

University of Washington / Fred Hutch Center for AIDS Research (CFAR)

2016 Request for Applications (RFA) for CFAR Concept Proposals

for

New or Re-Competing Cores

and

New Scientific Working Groups (SWGs)

In preparation for a 2017 application for 5-years of continued funding (2018-2023)

Release Date: September 19, 2016

Proposal Due Date: November 15, 2016

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UNIVERSITY of WASHINGTON

DEPARTMENT OF GLOBAL HEALTH



September 19, 2016

Dear Colleagues:

The UW/Fred Hutch Center for AIDS Research (CFAR) will be submitting a proposal for renewal of the CFAR for a 7th round of 5-year funding by NIH. We are beginning the process now for preparing the proposal, which is due to NIH in July 2017. At this point, we are inviting Concept Proposals for New and Re-competing Cores, and New or Reconfigured Scientific Working Groups. The proposal process timeline is as follows:

- November 15, 2016: Concept proposal submission deadline
- Dec-Jan: Concept Proposals reviewed by CFAR Leadership and the CFAR External Advisory Committee
- February 2016: Applicants whose concept proposals are selected will be invited to submit a full proposal
- May 2016: Full and final Core and SWG proposals submitted to Admin Core to integrate into the application

To guide applicants in the Concept Proposal process, attached are:

- 1. Guidelines for Concept Proposals for CFAR Cores
- 2. Guidelines for Concept Proposals for CFAR Scientific Working Groups (SWGs)
- 3. Attachment A: Current CFAR Mission, Vision, Strategic Research Priorities, Cores, SWGs, and CAB
- 4. Attachment B: NIH Office of AIDS Research (OAR) FY2017 Trans-NIH AIDS Research Priorities
- 5. Attachment C: White House National HIV/AIDS Strategy for the United States: Updated to 2020

Please feel free to contact me or Susan Mello (spmello@uw.edu) with any questions on this process. I look forward to receiving your proposals.

Best regards,

King K. Holmes, MD, PhD

In Klol

Director, UW/Fred Hutch Center for AIDS Research

Director, Center for AIDS and STD

Director of Research and Faculty Development, Department of Global Health

Professor of Global Health, Medicine, Microbiology,

Epidemiology, University of Washington



GUIDELINES FOR CFAR CORE CONCEPT PROPOSALS

PROPOSALS DUE: TUESDAY, NOVEMBER 15, 2016

Introduction

The UW/Fred Hutch Center for AIDS Research (CFAR) is inviting concept proposals for new and re-competing Cores to participate in the application for competitive renewal of our CFAR. The application for CFAR renewal will be finalized in June 2017 and if refunded, the new grant period will begin June 2018. Please see specific instructions below. The deadline for concept proposal submission is Tuesday, November 15, 2016.

Background Information on CFAR

The UW/Fred Hutch CFAR is one of 20 CFARs funded by the National Institutes of Health. The CFAR program began in 1988. The UW/Fred Hutch CFAR is one of three continuously funded CFARs and is in its 29th year. CFARs strive to foster interdisciplinary research in HIV/AIDS, to support the research of several NIH Co-Funding Institutes and Centers, including NIAID, NCI, NICHD, NHLBI, NIDA, NIMH, NIA, NIDDK, NIGMS, NIMHD, FIC, and OAR. The mission of the NIH Centers for AIDS Research (CFAR), along with background information on the National CFAR Program, can be found at the NIH CFAR Program website. For more background information on National CFAR Program objectives and goals, see the CFAR Program Announcement (PAR-14-041).

The current UW/Fred Hutch CFAR Mission, Vision, and Strategic Research Priorities, developed for our 2012 application to NIH, are included in Attachment A, along with a list of current CFAR Cores and Scientific Working Groups. These will be updated for the 2017 grant renewal submission.

Specific Instructions for Concept Proposals for Proposed New or Re-competing Cores

Applicants should consider the following in formulating their proposals:

- a. CFAR Program Announcement PAR-14-041 (http://grants.nih.gov/grants/guide/pa-files/PAR-14-041.html)
- b. Current UW/FH CFAR Mission, Vision, Strategic Research Priorities, Cores, Scientific Working Groups, and Community Action Board (Attachment A)
- c. NIH Office of AIDS Research FY2017 Trans-NIH AIDS Research Priorities (see Attachment B)
- d. National HIV/AIDS Strategy for the United States: Updated to 2020 (see Attachment C)

Provide the following (1-4) in one electronic file (Word or PDF):

1. Proposed Core Description

Include title of Core, Key Personnel with roles, and a brief description of the Core, including specific aims.

2. Proposed Budget

Include detail of first year budget, and total (five year) budget. [On average, Core budgets are approximately \$140K-200K (direct costs) per year for five years.]

3. Brief Budget Justification

4. Research Strategy

(limit of 4 pages, no less than ½" margins, Calibri 11 font or equivalent)

Applicants should address in their Research Strategy section three main components:

Significance. The effect that the proposed Core would have on CFAR investigators' HIV/AIDS research efforts. **For Science Cores:**

• Describe how the proposed Core will provide added value to HIV/AIDS research conducted at the institution(s). See description of added value in the CFAR PA, Part 2, Section I.



- Describe how the proposed Core will support the CFAR's <u>research base</u>, foster synergy, enhance HIV/AIDS research collaborations, and produce an economy of scale.
- Describe how the proposed Core will enhance proposed scientific communication, outreach, training efforts, international collaborations, and collaborations with industry as applicable.
- Describe the strengths of the proposed Core. Re-competing applicants should describe how any <u>HIV/AIDS</u> <u>programs</u> (scroll to: Section IV.2. Content and Form of Application Submission, Overall Component, PHS 398 Research Plan (see Table below)) at the UW, Fred Hutch, Center for Infectious Disease Research, and Seattle Children's supported by co-funding NIH Institutes and Centers, are and will be assisted by the proposed Core.
- Describe how the proposed Core will be able to support the next generation of HIV/AIDS researchers and how the Core will work with other CFAR Cores to accomplish this.

For Developmental Core:

- Describe how the proposed Core provides added value to HIV/AIDS research conducted at our CFAR consortium institutions. See description of added value in the CFAR PA, Part 2, Section I.
- Describe how the proposed Core will be able to support the next generation of HIV/AIDS researchers and how the Core will work with other CFAR Cores to accomplish this.
- Describe the strengths of the proposed Core.

Innovation.

Explain the unique utilization of Core resources to achieve the scientific goals of all HIV/AIDS investigators at the participating institution(s). Explain how the proposed Core would catalyze HIV work that might not otherwise happen in our research community without CFAR.

Approach.

- Describe the services that the proposed Core will offer and describe why these services are needed and will be utilized by CFAR members.
- Describe the operational structure of the proposed Core and a general plan for how the services will be
 offered.
- Describe how the Core will include both senior and junior investigators in Core leadership. Note: Core leaders who are junior investigators should be at the Assistant or Associate Professor (or equivalent) level and a stage in their career such that the Core leadership position will benefit, not detract from, their path toward achieving an independent research career.
- Elaborate on how the Core will receive input on Core priorities from members of the lay and scientific community (note that the CFAR has a <u>Community Action Board</u> that works with all Cores to foster interaction with the community).

SUBMIT PROPOSALS ELECTRONICALLY IN ONE FILE (Word or PDF) TO COLE BAZEMORE (colebaze@uw.edu) BY TUESDAY, NOVEMBER 15, 2016.

Questions may be addressed to CFAR Assistant Director, Susan Mello, at spmello@uw.edu, (206-744-2238).



GUIDELINES FOR CFAR SCIENTIFIC WORKING GROUP CONCEPT PROPOSALS

PROPOSALS DUE: TUESDAY, NOVEMBER 15, 2016

Introduction

The UW/Fred Hutch Center for AIDS Research (CFAR) is inviting concept proposals for new and re-configured CFAR Scientific Working Groups (SWGs). We highly encourage concept proposals for new SWGs. Since the NIH CFAR program views SWGs as temporary start-up programs, simple re-competing applications by existing CFAR SWGs will not be accepted – proposals by re-configured Scientific Working Groups must show significant evolution and innovation that address the most current needs and research priorities. The application for CFAR renewal will be finalized in June 2017 and if refunded, the new grant period will begin June 2018. Please see specific instructions below. The deadline for concept proposal submission is Tuesday, November 15, 2016.

Background Information on CFAR

The UW/Fred Hutch CFAR is one of 20 CFARs funded by the National Institutes of Health. The CFAR program began in 1988. The UW/Fred Hutch CFAR is one of three continuously funded CFARs and is in its 29th year. CFARs strive to foster interdisciplinary research in HIV/AIDS, to support the research of several NIH Co-Funding Institutes and Centers, including NIAID, NCI, NICHD, NHLBI, NIDA, NIMH, NIA, NIDDK, NIGMS, NIMHD, FIC, and OAR. The mission of the NIH Centers for AIDS Research (CFAR), along with background information on the National CFAR Program, can be found at the NIH CFAR Program website. For more background information on National CFAR Program objectives and goals, see the CFAR Program Announcement (PAR-14-041).

The current UW/Fred Hutch CFAR Mission, Vision, and Strategic Research Priorities, developed for our 2012 application to NIH, are included in Attachment A, along with a list of current CFAR Cores and Scientific Working Groups. These will be updated for the 2017 grant renewal submission.

Specific Instructions for Concept Proposals for Proposed Scientific Working Groups

Applicants should consider the following in formulating their proposals:

- a. CFAR Program Announcement PAR-14-041 (http://grants.nih.gov/grants/guide/pa-files/PAR-14-041.html)
- b. Current UW/FH CFAR Mission, Vision, Strategic Research Priorities, Cores, Scientific Working Groups, and CAB (Attachment A)
- c. NIH Office of AIDS Research FY2017 Trans-NIH AIDS Research Priorities (see Attachment B)
- d. National HIV/AIDS Strategy for the United States: Updated to 2020 (see Attachment C)

Include sections A-F as described below in your Scientific Working Group proposal. Page limit for sections C-E is 4 pages.

- A. <u>Title</u> of Proposed Scientific Working Group
- B. Personnel

Describe personnel to participate in the proposed Scientific Working Group (List Scientific Working Group Director(s), all Faculty and other Key Personnel, along with their Institutional Affiliation(s), Role in Program, and Proposed %FTE)

C. Research Strategy

Describe proposed aims and activities of the working group, including a description of why this area is important and timely; how the working group will interact with Cores; how activities will promote collaborative and interdisciplinary research, and facilitate procurement of funding for relevant projects; and how the working group will add value to the CFAR and the HIV research infrastructure at our institutions. Examples of working group aims/activities include but are not limited to: providing scientific leadership, promoting collaborative and interdisciplinary research, facilitating procurement of funding for relevant projects, assistance with faculty recruitment, mentoring, training, sponsoring events such as conferences or workshops, curriculum development.

D. <u>Policies and Procedures</u>

Briefly describe working group policies and procedures, i.e. how members and member projects are identified, and how they will participate in the working group; how funding will be sought for new projects in the chosen scientific area of interest; what are the objective evaluation/outcome measurements for the working group.

E. Member Projects

List of at least 3 existing NIH-funded projects at our CFAR's consortium institutions (UW, Fred Hutch, Center for Infectious Disease Research, Seattle Children's) to comprise the member projects of the working group (sponsor grant number, Title, PI, beginning and end dates of total project period).

F. <u>Budget Proposal</u>

- 1. Funds available: 10% salary for Director(s), plus an additional \$10K for activities; per year for up to three years. Budget proposal must include salary for director(s), unless prior approval is given to waive this request.
- 2. Provide a rough breakdown by cost category, and if a subcontract is involved, include the subcontractors' indirect costs.

SUBMIT PROPOSALS ELECTRONICALLY IN ONE FILE (Word or PDF) TO COLE BAZEMORE (colebaze@uw.edu) BY TUESDAY, NOVEMBER 15, 2016.

Questions may be directed to Susan Mello at 206-744-2238 or spmello@uw.edu.

Attachment A: Current CFAR Mission, Vision, Strategic Research Priorities, Cores, Scientific Working Groups, and Community Action Board

Attachment A: Current CFAR Mission, Vision, Strategic Research Priorities, Cores, Scientific Working Groups, and Community Action Board

Note: The intent is not to limit new applications to what is described below, rather to facilitate potential collaborations in the new application.

