 40 % of all persons living with an HIV diagnosis at the end of 2012, and 46 % of the estimated 156,000 persons who are infected with HIV but unaware of their serostatus [21, 57]. While the Ryan White program will continue to offer an important safety net for persons diagnosed and living with HIV,

there is no equivalent national safety net program in place for the much larger number of persons who are at risk for, but have not yet acquired, HIV. Given that the median Medicaid eligibility threshold for parents of dependent children in nonexpansion states is 44 % of FPL and only 1 out of these 20 states offer Medicaid coverage for low income childless adults, many residents in these states will continue to have inadequate access to the full array of HIV prevention services and support that could be available to them [58].

Second, studies have shown that insurance coverage is an important facilitator-but not a guarantor-of greater access to and utilization of care and preventive services [59, 60, 61...]. Benefit designs that place all drugs used to treat HIV (even generics) in formulary tiers associated with the highest levels of cost sharing are likely to undermine initiation of, and adherence to, both PrEP and ART [62., 63]. And, while supportive benefit designs-for example, first dollar coverage for preventive services-improve utilization, they do not necessarily lead to optimal utilization rates [59, 64–67]. Translating coverage to access and access to receipt of HIV prevention services will require additional investments in change at every level of the system. Patients may need to be educated about the preventive services they need, and where and how to access those services through their health plans. Providers may need to offer extended hours or adapt workflows (e.g., introduce routine collection and recording of sexual risk behavior) to optimize availability and delivery of recommended services. And, payers may need to reconsider what they cover and how these decisions affect the extent to which they realize the Triple Aim among their beneficiaries; for example, coverage of PrEP and ART may have limited value if coverage for the drugs is not coupled with coverage of adherence support counseling for those who need it.

Finally, an integrated *health* system—one that supports HIV prevention goals both within and beyond the *healthcare* system—is easier to envision than it will be to create. Fragmentation is not limited to the US healthcare system: It is also common in much of the public health and social service sectors. Moreover, in many communities, within sector fragmentation is coupled with cross-sector divisions that tend to limit community-wide collaboration and integration. Bringing public health, healthcare, and community together will require deft leadership capable of navigating and effectively bridging barriers that include laws, policy, organizational culture, technology, and professional training.

### Conclusion

Advances in HIV prevention have encouraged the nation to adopt a vision of itself as "a place where new HIV infections are rare and when they do occur, every person, regardless of age, gender, race/ethnicity, sexual orientation, gender identity, or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination [1]." Achieving this vision requires that persons living with or at risk for HIV have access to healthcare, that access to healthcare translates into receipt of recommended preventive and treatment services, and that delivery of these services is coordinated across the *health* system. The ACA provides the political and structural platform necessary for these requisites to become realities; actual success, however, will depend upon active involvement from, and collaboration among, a wide range of stakeholders, including those who represent public health, healthcare, and community service providers.

#### **Compliance with Ethics Guidelines**

**Conflict of Interest** Abigail H. Viall, Eugene McCray, Jonathan Mermin, and Pascale Wortley declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

#### References

Papers of particular interest, published recently, have been highlighted as:

- Of importance
- •• Of major importance
- 1.•• White House Office of National AIDS Policy. National HIV/AIDS Strategy for the United States: Updated to 2020. July 2015. https://www.aids.gov/federal-resources/national-hiv-aids-strategy/nhas-update.pdf. Accessed September 11, 2015. As part of its broader updates to the National HIV/AIDS Strategy, this document outlines how the ACA has, and will continue to, contribute to progress against the national goals of reducing new HIV infections; increasing access to care and improving health outcomes for people living with HIV; and reducing HIV-related disparities and health inequities.
- Agency for Health Research and Quality. Chapter 10. Access to Health Care. In: National Health Quality Report, 2013. May 2014. http://www.ahrq.gov/research/findings/nhqrdr/nhqr13/ chap10.html. Accessed September 2, 2015.
- Bradley H, Viall AH, Wortley PM, Dempsey A, Hauck H, Skarbinski J. Ryan White HIV/AIDS Program assistance and HIV treatment outcomes. Clinical Infectious Diseases. 2015. doi: 10.1093/cid/civ708.
- Health Resources and Services Administration. Ryan White HIV/ AIDS Program–2012 State Health Profiles. http://hab.hrsa.gov/ stateprofiles/State-Overview.aspx. Accessed August 31, 2015 2015.
- Cohen RA, Martinez ME. Health insurance coverage: early release of estimates from the National Health Interview Survey, 2013.