Mission: The mission of the UW/Fred Hutch CFAR is to advance knowledge in the clinical epidemiology, pathogenesis, treatment, and prevention of HIV/AIDS by fostering collaborative and interdisciplinary research, supporting career development in junior investigators, and providing research infrastructure and resources to researchers and scientists at our affiliated institutions.

<u>Vision</u>: With heterogeneous, complex domestic and global HIV epidemics continuing, and shrinking resources, and progression of the "AIDS Transition", meaning the "escalating number of persons living with HIV infection is far outpacing available funding for treatment and prevention, especially in Africa", and infected persons are growing older. CFAR -coordinated and supported research must provide the next generation of HIV/AIDS scientists with the resources and skills essential to address these challenges effectively. Our CFAR will seek pivotal discoveries leading to improved prevention of HIV infection, insights about related chronic morbidities, and curing HIV infection, while also prioritizing development, implementation, and evaluation of efficient and cost-effective approaches to treatment and prevention of HIV/AIDS and associated infections and malignancies.

Strategic Research Priorities

1. Prevent New Infections

 Ten proposed Cores and three proposed SWGs supporting basic science, and clinical, epidemiologic, sociobehavioral, and implementation science and substance abuse research, with our Community Action Board and health economics team will prioritize research on vaccines, microbicides, treatment, behavioral and structural interventions, and other prevention modalities.

2. Improve HIV Disease Outcomes

- Clinical and Retrovirology Research Core (CRRC), Clinical Epidemiology and Health Services Research Core (CE&HSR), Basic Discovery Science Cores, and AIDS-Associated Infections and Malignancies Core (AAIMs), and the Implementation Science Working Group will pursue new drug targets, and development and evaluation of investigational therapeutic agents; and support research on diagnosis and treatment of HIV infection, and of HIV-related Cancers and Co-infections and on implementation and scale up research, domestically and globally, at individual and population levels.
- Basic Discovery Science, Clinical and Retrovirology Research, and Clinical Epidemiology and Health Services Cores will address chronic inflammation-related morbidity.
- The health economics team, a new sub-Core of the International Core, will collaborate closely with the
 Implementation Science SWG and the CRRC, CE&HSR Core, and the Socio-Behavioral and Prevention
 Research Core, to incorporate health economics evaluations into research on HIV/AIDS treatment and
 prevention.

3. Expand Basic Discovery Research; Find the Cure

 Basic science and clinical cores and the Curative Therapies for HIV SWG will support interdisciplinary, collaborative research on pathogenesis, and potential approaches to HIV cure.

4. Reduce HIV-Related Disparities

- The CFAR will promote <u>Sexual Health</u> research, emphasizing positive outcomes (gain frame as opposed to loss-frame) and health equity. We will engage affected communities with our Community Action Board, across a wide spectrum of HIV research, including socio-behavioral, clinical, and epidemiological research, implementation science, and substance abuse research.
- The CFAR will characterize and monitor HIV-related health inequities.

Current Configuration of the UW/FH CFAR

The UW/Fred Hutch CFAR currently has 10 Cores, 3 Scientific Working Groups, and a Community Action Board. As the CFAR has evolved during its 29 year history, it has grown to from a few Cores to ten Cores. The goal of this RFA is to revisit the content of the Cores for the 2017 competitive renewal submission.

Cores

Administration: Coordinates planning, operations, and oversight of all CFAR activities. Director: King Holmes; Co-Directors: Ann Collier, Corey Casper; Assistant Director: Susan Mello

AIDS-Associated Infections and Malignancies: Provides assays and data instruments to enable studies of HIV-associated malignancies and HIV-associated infections. Director: Corey Casper; Associate Director: Warren Phipps

Biometrics: Provides a central resource of biostatistical expertise to improve the conception, design, and analysis of HIV/AIDS studies. Director: Sarah Holte; Co-Director: Barbra Richardson

Clinical and Retrovirology Research Core/HIV Specimen Repository: Helps investigators perform clinical studies by supporting enrollment of HIV-infected patients, facilitating use of frozen specimens, and assisting with overall study logistics and training. Provides laboratory testing for HIV markers. Co-Directors: Bob Harrington and Bob Coombs; Associate Directors: Jai Lingappa and Lisa Frenkel

Clinical Epidemiology and Health Services Research: Helps researchers access and interpret the comprehensive database of the UW HIV Cohort Study. Director: Mari Kitahata; Associate Director: Heidi Crane

Developmental: Supports the career development of young scientists and nurtures the early growth of new research ideas by funding pilot awards and providing opportunities for interdisciplinary collaboration and translational work. Director: Ann Collier; Associate Director: Roland Strong

Immunology: Provides advanced tools and training for evaluating humoral and cellular responses to HIV infection. Director: Steve De Rosa; Sub-Core Directors: Ana Gervassi, Deb Fuller, Tom Hawn

International: Collaborates with U.S. and non-U.S. scientists and administrators to improve the efficiency, quality, and durability of HIV/AIDS research performed in developing countries. Director: Grace John Stewart; Associate Directors: Scott McClelland, Joseph Zunt

Molecular Profiling and Computational Biology: Assists researchers in viral sequence analysis. Director: Marty McIntosh; Co-Director: Jim Mullins

Sociobehavioral and Prevention Research: Supports HIV research that seeks to integrate the social, behavioral, and clinical sciences. Director: Martina Morris; Co-Director: Matt Golden

Scientific Working Groups

Curative Therapies for HIV: Director: Keith Jerome; Associate Director: Daniel Stone

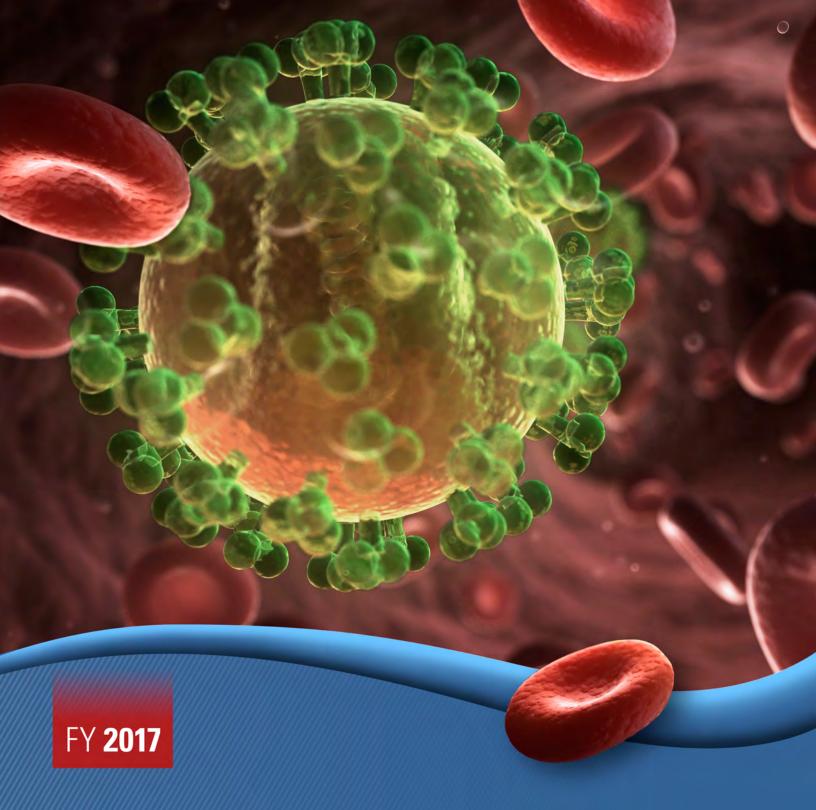
Implementation Science: Director: Kenny Sherr; Co-Directors: Steve Gloyd, Judy Wasserheit

Substance Abuse and HIV/STI: Director: Dennis Donovan; Co-Director: Jane Simoni

The CFAR <u>Community Action Board</u> is a group of key stakeholders from our community who serve in an advisory capacity, providing a community perspective on important issues in HIV/AIDS research.

For more information on current configuration of the UW/Fred Hutch CFAR, please view our website.

Attachment B: NIH Office of AIDS Research (OAR) FY2017 Trans-NIH AIDS Research Priorities



Trans-NIH Plan for HIV-Related Research





Dedicated to the Memory of William E. Paul, M.D.

(1936-2015)

Dr. Paul was a leader in the field of immunology and spent more than 30 years at the NIH. As Director of the NIH Office of AIDS Research (OAR) from 1994 to 1997, he refocused HIV/AIDS research with a priority on basic and vaccine research. He championed the establishment of the NIH Vaccine Research Center. The NIH and the global research community mourn his loss, but his legacy remains.

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Foreword

I am pleased to present the FY 2017 Trans-NIH Plan for HIV-Related Research. The Office of AIDS Research (OAR) is the only entity at the National Institutes of Health (NIH) that sets trans-NIH HIV/AIDS research priorities and builds a budget based on those priorities.

In August 2015, Dr. Francis Collins, the NIH Director issued a statement identifying the overarching HIV/AIDS research priorities for the NIH for the next 3 to 5 years (http://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-efforts-focus-research-end-aids-pandemic). The NIH also simultaneously issued new HIV/AIDS research priorities for determining HIV/AIDS funding (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-137.html).

We have made extraordinary strides in HIV/AIDS research, including the development, use and implementation of biomedical and behavioral modalities for HIV/AIDS diagnosis, prevention, and treatment. There is still a great deal more to do, however, both in the United States and internationally. The need for a safe and effective vaccine, strategies for achieving a cure, and the reduction of health disparities among various vulnerable populations with respect to HIV/AIDS outcomes are critical.

We remain strongly committed to supporting important and crucial HIV/AIDS research that will have a major impact on ending the AIDS pandemic. We encourage HIV/AIDS investigators to propose innovative strategies to prevent, treat, and eventually cure AIDS. This Strategic Plan provides a blueprint for progress forward to meet those challenges so that we can someday live in a world without AIDS.

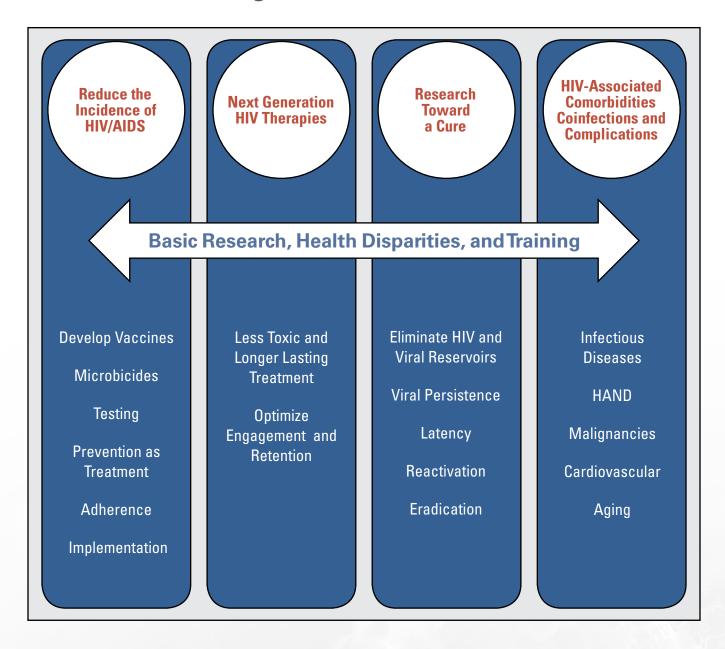
• Legislative Mandate Section 2353 of the Public Health Service Act requires that the Director of OAR shall: (1) establish a comprehensive Plan for the conduct and support of all AIDS activities of the agencies of the NIH; (2) ensure that the Plan establishes priorities among the AIDS activities that such agencies are authorized to carry out; (3) ensure that the Plan establishes objectives regarding such activities; (4) ensure that all amounts appropriate for such activities are expended in accordance with the Plan; (5) review the Plan not less than annually, and revise the Plan as appropriate; and (6) ensure that the Plan serves as a broad, binding statement of policies regarding AIDS activities of the agencies, but does not remove the responsibility of the heads of the agencies for the approval of specific programs or projects, or for other details of the daily administration of such activities, in accordance with the Plan.

The law also specifically requires that the Plan provides for basic research, applied research, research conducted by the NIH, research supported by the NIH, proposals developed pursuant to solicitations by the NIH and investigator-initiated proposals, and behavioral and social sciences research. In accordance with the law, the NIH Office of AIDS Research, a component of the NIH Office of the Director in the Division of Program Coordination, Planning, and Strategic Initiatives, has developed this Strategic Plan.

• The NIH HIV/AIDS research program is coordinated and managed by OAR, which functions as an "institute without walls" with responsibility for HIV/AIDS-related research supported by almost every NIH Institute and Center (IC). OAR coordinates the scientific, budgetary, and policy elements of this diverse trans-NIH research program. OAR plans and coordinates NIH HIV/AIDS research through development of the annual Trans-NIH Plan for HIV-Related Research that identifies the overarching research priorities. This process involves scientists from across the NIH and other federal agencies, nongovernment experts, and community constituency groups. The Plan also serves as the framework for developing the annual trans-NIH HIV/AIDS research budget to ensure that research dollars are invested in the highest priority areas of scientific opportunity that will lead to new tools ending the HIV/AIDS pandemic, developing a safe and effective AIDS vaccine, developing a cure, and achieving an AIDS-free generation. As required by law, the Director of OAR and Director of NIH together determine the total allocation of AIDS research dollars. OAR determines each IC's AIDS research allocation based on the Trans-NIH Plan for HIV-Related Research, scientific opportunities, the evolving clinical profile of the epidemic, and the IC's capacity to absorb and expend resources for the most meritorious science. It is not based on a formula. This process reduces redundancy, promotes harmonization, and ensures cross-Institute collaboration. The NIH investment in HIV/AIDS research has produced groundbreaking scientific advances, which continue to provide a critical foundation of knowledge, tools, and strategies for achieving the goals of the President's National HIV/AIDS Strategy. The NIH will continue to sponsor research in search of solutions to prevent, treat, and ultimately, cure HIV/AIDS.

> With sincere appreciation, Robert W. Eisinger, Ph.D. NIH Acting Associate Director for AIDS Research Acting Director, Office of AIDS Research

Overarching HIV/AIDS Research Priorities





- Reduce the incidence of HIV/AIDS, including: developing and testing promising vaccine, microbicide and pre-exposure prophylaxis candidates and novel methods of delivery, especially those with potential to mitigate adherence issues; and developing, testing, and studying strategies and the implementation of strategies to improve HIV testing, and entry, and maintenance in prevention care and services.
- Next generation of HIV therapies with better safety and ease of use, including: developing and testing HIV treatments that are less toxic, longer acting, have fewer side effects and complications, and easier to take and adhere to than current regimens; implementing research to understand how best to initiate treatment as soon as an HIV diagnosis has been made, improving engagement and retention in care; and achieving and maintaining optimal prevention and treatment responses.
- Research toward a cure, including: developing novel approaches and strategies to identify and eliminate viral reservoirs that could lead toward a cure or lifelong remission of HIV infection, including studies of viral persistence, latency, reactivation, and eradication.

- HIV-associated coinfections, comorbidities, and complications, including: addressing the impact of HIV-associated comorbidities, including tuberculosis, malignancies, cardiovascular, neurological, and metabolic complications; and premature aging associated with long-term HIV disease and antiretroviral therapy.
- **Crosscutting areas:** Basic research, health disparities, and training, including:
 - Basic Research: understanding the basic biology of HIV transmission and pathogenesis; immune dysfunction and chronic inflammation; host microbiome and host and viral genetics that impact susceptibility to infection and disease outcomes; and other fundamental issues that underpin the development of high-priority HIV prevention, cure, comorbidities, and treatment strategies.
 - Research to Reduce Health Disparities in the incidence of new HIV infections or in treatment outcomes of those living with HIV/AIDS.
 - Research Training of the workforce required to conduct high-priority HIV/AIDS or HIV/AIDS-related research.



Significant advances in treatment have had major impact on the health of millions of HIV-infected individuals. To bring an end to the HIV/AIDS pandemic, however, new infections need to be prevented. Multiple approaches will be necessary to end the pandemic. Specific areas of NIH prevention research include: active and passive vaccines; antiretroviral (ARV) and non-ARV microbicides; multipurpose prevention technologies (MPTs); voluntary medical male circumcision (VMMC); ARVs for the prevention of mother-to-child transmission; pre-exposure prophylaxis (PrEP); and treatment as prevention (TasP) to reduce the risk that an HIV-infected individual will transmit the virus to an uninfected partner. Prevention studies should include socio-behavioral strategies to reduce risk, synergize other prevention technologies, and gain and sustain prevention adherence. Appropriate animal models continue to be critical in responding to preclinical questions concerning strategies for HIV prevention, including understanding of the immune responses, viral uptake, and mechanisms of infection, and determining the safety and potential efficacy of agents prior to engaging in clinical research. Given that most HIV-infections occur at mucosal surfaces, it is essential to better understand mucosal immune functions and properties, including the role of the microbiome, which can contribute to protection from HIV infection.

Successful interventions and treatments depend on individual and community readiness, acceptance, and implementation into practice. The NIH supports behavioral and social sciences research to better understand the factors that support or prevent HIV risk, transmission, and acquisition, and influence demand for and adherence to effective prevention and treatment strategies. The NIH will continue to support a comprehensive HIV/AIDS research portfolio that includes basic and behavioral

and social sciences research for those populations at highest risk of infection, developing and incorporating socio-behavioral interventions, and implementing studies to reduce the incidence of HIV/AIDS.

High-priority research opportunities focused on reducing the incidence of HIV/AIDS include:

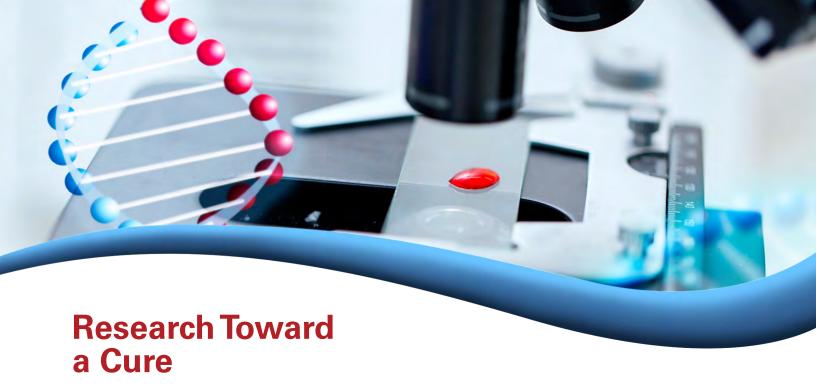
- Examining the relationship between the genital/rectal-anal tract microenvironment, host factors, immune function, microbiome, and HIV risk, transmission, and acquisition.
- Evaluating the role of immunity (including, but not limited to T cells, B cells, antigen-presenting cells, innate responses and host factors), particularly at mucosal sites, for protection in the context of studies on vaccines, microbicides, and long-acting antiretroviral agents.
- Conducting clinical trials for vaccines, microbicides, MPTs, PrEP, and other biomedical prevention modalities.
- Developing and testing standardized assays to better understand the mechanisms of infection and transmission that inform vaccine, microbicides, and PrEP efficacy.
- Developing models to study the contributions and interactions of behavioral, social, structural, and environmental factors in at-risk communities, as well as models for community engagement to reduce HIV/AIDS in different populations and cultural settings.
- Identifying strategies to overcome barriers to the adoption, adaptation, integration, scale-up and sustainability of evidence-based interventions and tools, as well as clinical guidelines (standards of care) while accounting for racial, ethnic, cultural, gender, sex, and age differences in diverse settings.



NIH-sponsored research has led to critical advances in the development and clinical testing of antiretroviral therapy (ART), which has transformed HIV into a chronic manageable disease. ART results in profound immune recovery and enhanced function in HIV-infected individuals who are able to adhere to prescribed HIV treatment regimens and tolerate the side effects and toxicities. With the expansion of the classes of antiretroviral drugs, simplified daily regimens, and an array of combination treatments, sustained viral suppression is routinely achievable. ART has not only delayed the progression of HIV disease to AIDS, but also it has been effective at maintaining viral suppression and thus innate immunity, with the accompanying benefit of delayed development of viral resistance. The NIH will continue to support a comprehensive HIV/AIDS therapeutics research portfolio that includes drug discovery, preclinical drug development, clinical testing of new drugs and multidrug therapeutic regimens with improved safety, and identification of new and novel targets to allow for durable suppression of viral activity.

High-priority research opportunities focused on next generation therapies for HIV/AIDS include:

- Elucidating the mechanisms of HIV persistence in persons on maximally suppressive ART and developing and testing strategies to promote and prevent the establishment of viral reservoirs as well as their elimination.
- Accelerating the discovery and validation of novel agents and strategies aimed at new and existing viral and cellular targets to develop safe, tolerable, low-cost, and maximally long-term suppressive antiviral activity.
- Developing and testing existing and novel agents that can be used alone or in combination with behavioral and other strategies to maximize viral suppression and adherence to antiretroviral drug regimens to prevent and treat HIV disease.



Combination ART has radically changed the course of HIV infection by improving health, prolonging life, and substantially reducing the risk of HIV transmission; however, it does not result in a cure. Although ART is effective in treating HIV disease, there remain toxic side effects, continued risks for HIV-associated clinical complications, and the need for lifelong therapy that are significant burdens on the HIV-infected individual, family and social structures, and the health systems that care for them. The experience of the "Berlin Patient" has demonstrated that sustained viral remission is possible. Subsequent research suggests that interventions resulting in sustained HIV remission off ART that are safe, effective, and scalable could be an achievable goal in the near term. Lifelong remission and/or viral eradication will be a more challenging and long-term goal. A major hurdle to achieving a cure is the ability of HIV to rapidly establish reservoirs of latent virus within the body through integration of viral genes into the genome of certain cell types. Additional research is needed to better understand the mechanisms and dynamics of HIV

persistence and latency in reservoirs of long-lived cells, even in the presence of effective ART. Further research on models of HIV infection in non-human primates and small animals will be critical, as is the need for continued studies to advance the development of novel cure interventions.

High-priority research opportunities focused on research towards a cure include:

- Understanding viral and host mechanisms—including differential tissue and cellular distribution—that direct HIV persistence, latency, and reservoir formation.
- Developing and testing novel interventions, including therapeutic vaccines and next-generation monoclonal antibodies and derivatives, to control or eliminate latent and/or persistent reservoirs of HIV in the presence of effective ART.
- Identifying and validating novel biomarkers, assays, and imaging techniques to advance research toward a cure.



HIV/AIDS is a disease in large part defined by coinfections and comorbid conditions. Frequently, HIV infection and its complications do not occur in isolation, but rather are preceded and co-occur with other health and mental health issues such as substance abuse, mental disorders, and malnutrition. With the advent and widespread use of ART, there has been a significant change in the types of HIV-associated coinfections, comorbidities, and complications that are seen, but the challenges of HIV clinical management continue globally. Examples are numerous and include, but are not limited to: tuberculosis, hepatitis B and C, and other sexually transmitted infections (STIs). Comorbidities include cardiovascular disease, metabolic abnormalities and diabetes/insulin resistance, bone and muscle disease, liver and kidney disease, neurological disorders, including cognitive decline, as well as AIDS-defining and non-AIDS defining cancers, and frailty in people aging with HIV. A unique challenge, particularly in low-resource and international settings, is the existence of multiple, preexisting, and concurrent comorbid conditions. Epidemiologic studies continue to identify new HIV-related comorbidities and help to differentiate effects related to long-term ART use from those related to HIV disease and suboptimal immune function. Development of new agents, alone and in combination, as well as novel sustained release formulations and delivery systems may impact

the prevention and treatment of co-infections, comorbidities, and other long-term HIV-associated complications.