National Center for Health Statistics. June 2014. http://www.cdc. gov/nchs/nhis/ releases.htm. Accessed September 9, 2015.

- Centers for Disease Control and Prevention. HIV Infection, Risk, Prevention, and Testing Behaviors among Persons Who Inject Drugs—National HIV Behavioral Surveillance: Injection Drug Use, 20 U.S. Cities, 2012. HIV Surveillance Special Report 11. Revised edition. Published August 2015. http://www.cdc.gov/hiv/ pdf/library/reports/surveillance/cdc-hiv-HSSR\_NHBS\_PWID\_ 2012.pdf. Accessed August 31, 2015.
- Centers for Disease Control and Prevention. HIV risk, prevention, and testing behaviors—National HIV Behavioral Surveillance System: men who have sex with men, 20 U.S. Cities, 2011. HIV Surveillance Special Report 8. Published September 2014. http:// www.cdc.gov/hiv/pdf/HSSR\_8\_NHBS\_MSM\_PDF-03.pdf. Accessed 17, 2015.
- Centers for Disease Control and Prevention. HIV Infection, Risk, Prevention, and Testing Behaviors among Heterosexuals at Increased Risk of HIV Infection—National HIV Behavioral Surveillance, 20 U.S. Cities, 2013. HIV Surveillance Special Report 13. Published August 2015. http://www.cdc.gov/hiv/pdf/ library/reports/surveillance/cdc-hiv-HSSR\_NHBS\_HET\_2013. pdf. Accessed September 1, 2015
- 9. Rosenbaum S, Westmoreland TM. The Supreme Court's surprising decision on the Medicaid expansion: how will the federal government and states proceed? Health Affairs. 2012;31(8):1663–72. This article summarizes the Supreme Court's decision in National Federation of Independent Business v. Sebelius, which upheld the constitutionality of some contested provisions of the ACA–including the so-called "individual mandate" (requiring all Americans to have health coverage)–while striking down others, the most notable of which was a requirement for states to expand their Medicaid programs or else risk losing their current Medicaid funding from the federal government. The article goes on to explore the ramifications of this decision for both the operation of existing Medicaid programs and the manner in Medicaid expansion is accomplished in those states that choose to move forward with it.
- 10.•• Patient Protection and Affordable Care Act (Affordable Care Act), Pub. L. No. 111–148, 124 Stat. 119 (2010) (codified as amended in scattered section of the U.S. Code), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111–152, 124 Stat. 1029. http://www.hhs.gov/healthcare/rights/law/. Accessed August 31, 2015. The Affordable Care Act was technically enacted through two separate laws: the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. The web-link above provides consolidated access to both parts of the ACA.
- Cohen RA, Martinez ME. Health insurance coverage: early release of estimates from the National Health Interview Survey, January– March 2015. 2015. http://www.cdc.gov/nchs/data/nhis/ earlyrelease/insur201508.pdf. Accessed August 14, 2015.
- 12.• Sommers BD, Gunja MZ, Finegold K, Musco T. Changes in selfreported insurance coverage, access to care, and health under the Affordable Care Act. JAMA. 2015;314(4):366–74. This study indicates that the first two open enrollment periods under the ACA were associated with marked gains in self-reported rates of insurance, as well as improvements in several self-reported measures of access to care (e.g., having a personal physician or access to needed medications). The study also demonstrates that, among low income adults, gains in coverage and selfreported indicators of access to care were significantly greater in states that expanded their Medicaid programs than in those states that did not.
- Centers for Medicare and Medicaid Services. Medicaid & CHIP. Monthly Applications, Eligibility Determinations and Enrollment Report. 2015. July 2015. http://www.medicaid.gov/medicaid-chip-

program-information/program-information/downloads/may-2015enrollment-report.pdf. Accessed August 31, 2015.