High-priority research opportunities focused on HIV-associated co-infections, comorbidities, and other complications include:

- Accelerating the discovery, testing, and validation of therapeutic strategies to prevent and treat HIVassociated comorbidities across the lifespan of HIVinfected individuals.
- Elucidating the mechanisms responsible for the pathogenesis of comorbid conditions of various organ systems, including the contribution of the immune system, inflammation, and long-term antiretroviral therapy on the development of these comorbidities.
- Defining the mechanisms that increase the risk of acquiring HIV-associated coinfections in diverse populations, and evaluating the interaction of coinfecting pathogens on HIV disease progression and vice versa.
- Examining the prevalent comorbidities such as substance use and abuse, mental disorders, and malnutrition within the context of HIV/AIDS.



A major proportion of HIV/AIDS research has relevance to not one, but all of the overarching NIH HIV/AIDS priority research areas. This includes basic research, health disparities research, and training.

Basic Research

Basic research provides the underlying foundation for all HIV/AIDS studies. This component of the NIH HIV/AIDS research portfolio includes research to examine HIV virology, transmission, acquisition, and host-viral interactions. Additionally, it includes critical research on the viral, cellular, and molecular mechanisms of HIV-associated clinical complications. This research is crucial to better understand the development of HIV-associated comorbidities, and the acquisition and pathogenesis of coinfections. These studies elucidate the genetic and immune mechanisms involved in HIV disease progression, as well as determine how sex, gender, age, ethnicity, culture, race, pregnancy, nutritional status, and other factors influence disease and treatment outcomes as well as susceptibility to HIV infection.

High-priority research opportunities focused on basic research include:

- Furthering the understanding of host-viral interactions, including cellular and immune responses, the role of the microbiome, host restriction, and host and viral genetics to inform the highest priority HIV/AIDS research.
- Developing and improving research models to advance research on HIV transmission, acquisition, acute and chronic infection, latency and persistence, pathogenesis, microbicides, vaccines, and treatment.
- Developing new tools, standards, biomarkers, systems biology, behavioral-social-contextual factor analytics, and other novel methodologies for the evaluation and design of biomedical and behavioral research interventions.

Health Disparities

Despite profound advances in research, there are significant health disparities with respect to HIV/AIDS treatment outcomes, particularly morbidity and mortality. These disparities can be linked to race, socioeconomic status, country of origin and gender, as well as in other marginalized, hidden, or "hard-to-reach" groups, such as refugees, migrant workers, adolescents, and rural populations. The NIH has and will continue to prioritize the enrollment and retention of individuals of diverse racial, ethnic, and cultural backgrounds, sex and gender minorities, and individuals with preexisting conditions in clinical trials. Studies have repeatedly delineated that these significant health disparities are critical drivers of the HIV/AIDS pandemic and are related to disproportionate HIV risk, acquisition, transmission, and poor treatment outcomes. Unraveling the complex interplay between these factors is essential to decrease the rates of HIV transmission and seroprevalence among these populations, but also increase-by extensionearly diagnosis and access to services, treatment adherence, reducing the gap in treatment outcomes, and minimizing HIVassociated comorbidities and comortalities. Biologic, social and behavioral, and implementation research is needed to identify not only the optimum combination of interventions and strategies, but also how effective these will be in achieving the goals of reduced acquisition and transmission, while enhancing HIV treatment adherence, retention in care, and improved outcomes. Such a broad agenda of research will require identifying opportunities for individual, community, and population level interventions.

High-priority research opportunities focused on HIV-related health disparities include:

- Utilizing clinical, epidemiological, behavioral, basic, and implementation science research to enhance the understanding of the impact of race, ethnicity, culture, socioeconomic status, gender, and other social determinants of health on HIV acquisition, prevention and transmission, diagnosis, treatment, and clinical management.
- Expanding existing research methods and developing innovative methodologies to accurately assess biological, contextual, social, and individual facilitators and inhibitors of HIV transmission, infection and disease progression in racial, ethnic, cultural, gender, and sexual minority populations across the lifespan.
- Developing HIV diagnostic, prevention, and therapeutic technologies, as well as expanding implementation science to determine the impact and cost effectiveness of existing interventions and strategy combinations, improving uptake and scale-up, and providing an evidence base to inform clinical practice in diverse settings.
- Strengthening the broad dissemination of HIV/AIDS research information to inform clinical practice in diverse populations and settings, including, but not limited to, the centralization and availability of large cohort data.

Training

The NIH supports the training of a research workforce to build the critical capacity and infrastructure to conduct HIV/AIDS research globally. This includes teaching, evaluating, and maintaining the highest bioethical standards in the conduct of HIV research, as well as developing and maintaining collaborations and leadership in HIV/AIDS research and its related sciences.

High-priority research opportunities focused on training include:

 Promoting and supporting training, capacity building, and infrastructure development critical to enhancing HIV/ AIDS research.



Attachment C: White House National HIV/AIDS Strategy for the United States: Updated to 2020

NATIONAL HIV/AIDS STRATEGY for the UNITED STATES:

UPDATED TO 2020

JULY 2015



VISION

The United States will become 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.

ACKNOWLEDGEMENTS

The National HIV/AIDS Strategy: Updated to 2020 is a result of contributions of people living with HIV; community groups and national organizations; providers from various disciplines; researchers; and other individuals working with Federal agencies, State, Tribal, and local governments to make their voices heard. The Office of National AIDS Policy (ONAP) hopes that dedication, inspiration, and hard work are reflected in this guiding national plan, and acknowledges that this Update would not be possible without full stakeholder participation.

ONAP also wishes to thank all partners throughout the Federal government who have contributed hours, weeks, and months to the creation of this document, and years of their careers to addressing the HIV epidemic in the United States and serving the American people.

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EXECUTIVE SUMMARY

The Nation's first comprehensive National HIV/AIDS Strategy for the United States (Strategy) was released in 2010, and in the subsequent five years, people and organizations have joined together around its vision and goals. The Strategy has changed the way the American people talk about HIV, prioritize and organize prevention and care services locally, and deliver clinical and non-clinical services that support people living with HIV to remain engaged in care, and has helped achieve the following:

- Implementation of the Affordable Care Act. Millions of Americans can access preventive services like HIV testing without a co-pay or deductible. People living with HIV can no longer be discriminated against because of their HIV status, and thousands more people living with HIV have new coverage options through Medicaid expansion or the Health Insurance Marketplace.
- Groundbreaking work by the National Institutes of Health (NIH), including the HIV Prevention Trials Network (HPTN) 052 study, which *Science* magazine called the scientific breakthrough of 2011, and which demonstrated that early treatment for HIV reduces the risk of onward transmission by 96 percent while simultaneously improving health outcomes. NIH also supported the Strategic Timing of Antiretroviral Therapy (START) trial, which demonstrated that those with HIV who received immediate treatment significantly reduced their risk of serious, adverse health outcomes.
- The introduction of PrEP (pre-exposure prophylaxis), a much-needed new biomedical prevention tool that helps people reduce their risk of HIV infection by taking a daily pill. Based on evidence from multiple clinical trials released from 2011 to 2013, the Food and Drug Administration approved PrEP in 2012, and in 2014 the U.S. Public Health Service issued clinical practice guidelines for PrEP.
- Vital work by the Centers for Disease Control and Prevention (CDC), including key guidance for the adoption of new testing technologies that enhance the ability to diagnose HIV soon after infection. These technologies broaden the window of opportunity for effective interventions during the acute phase of infection—a time when HIV is most likely to be transmitted to others.
- Critical funding increases for the AIDS Drug Assistance Program (ADAP) of the Health Resources
 and Services Administration (HRSA), which ensured access to lifesaving treatment by helping to
 eliminate ADAP waiting lists, and for additional services that support a system of care necessary for those
 with HIV to maintain health.
- Major strides in collaboration across the Federal government, establishing cross-agency partnerships, formulating recommendations for the HIV Care Continuum Initiative, and developing and implementing a core set of HIV program indicators to support data sharing and increased transparency in progress made. For example:

- A Federal interagency workgroup was established to investigate the intersection of HIV and violence against women and it resulted in more than 15 new initiatives within two years.
- The Department of Justice (DOJ) collaborated with CDC to publish a comprehensive examination of HIV-specific criminal laws. As a result, DOJ issued a best practices guide to reform these laws that help states ensure their policies do not place unnecessary burdens on individuals living with HIV/ AIDS and that they reflect an accurate understanding of HIV transmission routes and associated benefits of treatment.
- Demonstration projects funded through the Secretary's Minority AIDS Initiative Fund (SMAIF) have engaged multiple HHS agencies—including CDC, HRSA, and the Substance Abuse and Mental Health Services Administration (SAMHSA)—to foster coordination and collaboration across agencies and evaluate agency policies that may act as barriers to coordinated planning, implementation, delivery, and evaluation of HIV/AIDS services at the state and local levels.

These and other accomplishments have resulted in important gains toward targets for increasing the percentage of persons living with HIV who know their status, are linked to care, and have achieved viral suppression, as well as reducing death rates. Despite this progress, the level of infection is stable overall. While declines in diagnoses have occurred for women, persons who inject drugs, and heterosexuals, the epidemic among gay and bisexual men remains severe, with increases in new diagnoses. Achieving the goals of the Strategy will require intensified efforts for this population in order to realize the greatest impact.

The Nation has the tools to slow, and eventually end, the epidemic in the United States. With ongoing leadership, sustained funding commitments, strategic action, and emerging digital tools and technologies to help inform and educate, the American people are closer than ever to the day when the Strategy's vision will be attained. Together, people living with HIV and those affected, state, Tribal, and local governments, health providers, government and industry scientists, faith leaders, and community partners have fundamentally transformed the response to HIV/AIDS in the United States. The Strategy has truly become the roadmap for collective action and has brought new energy and commitment in States and local communities across the country.

This is the first update of the Strategy (Update), which is designed to look ahead to 2020. The Update reflects the hard work accomplished and the lessons learned since 2010. Moreover, it incorporates the scientific advances that could one day bring the United States, and the world, closer to virtually eliminating new HIV infections, effectively supporting all people living with HIV to lead long and healthy lives and eliminating the disparities that persist among some populations.

The Strategy remains a steady foundation on which to build future efforts. As such, this Update retains its vision and four main goals through 2020. At the same time, the Strategy is also a living document, designed to be updated. The Update includes the following changes:

- The **Steps and Recommended Actions** under each of the goals have been revised to reflect past progress and activities to meet the Strategy goals (see "At-A-Glance" summaries on pages 8-11).
- The Update has **10 quantitative indicators**—some of which are new additions, and some of which are revised—to better monitor progress and ensure that the Nation is constantly moving in the right direction to achieve its goals (see list on page 12 and detailed information in the Indicator Development and Progress Appendix). In addition, three areas have been identified as priorities for developing indicators: PrEP, stigma, and HIV among transgender persons.

• The objectives and recommendations of both the HIV Care Continuum Initiative and the Federal Interagency Working Group on the Intersection of HIV/AIDS, Violence against Women and Girls, and Gender-Related Health Disparities have been fully integrated into the Steps and Recommended Actions (see Tables on pages 13 and 14).

As a guiding document, the Update is a National plan, not just a Federal plan. Federal efforts are vitally important but the goals of the Strategy can only be achieved by engagement at the national, state, Tribal, and local levels and across all sectors. It is especially important that people who work in communities play an active role in implementing this Strategy. It is on the ground that the work is accomplished, and it is on the ground where the Strategy's implementation has improved the lives of Americans impacted by HIV.

The Update looks toward 2020 with the following statements in mind:

- There is still an HIV epidemic and it remains a major health issue for the United States.
- Most people can live long, healthy lives with HIV if they are diagnosed and get treatment.
- For a variety of reasons, certain populations bear a disproportionate burden of HIV.
- People across the Nation deserve access to tools and education to prevent HIV transmission.
- Every person diagnosed with HIV deserves immediate access to treatment and care that is nonstigmatizing, competent, and responsive to the needs of the diverse populations impacted by HIV.

The Update allows for opportunities to refresh the ongoing work in HIV prevention, care, and research. Advances in four key areas are of critical focus for the next five years:

- Widespread testing and linkage to care, enabling people living with HIV to access treatment early.
- Broad support for people living with HIV to remain engaged in comprehensive care, including support for treatment adherence.
- Universal viral suppression among people living with HIV.
- Full access to comprehensive PrEP services for those whom it is appropriate and desired, with support for medication adherence for those using PrEP.