- Centers for Medicare and Medicaid Services. June 30, 2015 Effectuated Enrollment Snapshot. September 8, 2015. https:// www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/ 2015-Fact-sheets-items/2015-09-08.html. Accessed September 15, 2015
- 15. Kates J, Garfield R, Young K, Quinn K, Frazier E, Skarbinski J. Assessing the impact of the Affordable Care Act on health insurance coverage of people living with HIV. Kaiser Family Foundation Issue Brief. January 2014. https://kaiserfamilyfoundation.files. wordpress.com/2013/12/8535-assessing-the-impact-of-theaffordable-care-act-on-health-insurance-coverage.pdf. Accessed July 1, 2015
- Snider JT, Juday T, Romley JA, Seekins D, Rosenblatt L, Sanchez Y, et al. Nearly 60,000 uninsured and low-income people with HIV/ AIDS live in states that are not expanding Medicaid. Health Affairs. 2014;33:386–93.
- Donohue JM, Papademetriou E, Henderson RR, Frazee SG, Eibner C, Mulcahy AW, et al. Early marketplace enrollees were older and used more medication than later enrollees; marketplaces pooled risk. Health Affairs. 2015;34:1049–56.
- Centers for Disease Control and Prevention. HIV risk, prevention, and testing behaviors among men who have sex with men— National HIV Behavioral Surveillance System: 20 U.S. Cities, 2014. HIV Surveillance Special Report 15. http://www.cdc.gov/ hiv/library/reports/surveillance/#panel2. Accessed Feb 5, 2016.
- Berwick DM, Nolan TW, Whittington J. The Triple Aim: care, health, and cost. Health Affairs. 2008;27:759–69.
- Chen M, Rhodes PH, Hall IH, Kilmarx PH, Branson BM, Valleroy LA. Prevalence of undiagnosed HIV infection among persons aged >/=13 years–National HIV Surveillance System, United States, 2005–2008. MMWR. 2012;61:57–64.
- Hall HI, An Q, Tang T, Song R, Chen M, Green T, et al. Prevalence of diagnosed and undiagnosed HIV infection - United States, 2008– 2012. MMWR. 2015;64:657–62.
- Branson BM, Handsfield HH, Lampe MA, Janssen RS, Taylor AW, Lyss SB, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. MMWR Recommendations and Reports. 2006;55:1–17.
- Moyer VA, on behalf of the U.S. Preventive Services Task Force. Screening for HIV: U.S. Preventive Services Task Force Recommendation Statement. Ann Intern Med. 2013;159:51–60.
- Ward BW, Clarke TC, Freeman G, Schiller JS. Early release of selected estimates based on data from the 2014 National Health Interview Survey. National Center for Health Statistics. June 2015. http://www.cdc.gov/nchs/data/nhis/earlyrelease/ earlyrelease201506.pdf. Accessed September 10, 2015.
- 25. Van Handel M, Lyons B, Oraka E, Nasrullah M, DiNenno E, Dietz P. Factors associated with time since last HIV test among persons at high risk for HIV infection, National Survey of Family Growth, 2006–2010. AIDS Patient Care and STDs. 2015. doi:10.1089/apc. 2015.0078.
- Copen CE, Chandra A, Febo-Vazquez I. HIV testing in the past year among the U.S. household population aged 15–44: 2011–2013. National Center for Health Statistics. June 2015. http://www.cdc. gov/nchs/data/nhis/earlyrelease/earlyrelease201506.pdf. Accessed September 10, 2015.
- 27.•• Coverage of Certain Preventive Services Under the Affordable Care Act, 80 FR 41317 (July 14, 2015). Final rule that outlines coverage requirements for classes of preventive services (e.g., USPSTF or ACIP recommended) specifically cited in the ACA. Among other things, the rule outlines when copays may or may not be applicable, as well as how when plans must begin offering coverage for interventions and services covered by recommendation or guidelines issued after September 23, 2010.
- 🖄 Springer