A COLLABORATIVE NATIONAL RESPONSE

By working in the direction of shared national goals and aligning efforts across sectors with the principles and priorities of the updated Strategy, the Nation can advance toward the life-saving HIV goals.

GOAL 1: REDUCING NEW HIV INFECTIONS

HIV does not impact all Americans equally. While anyone can become infected, the HIV epidemic is concentrated in key populations and geographic areas. In 2010, the Strategy called for a path that followed epidemiological data. This Update continues along that path by calling for Federal agencies to ensure that funding is allocated according to the current epidemiological profile of each jurisdiction, and that cost-effective, scalable interventions are prioritized in the communities where HIV is most concentrated for the following groups:

- Gay, bisexual, and other men who have sex with men of all races and ethnicities (noting the particularly high burden of HIV among Black gay and bisexual men)
- Black women and men
- Latino men and women
- People who inject drugs
- Youth aged 13 to 24 years (noting the particularly high burden of HIV among young Black gay and bisexual men)
- People in the Southern United States
- Transgender women (noting the particularly high burden of HIV among Black transgender women)

Over the next five years, the Nation must ensure that programmatic funding is appropriately allocated and supports the most effective interventions, including research into innovative ways to prevent new infections.

The HIV prevention toolbox has grown. Based on scientific and technological advances in the past five years, new guidelines and recommendations have expanded the number of options for prevention. CDC has issued guidance to providers recommending PrEP be considered for those at substantial risk for HIV. In addition, guidelines from the U.S. Department of Health and Human Services (HHS) now recommend that all persons with HIV be offered treatment not only for their own health, but also because antiretroviral treatment significantly reduces the risk of HIV transmission to others. Additionally, the U.S. Preventive Services Task Force (USPSTF) recommends that all people aged 15 to 65 years, and all pregnant women, be screened for HIV. CDC has also provided guidance for the adoption of new testing technologies that enhance the ability to diagnose HIV soon after infection, broadening the window of opportunity for effective interventions during the acute phase of infection—a time when HIV is most likely to be transmitted to others.

Over the next five years sustained effort is required to realize the promise of these and other scientific advances, and to adopt and embrace emerging beneficial research findings. These may include the availability of sustained release antiretroviral agents either for PrEP or for treatment, new developments in microbicides or vaccines, or more effective delivery of HIV care services.

HIV information should be universally integrated into appropriate educational access points. All Americans deserve scientifically accurate, easy-to-access information about HIV transmission and prevention. This entails providing clear, specific, consistent, and scientifically up-to-date messages about risk and prevention strategies—followed by active deployment of this information to develop and disseminate education campaigns, prevention programs, and risk assessment tools. These interventions should leverage digital strategies and new technologies to reach the broadest number of people at relevant access points.

GOAL 2: INCREASING ACCESS TO CARE AND IMPROVING HEALTH OUTCOMES FOR PEOPLE LIVING WITH HIV

Health care coverage matters for people living with HIV. Due to the Affordable Care Act, people living with HIV can no longer be discriminated against on the basis of their HIV status or other pre-existing health conditions when seeking health care coverage. In addition, thousands more people living with HIV have new access to Medicaid or a Marketplace health insurance plan. And for people who already have health care coverage, there are new limits on out-of-pocket spending and other protections to make coverage more secure. Additionally, the Administration, with strong bipartisan support from Congress, has been unwavering in its commitment to sustaining the Ryan White HIV/AIDS Program, administered by HRSA. Critical funding increases for the ADAP have been provided to ensure access to lifesaving treatment and support for the clinics and additional services necessary for those with HIV to maintain health. Finally, successful access to care is often precluded by unmet basic needs such as housing. Supplementing care services with robust policies in support of basic needs is crucial for timely linkage to and retention in HIV care.

Improving outcomes at every step of the HIV care continuum must remain a priority. In 2013, President Obama issued an Executive Order establishing the HIV Care Continuum Initiative, calling for coordinated action among Federal agencies to mobilize efforts in line with the recent advances in HIV treatment. These efforts are expected to yield longer lives and fewer new infections. Going forward, efforts must be directed toward improving outcomes at every step of the continuum, from testing to diagnosis, linkage and engagement in care, treatment, and ultimately, viral suppression. Key to this effort will be the identification and re-engagement of people who have been lost to care. Promising initiatives in several cities and States across the country have already demonstrated successful strategies, using HIV surveillance data and clinical care data. An essential next step is to enhance capacity in all states to systematically identify and re-engage people living with HIV. This will also allow more rigorous monitoring of the continuum at all stages of care.

Developing models of competent care that treat the whole person, as well as the virus, is crucial. People living with HIV—after being diagnosed, entering the healthcare system, and being prescribed treatment—require supports to remain engaged in care. A culturally competent and skilled workforce is vital to this effort, and includes a range of providers such as peer navigators, nurses, doctors, case managers, pharmacists, and social workers. Key priorities for improving outcomes along the care continuum include expanding the workforce by engaging and training non-traditional providers and expanding proven models of team-based, patient-centered care that facilitate ongoing engagement in care. Implementation science research is also essential to develop evidence-based models of care that are proven to deliver life-enhancing services.

SCIENTIFIC DISCOVERY REQUIRES A LONG-TERM COMMITMENT

The scientific advances that have led to current treatment and prevention interventions are the result of ongoing Federal investments in basic, biomedical, behavioral, and social science research. In 2013, President Obama announced that NIH would redirect \$100 million to launch an HIV Cure Initiative to further advance HIV/AIDS research with the hope of catalyzing a new generation of therapies aimed at curing HIV or inducing lifelong remission. Today, the science directly points to the benefit of getting all people living with HIV on treatment as soon as possible. The NIH has supported groundbreaking work, including the HPTN 052 study, called the scientific breakthrough of 2011 by *Science* magazine, which demonstrated that early treatment for HIV reduces the risk of onward transmission by 96 percent while simultaneously improving health outcomes, and the START trial demonstrated that those with HIV who received immediate treatment significantly reduced their risk of illness and death. Combined with the treatment-as-prevention benefit previously demonstrated by the HPTN 052 study, **the emphasis on optimizing the continuum of care and making access to lifesaving antiretroviral therapy a right, not a privilege, becomes a core tenet of the Strategy.**

GOAL 3: REDUCING HIV-RELATED DISPARITIES AND HEALTH INFOUITIES

The Nation cannot meet the Strategy goals without reducing disparities. Poor social and environmental conditions, coupled with high rates of HIV among specific populations and in geographic areas, contribute to stubbornly persistent—and in some cases, growing—HIV-related health disparities. These disparities include higher rates of HIV infection, lower rates of access to HIV care, lower HIV viral suppression rates and higher HIV-related complications, and higher HIV-related death rates; and they affect Black, Latino, and American Indian/Alaska Native people, transgender people, and young people.

Structural approaches can reduce risk of HIV transmission at community and societal levels.

It is imperative that the conditions in which people live, learn, work, play, and pray facilitate—rather than detract from—their ability to lead healthy lives. Such conditions include the background prevalence of HIV in sexual and drug networks as well as housing, education, employment, and family and social support systems. It has become abundantly clear that these social determinants of health are significant factors in the ability to meet the goals of the Strategy. More work is needed to test new models that advance health in a variety of settings. Work is underway to develop models for trauma-informed primary care that offer promise to change the health care environment in ways that reduce stress on patients and providers alike, and improve HIV and other health outcomes.

Stigma and discrimination must be eliminated in order to diminish barriers to HIV prevention, testing, and care. HIV-related stigma can be confounded by or complicated with stigma related to substance use, mental health, sexual orientation, gender identity, race/ethnicity, or sex work. Stigma can lead to many negative consequences for people living with HIV. It is imperative that all levels of government recognize that these various biases exist and work to combat stigma and discrimination in order to reduce new infections and improve health outcomes for people living with HIV. In the legal arena, this requires ensuring that all Federal and state criminal laws regarding HIV transmission and prevention are scientifically based, and that prosecutors and others in law enforcement have an accurate understanding of transmission risks.

GOAL 4: ACHIEVING A MORE COORDINATED NATIONAL RESPONSE TO THE HIV EPIDEMIC

Recognizing that improved coordination has occurred since the release of the Strategy in 2010, **even greater coordination is possible and essential**. Further effort should be directed toward identifying, learning from and replicating international, state, Tribal, and local successes. Federal leadership is critical in identifying overarching national priorities, as well as supporting research to evaluate which activities are most effective and ensure that Federal resources deployed will have maximum effect. The White House Office of National AIDS Policy (ONAP) will work collaboratively with the Office of National Drug Control Policy and other White House offices, as well as other Federal agencies, to further the goals of the Strategy.

As with the 2010 Strategy, this Update provides specific recommendations to help us meet the goals as well as indicators to measure progress. A system of regular public reporting will help to sustain nationwide public attention and support for the Strategy.

Working together, ONAP, the Office of the Assistant Secretary for Health at HHS, and other Federal agencies will develop a Federal Action Plan during 2015 that outlines the specific steps to be taken by Federal agencies to implement the priorities set by the Update. In addition, an action plan framework, similar to the

Federal Action Plan structure, will be created to assist non-Federal partners such as state and local health departments, Tribal governments, community-based organizations, coalitions of persons living with HIV, and other stakeholders to identify specific actions that they can take—tailored to their own specific missions and priorities—to ensure that the Nation is working to meet the goals of the Strategy. Shared priorities, streamlined grantee requirements, evidence-based strategies, and data-informed resource allocation will help get us there.

CALL TO ACTION

The Obama Administration demonstrated its commitment to reinvigorating the collective domestic response to HIV when the Strategy was released in 2010. Since then, the Nation has aligned its efforts to move closer toward achieving the goals of the Strategy and the national dialogue around HIV/AIDS has evolved to imagining a future free of new HIV infections in the United States and healthier, longer lives for people living with HIV. However, major challenges remain. Working together with renewed focus and vigor will advance that vision. Key focus areas for the Update include HIV testing with linkage to care for those with HIV infection, along with support for retention in care and treatment adherence to ensure that persons living with HIV remain virally suppressed, and for those testing negative but at substantial risk, linkage to PrEP and support for medication adherence. This Update is a call to action to myriad systems: **everyone is needed to put this Strategy into action and end the HIV epidemic.**

The Strategy is not a budget document and does not imply approval for any specific action under Executive Order 12866 or the Paperwork Reduction Act. The Strategy will inform the Federal budget and regulatory development processes within the context of the goals articulated in the President's Budget. All activities included in the Strategy are subject to budgetary constraints and other approvals, including the weighing of priorities and available resources by the Administration in formulating its annual budget and by Congress in legislating appropriations.

ACTIONS AT-A-GLANCE

GOAL 1: REDUCING NEW HIV INFECTIONS

STEP 1.A

Intensify HIV prevention efforts in communities where HIV is most heavily concentrated.

1.A.**1**



Allocate public funding consistent with the geographic distribution of the epidemic.

1.A.**2**



Focus on high-risk populations.

1.A.**3**



Maintain HIV prevention efforts in populations at risk but that have a low national burden of HIV.

STEP 1.B

Expand efforts to prevent HIV infection using a combination of effective, evidence-based approaches.

1.B.**1**



Design and evaluate innovative prevention strategies and combination approaches for preventing HIV infection in high-risk populations and communities, and prioritize and promote research to fill gaps in HIV prevention science among the highest risk populations and communities.

1.B.**2**



Support and strengthen integrated and patient-centered HIV and related screening (sexually transmitted infections [STI], substance use, mental health, intimate partner violence [IPV], viral hepatitis infections) and linkage to basic services (housing, education, employment).

1.B.3



Expand access to effective prevention services, including pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).

1.B.**4**



Expand prevention with persons living with HIV.

STEP 1.C

Educate all Americans with easily accessible, scientifically accurate information about HIV risks, prevention, and transmission.

1.C.1



Provide clear, specific, consistent, and scientifically up-to-date messages about HIV risks and prevention strategies.

1.C.2



Utilize evidence-based social marketing and education campaigns, and leverage digital tools and new technologies.

1.C.**3**



Promote age-appropriate HIV and STI prevention education for all Americans.