- Benchmark Benefit and Benchmark-Equivalent Coverage, 42 C.F.R. § 440(c) (2013).
- 29. Essential Health Benefits Package, 45 C.F.R. § 156 (2013).
- Giordano TP, Gifford AL, White Jr AC, Suarez-Almazor ME, Rabeneck L, Hartman C, et al. Retention in care: a challenge to survival with HIV infection. Clinical Infectious Diseases. 2007;44:1493–9.
- Mugavero MJ, Amico KR, Westfall AO, Crane HM, Zinski A, Willig JH, et al. Early retention in HIV care and viral load suppression: implications for a test and treat approach to HIV prevention. Journal of Acquired Immune Deficiency Syndromes. 2012;59:86– 93.
- 32. Horberg MA, Hurley LB, Silverberg MJ, Klein DB, Quesenberry CP, Mugavero MJ. Missed office visits and risk of mortality among HIV-infected subjects in a large healthcare system in the United States. AIDS Patient Care and STDs. 2013;27:442–9.
- 33. Mugavero MJ, Westfall AO, Cole SR, Geng EH, Crane HM, Kitahata MM, et al. Beyond core indicators of retention in HIV care: missed clinic visits are independently associated with allcause mortality. Clinical Infectious Diseases. 2014;59:1471–9.
- 34. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. April 2015. http://www.aidsinfo.nih.gov/ContentFiles/ AdultandAdolescentGL.pdf. Accessed September 11, 2015.
- 35.• Skarbinski J, Rosenberg E, Paz-Bailey G, Hall HI, Rose CE, Viall AH, et al. Human immunodeficiency virus transmission at each step of the care continuum in the United States. JAMA Internal Medicine. 2015;175(4):588–96. For each step along the HIV care continuum, this study estimates the rate and number of HIV transmissions from HIV-infected persons in the United States. It thus provides important guidance for policymakers and programs seeking to allocate available prevention resources in ways that maximize their epidemiological returns on investment.
- Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Prevention of HIV-1 infection with early antiretroviral therapy. The New England Journal of Medicine. 2011;365:493–505.
- 37.• The INSIGHT START Study Group. Initiation of Antiretroviral Therapy in Early Asymptomatic HIV Infection. The New England Journal of Medicine. 2015;373(9):795–807. This article summarizes the results of the START study, a large, randomized controlled trial that has demonstrated immediate initiation of antiretroviral therapy—without regard to CD4+ count- confers significant individual health benefits on persons living with HIV infection.
- U.S. Public Health Service. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2014 Clinical Practice Guideline. May 2014. http://www.cdc.gov/hiv/pdf/ PrEPguidelines2014.pdf. Accessed August 27, 2015.
- 39. A Liu et al. Adherence, sexual behavior and HIV/STI incidence among men who have sex with men (MSM) and transgender women (TGW) in the US PrEP Demonstration (Demo) Project. Oral abstract at the 8th International AIDS Society Conference on HIV Pathogenesis, Treatment & Prevention (IAS 2015) in Vancouver, Canada. Program number TUAC0202, track C. Presented July 21, 2015.
- 40. Grant RM, Anderson PL, McMahan V, Liu A, Amico KR, Mehrotra M, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. The Lancet Infectious Diseases. 2014;14:820–9.
- 41. Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas—2013. HIV

Surveillance Supplemental Report 2015; 20 (No. 2). http://www. cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hivsurveillancereport vol20 no2.pdf. Accessed September 11, 2015.

- 42. Smith DK, Van Handel M, Wolitski RJ, Striker JE, Hall HI, Prejean J, Koenig LJ, Valleroy LA. Vital signs: estimated percentages and numbers of adults with indications for preexposure prophylaxis to prevent HIV acquisition—United States, 2015. MMWR (Early Release). 2015; 64: 1–6. Available at: http://www.cdc.gov/mmwr/pdf/wk/mm64e1124a1.pdf (accessed November 24, 2015).
- 43. Brooks RA, Landovitz RJ, Regan R, Lee SJ, Allen Jr VC. Perceptions of and intentions to adopt HIV pre-exposure prophylaxis among black men who have sex with men in Los Angeles. International Journal of STD & AIDS. 2015. doi:10.1177/ 0956462415570159.
- 44. Eaton LA, Driffin DD, Bauermeister J, Smith H, Conway-Washington C. Minimal Awareness and Stalled Uptake of Pre-Exposure Prophylaxis (PrEP) Among at Risk, HIV-Negative, Black Men Who Have Sex with Men. AIDS Patient Care and STDs. 2015;29:423–9.
- Flash C, Landovitz R, Giler RM, Ng L, Magnuson D, Wooley SB, et al. Two years of Truvada for pre-exposure prophylaxis utilization in the US. Journal of the International AIDS Society. 2014;17: 19730. doi:10.7448/ias.17.4.19730.
- Pharmaceutical Research and Manufacturers of America. Access to HIV/AIDS medications in exchange plans. 2014. http://www. phrma.org/sites/default/files/pdf/exchanges-hiv-aids.pdf. Accessed September 11, 2015.
- 47.• Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10749 (Effective date: April 28, 2015) (to be codified at 45 CFR parts 144, 147, 153, 154, 155, 156, and 158). This rule finalizes a number of revised standards relating to essential health benefits (EHBs), including those governing coverage of prescription drugs. This rule also provides examples of plan designs that may be judged discriminatory and outlines the oversight and enforcement mechanisms HHS will use to prevent or respond to such design practices. Finally, the rule amends requirements for essential community providers (ECPs).
- National Prevention Council, National Prevention Strategy, Washington, DC: U.S. Department of Health and Human Services, Office of the Surgeon General, 2011. http://www. surgeongeneral.gov/priorities/prevention/strategy/report.pdf. Accessed September 1, 2015
- Frieden TR. A framework for public health action: the health impact pyramid. American Journal of Public Health. 2010;100:590–5.
- Centers for Medicare and Medicaid Services Innovation Center. About the CMS Innovation Center http://innovation.cms.gov/ About/index.html. Accessed September 1, 2015.
- Centers for Medicare and Medicaid Services Innovation Center. State Innovation Models Initiative: Round Two Funding Opportunity Announcement (FOA) 2014. http://innovation.cms. gov/initiatives/State-Innovations/archive.html. Accessed September 1 2015.
- 52. New York City Department of Health and Mental Hygiene. Health Department Launches New PrEP & PEP Campaign: new ways to prevent HIV—New PrEP & PEP Detailing Kit to Reach 600 Practices Citywide. January 12, 2015. http://www.nyc.gov/html/ doh/html/pr2015/pr003-15.shtml. Accessed September 1, 2015.
- Dresser MG, Short L, Wedemeyer L, Bredow VL, Sacks R, Larson K, et al. Public health detailing of primary care providers: New York City's experience, 2003–2010. American Journal of Preventive Medicine. 2012;42:S122–34.
- 54.• Centers for Disease Control and Prevention. Data to Care. 2014. https://effectiveinterventions.cdc.gov/en/HighImpactPrevention/ PublicHealthStrategies/DatatoCare.aspx. Accessed September 1 2015. This website offers access to CDC's Data to Care toolkit

for state and local health departments interested in better using their HIV surveillance data to identify HIV-diagnosed individuals not in care, link them to care, and support the HIV Care Continuum.