1.C.4



Expand public outreach, education, and prevention efforts on HIV and intersecting issues, such IPV.

1.C.**5**



Tackle misperceptions, stigma, and discrimination to break down barriers to HIV prevention, testing, and care.

ACTIONS AT-A-GLANCE

GOAL 2: INCREASING ACCESS TO CARE AND IMPROVING HEALTH OUTCOMES FOR PEOPLE LIVING WITH HIV

STEP 2.A

Establish seamless systems to link people to care immediately after diagnosis, and support retention in care to achieve viral suppression that can maximize the benefits of early treatment and reduce transmission risk.

2.A.**1**



Ensure continuity of high-quality comprehensive health care coverage to support access to HIV care.

2.A.**2**



Ensure linkage to HIV medical care and improve retention in care for people living with HIV.

2.A.**3**



Support and strengthen capacity to implement innovative and culturally appropriate models to more effectively deliver care along the care continuum.

2.A.**4**



Prioritize and promote research to fill gaps in knowledge along the care continuum.

2.A.**5**



Provide information, resources, and technical assistance to strengthen the delivery of services along the care continuum, particularly at the State, Tribal, and local levels.

STEP 2.B

Take deliberate steps to increase the capacity of systems as well as the number and diversity of available providers of clinical care and related services for people living with HIV.

2.B.1



Increase the number of available providers of HIV care.

2.B.**2**



Strengthen the current provider workforce to ensure access to and quality of care.

2.B.3



Support screening for and referral to substance use and mental health services for people living with HIV.

STEP 2.C



2.C.1



Address policies to promote access to housing and other basic needs and other supportive services for people living with HIV.

2.C.**2**



Improve outcomes for women in HIV care by addressing violence and trauma, and factors that increase risk of violence for women and girls living with HIV.

GOAL 3: REDUCING HIV-RELATED DISPARITIES AND HEALTH INEQUITIES

STEP 3.A

Reduce HIV-related disparities in communities at high risk for HIV infection.

3.A.**1**

Expand services to reduce HIV-related disparities experienced by gay and bisexual men (especially young Black gay and bisexual men), Black women, and persons living in the Southern United States.

3.A.**2**



Support engagement in care for groups with low levels of viral suppression, including youth and persons who inject drugs.

STEP 3.B

Adopt structural approaches to reduce HIV infections and improve health outcomes in high-risk communities.

3.B.**1**



Scale up effective, evidence-based programs that address social determinants of health.

3.B.**2**



Support research to better understand the scope of the intersection of HIV and violence against women and girls and develop effective interventions.

STEP 3.C

Reduce stigma and eliminate discrimination associated with HIV status.

3.C.**1**



Promote evidence-based public health approaches to HIV prevention and care.

3.C.**2**



Strengthen enforcement of civil rights laws, and assist States in protecting people with HIV from violence, retaliation, and discrimination associated with HIV status.

3.C.3



Mobilize communities to reduce HIV-related stigma.

3.C.**4**



Promote public leadership of people living with HIV.

GOAL 4: ACHIEVING A MORE COORDINATED NATIONAL RESPONSE TO THE HIV EPIDEMIC

STEP 4.A

Increase the coordination of HIV programs across the Federal government and between Federal agencies and State, territorial, Tribal, and local governments.

4.A.**1**



Streamline reporting requirements for Federal grantees.

4.A.**2**



Strengthen coordination across data systems and the use of data to improve health outcomes and monitor use of Federal funds.

4.A.**3**



Ensure coordinated program planning and administration.

4.A.**4**



Promote resource allocation that has the greatest impact on achieving the Strategy goals.

STEP 4.B

Develop improved mechanisms to monitor and report on progress toward achieving national goals.

4.B.**1**



Strengthen the timely availability and use of data.

4.B.**2**



Provide regular public reporting on Strategy goals.

4.B.**3**



Enhance program accountability.

INDICATORS AT-A-GLANCE

| indicator 1 | Increase the percentage of people living with HIV who know their serostatus to at least 90 percent . |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| INDICATOR 2 | Reduce the number of new diagnoses by at least 25 percent . |
| INDICATOR 3 | Reduce the percentage of young gay and bisexual men who have engaged in HIV-risk behaviors by at least 10 percent . |
| INDICATOR 4 | Increase the percentage of newly diagnosed persons linked to HIV medical care within one month of their HIV diagnosis to at least 85 percent . |
| INDICATOR 5 | Increase the percentage of persons with diagnosed HIV infection who are retained in HIV medical care to at least 90 percent . |
| INDICATOR 6 | Increase the percentage of persons with diagnosed HIV infection who are virally suppressed to at least 80 percent . |
| indicator 7 | Reduce the percentage of persons in HIV medical care who are homeless to no more than 5 percent . |
| INDICATOR 8 | Reduce the death rate among persons with diagnosed HIV infection by at least 33 percent . |
| indicator 9 | Reduce disparities in the rate of new diagnoses by at least 15 percent in the following groups: gay and bisexual men, young Black gay and bisexual men, Black females, and persons living in the Southern United States. |
| INDICATOR 10 | Increase the percentage of youth and persons who inject drugs with diagnosed HIV infection who are virally suppressed to at least 80 percent . |

REDUCING INCIDENCE, MEASURING DIAGNOSIS

Although HIV incidence estimates were used previously as an indicator for the Strategy to measure reductions in new infections, these estimates do not provide a timely and consistent way to monitor progress. The estimated number of new infections has changed, and likely will continue to change over time, due to changes in HIV testing technology and incidence estimation methods. These changes make it difficult to use these data as an indicator, to measure progress over time. In contrast, HIV diagnosis data as a way to monitor progress towards reducing new infections are published in a routine and standardized format and available for all States. Given these advantages, HIV diagnosis data are used for the indicator in this Update.

Using diagnosis data to track progress in reducing new HIV infections has some challenges. First, these data must be interpreted with consideration for trends in HIV testing, as changes in testing can lead to changes in diagnosis trends that are not related to trends in new infections. For example, if HIV diagnosis trends decrease in a particular population, evaluation is required to determine whether this decrease is due to fewer HIV tests being conducted or HIV tests being performed on persons at lower risk, versus an indication that new HIV infections are decreasing. Second, efforts to increase the percentage of people living with HIV who know their HIV status require an increase in diagnoses—meaning that, at least initially, achieving progress toward Indicator 1 may have a negative impact on progress toward Indicator 2. Over the longer term, diagnosing individuals who were previously undiagnosed will ultimately result in increased linkage to and retention in care and treatment, increased viral suppression, and decreased transmission to uninfected partners. This will reduce new infections, which will be reflected in a decrease in the number of new diagnoses.

Diagnosis data are used throughout this document to describe the burden of HIV and quantify disparities in populations and communities. These data are used to guide public health action at the Federal, State, and local levels.

ACTIONS AT-A-GLANCE COMPARISON

INTERSECTION OF HIV/AIDS, VIOLENCE AGAINST WOMEN AND GIRLS, AND GENDER-RELATED HEALTH DISPARITIES

In 2012 a Federal Interagency Working Group was established as part of a Presidential Memorandum that committed the Administration to improving efforts to understand and address the intersection of HIV/AIDS, violence against women and girls, and gender-related health disparities. This group developed five recommendations that were core objectives for action. Those recommendations have been incorporated into the Update, as shown in the table below.

FEDERAL INTERAGENCY WORKING GROUP RECOMMENDATIONS (2013)

AS INTEGRATED INTO THE UPDATED NATIONAL HIV/AIDS STRATEGY

1 Improve health and wellness for women by screening for intimate partner violence (IPV) and HIV.



1.B.2 Support and strengthen integrated and patient-centered HIV and related screening (STIs, substance use, mental health, IPV, viral hepatitis infections) and linkage to basic services (housing, education, employment).*

2 Improve outcomes for women in HIV care by addressing violence and trauma.



- **2.C.2** Improve outcomes for women in HIV care by addressing violence and trauma, and factors that increase risk of violence for women and girls living with HIV.
- 3 Address certain contributing factors that increase the risk of violence for women and girls living with HIV.



- **2.C.1** Address policies to promote access to housing and other basic needs and other supportive services for people living with HIV.
- → Federal efforts should be enhanced to address HIV and IPV among homeless and marginally housed women and girls.
- 4 Expand public outreach, education, and prevention efforts regarding HIV and violence against women and girls.



- **1.C.4** Expand public outreach, education, and prevention efforts on HIV and intersecting issues, such as IPV.
- → Empowering youth with information about their physical health and social and emotional well-being must continue to be part of a comprehensive approach to prevention and responding to HIV and violence; reaching Black and Latina women and girls should be a priority.
- 5 Support research to better understand the scope of the intersection of HIV/ AIDS and violence against women and girls, and develop effective interventions.



3.B.2 Support research to better understand the scope of the intersection of HIV and violence against women and girls, and develop effective interventions.

^{*} The specific recommendation on screening for IPV among women was incorporated into the broader recommendations for screening for multiple conditions, including IPV, for all persons

HIV CARE CONTINUUM INITIATIVE

The HIV Care Continuum Initiative was established by Executive Order in 2013 to accelerate improvements in HIV prevention and care. Recommendations and action steps from the Federal Interagency HIV Care Continuum Working Group were developed to guide ongoing implementation of the Strategy. Those recommendations have been integrated into the Update, as shown in the table below.

HIV CARE CONTINUUM RECOMMENDATIONS (2013)

AS INTEGRATED INTO THE UPDATED NATIONAL HIV/AIDS STRATEGY

Support, implement, and assess innovative models to more effectively deliver care along the care continuum.



2.A.3 Support and strengthen capacity to implement innovative and culturally appropriate models to more effectively deliver care along the care continuum.

2 Tackle misperceptions, stigma, and discrimination to break down barriers to care.



1.C.5 Tackle misconceptions, stigma, and discrimination to break down barriers to HIV prevention, testing, and care.

3 Strengthen data collection, coordination, and use of data to improve health outcomes and monitor use of Federal resources.



4.A.2 Strengthen coordination across data systems, and the use of data to improve health outcomes and monitor use of Federal funds.

4 Prioritize and promote research to fill gaps in knowledge along the care continuum.



2.A.4 Prioritize and promote research to fill gaps in knowledge along the care continuum.

Frovide information, resources, and technical assistance to strengthen the delivery of services along the care continuum, particularly at the state and local levels.



2.A.5 Provide information, resources, and technical assistance to strengthen the delivery of services along the care continuum, particularly at the State, Tribal, and local levels.

THE OPPORTUNITY

The best ways to reduce new HIV infections are to ensure timely diagnosis and engagement in care and treatment for those who are living with HIV; target prevention resources to the places with the largest burden of disease and the populations at greatest risk; ensure that the most effective prevention strategies are prioritized and widely implemented; and continue to conduct research on PrEP, microbicides, and vaccines. More than three decades into the HIV epidemic, great progress has been made both domestically and internationally in controlling the spread of infections, although more still needs to be done.

Early on, the United States succeeded in mounting a response that involved people living with HIV; businesses; the public sector; foundations; pharmaceutical companies; scientific, medical, social work, and public health professionals; faith communities; and others. Their collective efforts have helped contribute to major successes in reducing HIV infections:

- Development of HIV diagnostic tests and widespread testing efforts
- Effective screening of the blood supply so that transfusion-transmitted infections are rare
- Screening and treating expectant mothers during pregnancy to reduce perinatal transmission
- Increased access to new, sterile syringes and other injection equipment to minimize infections from injection drug use

In addition, in the five years since the National HIV/AIDS Strategy was released, there have been trailblazing scientific advances, major policy shifts, and significant changes in the way HIV prevention dollars are distributed. Milestones during this period include:

- Definitive evidence that early treatment promotes improved health outcomes for those infected and reduces risk of transmission to their partners.^{1, 2}
- Groundbreaking studies showing that PrEP is effective in reducing acquisition of infection.³⁻⁶
- Implementation of the Affordable Care Act, which increased the number of Americans—including
 persons living with and at risk for HIV—who have access to health care coverage and preventive services
 such as HIV testing that are covered without cost sharing.
- **Shifting funding for HIV prevention programs** to align with the number of people living with diagnosed HIV infection so the funding can have the greatest impact.⁷

To achieve the goal of reducing new infections, however, the following challenges must be addressed:

- Too many people living with HIV are unaware of their status or diagnosed late: in 2012, 13 percent, or about 156,300 of those infected, were undiagnosed, and in 2012, 24 percent of persons diagnosed with HIV had a stage 3 (AIDS) classification at the time of diagnosis.⁸
- Too many people living with HIV are not retained in care and, thus are not able to reap the benefits of treatment, prevention, and other services.⁸
- Too many Americans do not have the basic facts about HIV, other STIs, and infection risk associated with substance use.⁹
- Diagnoses of HIV infection are increasing in young gay and bisexual men, and the impact of HIV among gay and bisexual men of all ages remains severe.¹⁰
- Increases in substance use disorders related to prescription drug use, overdose, and viral hepatitis infections have complicated the ability to address HIV and require sustained access to prevention and treatment services so as not to erode successes in reducing HIV among people who inject drugs. 11-14

SUMMARY OF STEPS

It is essential to pursue a concerted national effort to reduce new HIV infections. The following steps are critical to achieving success:

STEP 1.A

Intensify HIV prevention efforts in communities where HIV is most heavily concentrated.

STEP 1.B

Expand efforts to prevent HIV infection using a combination of effective, evidence-based approaches.

STEP 1.C

Educate all Americans with easily accessible, scientifically accurate information about HIV risks, prevention, and transmission.

INDICATORS OF PROGRESS

Working together on these critical steps, we aim to meet the following targets by 2020:



INDICATOR 1

Increase the percentage of people living with HIV who know their serostatus to at least **90 percent**.



INDICATOR 2

Reduce the number of new diagnoses by at least **25 percent**.



INDICATOR 3

Reduce the percentage of young gay and bisexual men who have engaged in HIV-risk behaviors by at least **10 percent**.

STEP 1.A

Intensify HIV prevention efforts in communities where HIV is most heavily concentrated.

In the beginning of the HIV epidemic, there was widespread fear that it would spread throughout the general population. More than three decades later, the United States epidemic has not run the course that was previously feared. HIV cases in the United States are largely concentrated in specific locations and among key populations. For example, while more than one third of the population lives in southern states, this region accounts for more than half of all HIV diagnoses. Among the United States territories, high numbers of HIV diagnoses are found in Puerto Rico.

In 2012, a major shift was made in how Federal HIV prevention funding was provided to state and territorial health departments to better align resources with epidemiology by allocating funding based on the number of persons living with diagnosed HIV infection; in addition, specific activities directed to hard-hit populations were prioritized to achieve the highest impact. Going forward, more must be done to ensure that prevention resources at the state and local level are strategically concentrated in specific communities with high levels of risk for HIV infection. Intensifying efforts in communities where HIV is concentrated, and focusing on interventions that are effective and scalable can have the biggest impact, lowering all communities' collective risk of acquiring HIV infection.

Several jurisdictions have, through focused efforts, seen decreasing trends in HIV, including the States of New York and Massachusetts and the cities of San Francisco and Los Angeles. ¹⁵⁻¹⁸ In addition, some States and local areas have put forth their own plans to "end AIDS," such as New York State, Washington State, and San Francisco. ¹⁹⁻²¹

STATE AND LOCAL PLANS TO END AIDS

States and local jurisdictions have heeded the call to action of the National HIV/AIDS Strategy and developed local plans to improve care continuum outcomes and dramatically reduce HIV infections in their regions.

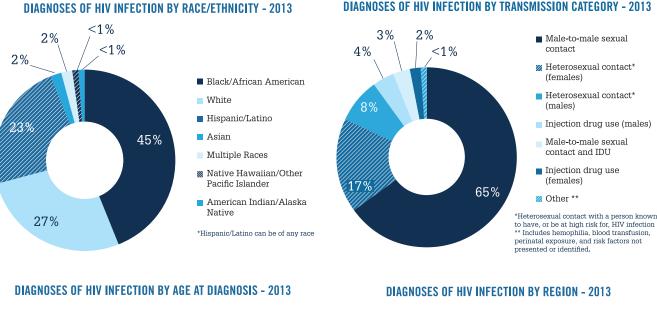
State of New York: Guided by an overarching three-point "End AIDS" plan to identify undiagnosed person with HIV, link and retain HIV-diagnosed persons in care and treatment, and facilitate access to PrEP, by 2020 New York State aims to reduce new HIV infections to 750. www.health.ny.gov/diseases/aids/ending_the_epidemic/docs/blueprint.pdf

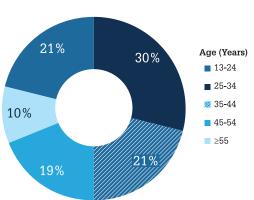
State of Washington: End AIDS Washington, through Washington Health Plan Finder, local clinical and community-based testing centers, PrEP drug assistance program, an academic clinic and local AIDS Drug Assistance Program working in collaboration, aims to reduce new HIV infections by 50 percent by 2020 by "Getting Insured, Getting Tested, Getting PrEP, and Getting Treatment." www.endaidswashington.org

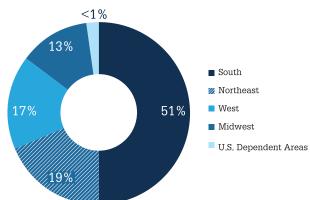
City and County of San Francisco: "Zero HIV infections, zero HIV deaths, zero HIV stigma" are the goals of San Francisco's "Getting to Zero" consortium, consisting of the local government, health department, planning councils, universities, community-based organizations, and care providers, large and small. www.sfhiv.org/wp-content/uploads/1113-Getting-to-Zero.pdf

A critical part of making the best use of investments and maximizing impact is to focus attention and resources on persons living with HIV infection and those who are at greatest risk for acquisition. Figure 1 shows the populations that accounted for the largest share of HIV diagnoses in the United States in 2013, the most recent year for which data are available. 10 These populations represent persons at greatest risk for acquiring HIV.

FIGURE 1: Diagnoses of HIV infection among adults and adolescents, by race/ethnicity, transmission category, age, and region—United States and 6 dependent areas, 2013 (N= 48, 145) 10







Although they do not represent a large share of the overall number of persons living with HIV infection, the prevalence of HIV infection is high among transgender women. Some studies have found that as many as 30 percent of transgender individuals are living with HIV infection.²² Historically, efforts focused on this population have been limited, particularly those for transgender women of color. The Federal government has improved those efforts since 2010 but must remain vigilant in increasing knowledge and appropriate support and interventions for this population.

It is important to note the overlap of the above population groups. For example, many gay and bisexual men living with or at risk of acquiring HIV are also Black, and many Black women and men with HIV may also have substance use disorders. Another cross-cutting factor is age; there is a notable burden of HIV among youth aged 13-24 years, primarily among young gay and bisexual men.²³

Within these groups there are additional considerations for providing prevention services. Some men who have sex with men do not identify as "gay," "bisexual," or "same gender loving." Many adolescents and other young people experience periods of sexual fluidity, which can complicate targeting programs, resources, and services. Some subpopulations, such as members of the House and Ball Community, may be difficult to reach with traditional messaging and prevention efforts; however, this population still requires intentional, culturally responsive, and asset-based preventions efforts. Additionally, the differing biological, psychological, and cultural factors between women and men contribute to women's increased vulnerability to infection and affect their success at achieving viral suppression. Negotiating safer sexual practices can be especially challenging for women who may be vulnerable to IPV, or who may be economically dependent on men. Given the disparities in infection rates among Black women and Latinas when compared to White women, it is also important to consider the factors that place them at higher risk for infection.

Even when individuals in these groups do not engage in greater risk behaviors than others, they still can be more likely to become infected with HIV because of the high number of persons with HIV infection in their communities.²⁴ As a result, any instance of risk behavior carries a far greater likelihood of infection than other communities with fewer cases of HIV.

Another consideration is appropriately responding to HIV among groups that represent a small share of both the population and of HIV infections. Although it is vital to focus national efforts in communities with the highest burden, HIV prevention must continue to be supported in localities with concentrations of groups such as Asian Americans and Pacific Islanders and American Indian/Alaska Natives, and informed by the best available data.25, 26

Similarly, there is a requirement to remain vigilant in monitoring infections where trends show declines in HIV, such as among women as well as persons who inject drugs.¹⁰ During 2015, the State of Indiana had an outbreak of HIV infection, largely attributed to prescription drug injection.²⁷ Funding levels must be adequate to deliver the highest impact prevention strategies to maintain low levels of transmission and to detect and respond to outbreaks in these populations when they occur.

RECOMMENDED ACTIONS

To intensify HIV prevention efforts in communities where HIV is most heavily concentrated, the following actions are needed:

- 1.A.**1** Allocate public funding consistent with the geographic distribution of the epidemic.
- Governments at all levels should ensure that HIV prevention funding is allocated to grantees according to the latest epidemiological data so that funds reach areas with the highest burden of disease.
- 1.A.**2** Focus on high-risk populations.
- Federal agencies should ensure that funding to State and local health departments and community-based organizations is allocated according to the epidemiological profile within the jurisdiction and is directed to high-risk populations accordingly.
- 1.A.3 Maintain HIV prevention efforts in populations at risk but that have a low national burden of HIV.
- Federal, State, Tribal, and local agencies should make the best use of surveillance and other appropriate data, including the HIV care continuum, to characterize the burden of disease and apply high-impact prevention strategies for populations such as Asian Americans, Native Hawaiians and other Pacific Islanders, American Indians, and Alaska Natives.

POLICY AND ACTION

STEP 1.B

Expand efforts to prevent HIV infection using a combination of effective, evidence-based approaches.

The HIV epidemic has made clear that multiple, combination strategies are essential to stem the tide of new HIV infections. Simultaneously employing, scaling, and appropriately directing various scientifically proven methods will have a greater impact than any single strategy. Additional research can also help identify new prevention strategies and the most cost-effective approaches and combinations of approaches to prevent new HIV infections. Demonstration projects, such as those supported by SMAIF, are also critical for implementation of large-scale, multi-sectorial approaches to HIV prevention and care.28 It is imperative to offer and fund outcomes-driven capacity building, training, and technical assistance to help ensure the successful implementation of effective programs.

Care and treatment endeavors for people living with HIV are also critical to reducing new HIV infections. It is critical to ensure that all people living with HIV know their HIV status and are linked to and maintained in high-quality care that promotes adherence to antiretroviral therapy, consistent with current clinical practice standards.²⁹ It is estimated that more than 90 percent of new HIV infections in the United States could be averted by diagnosing people living with HIV and ensuring they receive prompt, ongoing care and treatment.³⁰ These actions will reduce risk for HIV transmission, as well as improve health outcomes for persons living with HIV. The benefits of early treatment, coupled with a high proportion of late-stage HIV diagnoses, lend additional urgency to the need for early diagnosis and treatment. 2, 10 In addition to treatment, all people who are diagnosed with HIV should receive assistance with notifying recent sex and drug-use partners of their need to get tested for HIV; have access to behavioral and biomedical interventions that have been shown to sustainably reduce the probability of transmitting HIV to others and reduce acquisition of other sexually transmitted diseases; and be screened for, and linked to, other medical and social services, that support individuals in reducing their transmission risk.31

In accordance with guidelines, HIV-negative people at high risk for HIV infection should be tested at least annually for HIV and STIs and screened for hepatitis B and hepatitis C virus infections, depression, and history of IPV.32-37 CDC recommends STI screening among MSM at risk every 3-6 months.33 They should also have access to scientifically proven, effective biomedical and behavioral interventions that reduce the probability of HIV acquisition. In addition, people at high risk for HIV infection should be screened for and receive other medical and social services that reduce the risk of acquiring HIV, such as substance use and mental health and IPV services, as well as housing, education, and employment assistance.