- 55. Forum PHL. The high achieving governmental health department in 2020 as the community chief health strategist. 2014. http://www. resolv.org/site-healthleadershipforum/files/2014/05/The-High-Achieving-Governmental-Health-Department-as-the-Chief-Health-Strategist-by-2020-Final1.pdf. Accessed September 1, 2015.
- 56. Centers for Disease Control and Prevention and Health Resources and Services Administration. 2017–2021 Integrated HIV Prevention and Care Plan, Including the Statewide Coordinated Statement of Need. June 2015. http://www.cdc.gov/hiv/pdf/ funding/announcements/ps12-1201/cdc-hiv-integrated-hivprevention-care-plan-guidance.pdf. Accessed September 1, 2015.
- Centers for Disease Control and Prevention. HIV Surveillance Report, 2013; vol. 25. February 2015. http://www.cdc.gov/hiv/ pdf/g-l/hiv\_surveillance\_report\_vol\_25.pdf. Accessed August 14, 2015.
- 58. Kaiser Commission on Medicaid and the Uninsured. Modern Era Medicaid: findings from a 50-state survey of eligibility, enrollment, renewal, and cost-sharing policies in Medicaid and CHIP as of January 2015. January 2015. http://files.kff.org/attachment/reportmodern-era-medicaid-findings-from-a-50-state-survey-ofeligibility-enrollment-renewal-and-cost-sharing-policies-inmedicaid-and-chip-as-of-january-2015. Accessed August 14, 2015.
- 59. Brook, Robert H., John E. Ware, William H. Rogers, Emmett B. Keeler, Allyson Ross Davies, Cathy D. Sherbourne, George A. Goldberg, Kathleen N. Lohr, Patricia Camp and Joseph P. Newhouse, The effect of coinsurance on the health of adults: results from the RAND Health Insurance Experiment, Santa Monica, Calif.: RAND Corporation, R-3055-HHS, 1984. http://www.rand. org/pubs/reports/R3055.html. Accessed September 14, 2015.
- 60. Lohr KN, Brook RH, Kamberg C, Goldberg GA, Leibowitz A, Keesey J, et al. Use of Medical Care in the RAND Health Insurance Experiment: diagnosis- and service-specific analyses in a randomized controlled trial. Santa Monica, CA: RAND Corporation; 1986. http://www.rand.org/pubs/reports/R3469. Accessed Sep 14, 2015.
- 61... Baicker K, Taubman SL, Allen HL, Bernstein M, Gruber JH, Newhouse JP, et al. The Oregon experiment-effects of Medicaid on clinical outcomes. The New England Journal of Medicine. 2013;368(18):1713-22. doi:10.1056/NEJMsa1212321. This paper summarizes outcomes among low income adults who-on the basis of a lottery process implemented by the state- were and were not offered an opportunity to apply for Medicaid through the Oregon Health Plan Standard (Oregon's program for low-income, uninsured, able-bodied adults who are not eligible for other forms of public insurance). Two years after the lottery began, the authors find evidence that Medicaid coverage generally increases access to and utilization of medical care; however, these gains were not uniform or statistically significant across all services and conditions examined (e.g., statistically significant increases in cholesterol screening but not in colonoscopies among persons 50 years of age or older).
- 62.•• Jacobs DB, Sommers BD. Using drugs to discriminate-adverse selection in the insurance marketplace. The New England Journal of Medicine. 2015;372(5):399–402. This study documents evidence of adverse tiering (defined by the authors as "plac[ing] all HIV drugs in the highest cost-sharing tier......[presumably] to deter certain people [like PLWH] from enrolling in the first place") in a sample of 48 "silver" plans offered in 12 states that used the federal marketplace.
- 63. Avalere Health. Avalere PlanScape<sup>®</sup> Analysis of Prescription Drug Tier Placement and Cost Sharing in Health Insurance Exchange Plans. February 11, 2015. http://go.avalere.com/acton/attachment/

12909/f-017c/1/-/-/-/20150211\_Avalere%20Planscape% 202015\_Class%20Tiering%20Analysis.pdf. Accessed September 14, 2015.

- Meeker D, Joyce GF, Malkin J, Teutsch SM, Haddix AC, Goldman DP. Coverage and preventive screening. Health Services Research. 2011;46:173–84.
- Okoro CA, Dhingra SS, Coates RJ, Zack M, Simoes EJ. Effects of Massachusetts health reform on the use of clinical preventive services. Journal of General Internal Medicine. 2014;29:1287–95.
- Fox JB, Shaw FE. Relationship of income and health care coverage to receipt of recommended clinical preventive services by adults—United States, 2011–2012. MMWR. 2014;63:666–70.
- 67. Han X, Robin Yabroff K, Guy Jr GP, Zheng Z, Jemal A. Has recommended preventive service use increased after elimination of cost-sharing as part of the Affordable Care Act in the United States? Preventive Medicine. 2015;78: 85–91.