Abstaining from sexual activity and substance use eliminates the risk of HIV infection through sexual or injection routes of transmission. If and when people engage in sexual activity, other approaches can lower the risk of acquiring HIV. Figure 2 shows scientifically proven biomedical and behavioral approaches that reduce the probability of HIV acquisition and transmission:

HIV TESTING

There is evidence that **people who test HIV-positive take steps to keep others from being exposed to the virus**. ³⁸ People who are unaware of their HIV status miss out on the benefits from treatment, and they may unintentionally expose others to HIV. Newer HIV test technologies and diagnostic algorithms can improve ability to detect HIV infection sooner, including acute HIV infection. ³⁹

PrEP and PEP

PrEP uses the same medicines that keep the virus under control in people who are infected with HIV to prevent HIV acquisition in those who may be exposed. **Studies have shown greater than 90 percent effectiveness of PrEP to prevent HIV infection when it is taken regularly.** U.S. Public Health Service clinical practice guidelines were released in 2014 to assist clinicians in providing PrEP and associated services to their patients at substantial risk for HIV infection.⁴⁰ There are also specific HIV medications (PEP) that a person can take immediately after being exposed to HIV that can reduce the risk of HIV infection.⁴¹

PREVENTION WITH PEOPLE WITH HIV

There are effective approaches that support people living with HIV in avoiding transmitting HIV. **Guidelines** for prevention with persons with HIV recommend 11 strategies for reducing the likelihood of HIV transmission.³¹

HIV TREATMENT AS PREVENTION

In addition to benefiting their own health and longevity, people living with HIV who adhere to effective antiretroviral therapy and have suppressed viral load can **reduce the risk of sexual transmission of HIV by 96 percent**. Antiretroviral therapy for pregnant women with HIV also dramatically reduces the risk of transmission during pregnancy and childbirth.⁴²

CONDOM USE

Condom use is one of the most effective methods to reduce risk of HIV infection during sexual activity. Correct and consistent use of male condoms is estimated to **reduce the risk of HIV transmission by 70-80 percent**. 43, 44

ACCESS TO STERILE NEEDLES AND SYRINGES

Among persons who inject drugs, sharing needles and other drug paraphernalia increases the risk of HIV and other blood borne infections such as viral hepatitis infections. **Providing new, sterile syringes and other injection equipment to persons who inject drugs should be part of a comprehensive HIV prevention strategy**. Studies have shown that these programs substantially reduce risk of HIV infection, increase linkage to drug treatment, and **do not increase drug use**. 45

Behavioral interventions that have been proven highly effective in reducing HIV risk at the lowest cost should be prioritized, and delivered in conjunction with other effective strategies listed above. ⁴⁶ Behavioral interventions that particularly support engagement in care and adherence to treatment and that enable individuals to successfully adhere to PrEP or post-exposure prophylaxis (PEP) are essential components of the effective use of these biomedical interventions. ⁴⁷

Models of care are necessary to provide comprehensive screening and appropriate linkage to care for multiple factors associated with HIV—such as STIs, substance use, mental health, and IPV. For example, many new HIV infections are diagnosed in sexually transmitted disease (STD) clinics and about one in ten gay and bisexual men with syphilis or rectal gonorrhea acquire HIV within one year of their STI diagnosis.³² PrEP has also been offered through STD clinics in some jurisdictions. Care models within STD clinics that include routine screening, partner services, and provision of PrEP may be highly effective in preventing HIV, as well as preventing and treating STIs.

Funding models for prevention strategies must also be considered. One such model includes implementing sustainable HIV testing programs that involve billing insurance or Medicaid for testing in health department clinics and other health care settings (e.g., emergency departments, health centers). Integration of HIV testing into the daily practice flow in clinics and hospitals is necessary to implement sustainable testing practices that are not solely dependent on program resources. Another type of funding model is public-private partnerships, which are commonly used agreements for scaling up delivery of public services through collaboration with the private sector by leveraging resources from both. With agreements based on a set of shared objectives, these partnerships can enhance the governmental response to HIV prevention and care. An additional model is PrEP drug assistance programs, which operate similar to AIDS Drug Assistance Programs. The experiences with these models in New York State and Washington State may be applicable to other jurisdictions as they seek to increase access to PrEP programs.

Research priorities for PrEP include the development of sustained release agents and delivery systems such as injections or vaginal rings to mitigate problems with low levels of adherence to daily pill regimens and to enhance drug delivery to sites of transmission. Implementation research is needed to promote the uptake of effective program models so that PrEP can be incorporated into routine medical care and can improve the quality and effectiveness of health care for those at high risk for HIV infection. Research is also needed to identify structural interventions that are effective in reducing new infections, as well as addressing HIV-related stigma and disparities in rates of HIV infection.

Investments must be prioritized for maximum impact. Economic evaluations of HIV prevention strategies, including cost-effectiveness analyses of single and combination HIV prevention interventions, are needed to provide stakeholders with tools to set priorities and measure impact for high-risk populations. Resource allocation models are necessary to identify optimal prevention funding allocation among populations and programs to maximize the impact of HIV care and prevention at the national and local levels. 48 Cost effectiveness studies and research to develop and implement resource allocation models are needed to ensure that such tools are available to and relevant for state. Tribal and local levels.

Current approaches to preventing HIV must be coupled with research on new and innovative prevention methods that can have a long-term impact. Vaccines and microbicides are two promising biomedical approaches, but safe and effective vaccines and microbicides are not yet available and investments in research to produce effective vaccines as well as both vaginal and rectal microbicides must continue.

Another high priority is cure research, which is focused on developing strategies to eliminate viral reservoirs, or places in the body where HIV hides, to achieve lifelong remission of HIV infection. Research toward a cure is a high priority because of the continued risks for clinical complications with the use of antiretroviral therapy, the side effects of the drugs, and because the need for lifelong therapy is in itself a heavy burden on people living with HIV.

RECOMMENDED ACTIONS

To expand efforts to prevent HIV infection using a combination of effective, evidence-based approaches, the following actions are needed:

- 1.B.**1** Design and evaluate innovative prevention strategies and combination approaches for preventing HIV infection in high-risk populations and communities, and prioritize and promote research to fill gaps in HIV prevention science among the highest risk populations and communities.
- Government agencies should fund implementation research and demonstration projects to identify and scale prevention approaches that are cost-effective, have the greatest impact on reducing new infections, and maximize investment of HIV prevention funding.
- Continued support is critical for basic and applied research that provides foundations for prevention tools, programs, and services, including development of additional women-controlled prevention methods (e.g., pills, rings, gels, or injectables).
- 1.B.**2** Support and strengthen integrated and patient-centered HIV and related screening (STIs, substance use, mental health, IPV, viral hepatitis infections) and linkage to basic services (housing, education, employment).
- Health care providers should ensure that the services endorsed by the USPSTF at an A or B level are fully implemented for persons living with HIV and those at risk.
- Prevention and care programs should help people access and navigate complex insurance and medication assistance programs that help pay for these services.
- Federal agencies should consider additional efforts to support housing assistance and other services—such as transportation, childcare, and nutrition—that may enable people at risk for HIV to sustain risk reduction efforts, including adherence to PrEP.
- 1.B.3 Expand access to effective HIV prevention services, including PrEP and PEP.
- Federal funds should support—and State, Tribal, and local governments should encourage—bringing to scale and expanding access to effective HIV prevention services that optimize investments and have the greatest potential for impact for high-risk populations.
- Federal, and local agencies should increase awareness of PrEP and PEP among persons at risk for HIV infection, educate and train health care providers and identify mechanisms to ensure access to PrEP and PEP for persons who can benefit most, including use of prevention funds.
- In accordance with Federal, State, and local laws, communities should provide new, sterile syringes and other injection equipment for persons who inject drugs and ensure access to medication-assisted therapies for persons with opioid addiction.
- 1.B.4 Expand prevention with persons living with HIV.
- Health care providers should ensure rapid linkage to care at the time of HIV diagnosis, and ongoing services to support retention in care and access to interventions that address reductions in sexual and substance use risks.

POLICY AND ACTION

STEP 1.C

Educate all Americans with easily accessible, scientifically accurate information about HIV risks, prevention, and transmission.

The HIV epidemic has made clear that multiple, combination strategies are essential to stem the tide of new HIV infections. Simultaneously employing, scaling, and appropriately directing various scientifically proven methods will have a greater impact than any single strategy. Additional research can also help identify new prevention strategies and the most cost-effective approaches and combinations of approaches to prevent new HIV infections. Demonstration projects, such as those supported by the SMAIF, are also critical for implementation of large-scale, multi-sectorial approaches to HIV prevention and care.²⁸ It is imperative to offer and fund outcomesdriven capacity building, training, and technical assistance to help ensure the successful implementation of effective programs.

Achieving an end to the HIV epidemic requires widespread public support to sustain a long-term effort, which is predicated on all Americans having access to a common baseline of information about the current HIV epidemic. This includes knowing how HIV is transmitted and prevented. Today's era of HIV prevention is characterized by rapidly evolving science on the effectiveness of a range of prevention methods. People have more prevention options, and more accurate and easy-to-access digital tools, making more urgent the need for clear information to guide complex decisions.

HIV awareness and education should be universally integrated into all educational environments and health and wellness initiatives. All health and wellness practitioners (peer counselors, intake specialists, doctors, nurses, and other health professionals) must be educated about HIV, especially in programs for underserved communities, and equipped to deliver education that is culturally appropriate and inclusive of lesbian, gay, bisexual, and transgender (LGBT) people. The focus of the education and awareness effort is to improve individual understanding of HIV infection, HIV-related risk factors and risk reduction, and reduce HIV-related stigma and discrimination.

It is important to educate Americans on HIV transmission routes. A 2012 Kaiser Family Foundation survey found that one in three Americans believed that HIV could be transmitted through sharing a drinking glass, touching a toilet seat, or swimming in a pool with someone who is HIV-positive.9 Strikingly, the percentage of the American public that holds these misperceptions has not changed since 1987. Among gay and bisexual men, a 2014 Kaiser Family Foundation survey showed, many were unaware that the number of HIV infections is increasing in their community, and few were aware that PrEP exists or is an option for their HIV prevention practices.⁴⁹

Educating the public about HIV is not simply the job of governments or schools. Over the past three decades, communities have taken it upon themselves to educate people in their areas about how HIV is and is not transmitted, and how to successfully utilize prevention tools—using destigmatizing and culturally appropriate methods. Especially in places where it is not feasible for the Federal, State, Tribal, and local governments to act, it remains the role of community-based organizations, faith-based leaders, constituent organizations, national associations, trade associations, and peer networks to provide educational materials, trainings, and digital tools for their specific community's needs.

Broader HIV education is also needed across generations. One in five new HIV diagnoses in 2013 were among persons aged 13-24 years, and 10 percent of new HIV diagnoses in 2013 occurred in persons aged 55 years and older. 10 Sustained and reinforcing evidence-based education is needed to effectively encourage people across generations to take steps to reduce their risk for infection.

Educating young people about HIV before they begin engaging in behaviors that place them at risk for HIV infection should be a priority. Without question, it is the role of parents to instill values and to provide the moral and ethical foundation for their children. Parents should be equipped with information and skills to communicate effectively with their children about sexual health and substance use. Diversity in family structures—including foster families, adopted families, single-parent families, and other chosen families—also must be acknowledged to ensure access to these communication resources. Young people, no matter their circumstance, need spaces to access accurate information for their own health. In addition, schools play a fundamental role in providing current and accurate information about the biological and scientific aspects of health education. It is vital to create learning environments that are safe, inclusive, and destigmatizing, while providing access to a baseline of health information grounded in the benefits of abstinence and delaying or limiting sexual activity, and ensuring that young people who are sexually active have the information and tools they need to prevent infections.

I√I RECOMMENDED ACTIONS

To educate all Americans with easily accessible, scientifically accurate information about HIV risks, prevention, and transmission, the following actions are needed:

- 1.C.1 Provide clear, specific, consistent, and scientifically up-to-date messages about HIV risks and prevention strategies.
- Government, schools, faith leaders, national associations and communitybased organizations should make information about HIV risks and prevention strategies easily available to the public. The information should be used to develop and disseminate education campaigns, prevention programs, and risk assessment tools.
- 1.C.**2** Utilize evidence-based social marketing and education campaigns, and leverage digital tools and new technologies.
- Outreach and engagement through multiple media channels must be increased by both the public and private sectors to educate and engage the public about how HIV is transmitted and prevented.
- It is critical to utilize digital tools and new technologies, such as social media and popular mobile apps, to enable the American people to access high-quality HIV information anywhere, anytime, on any device.
- 1.C.3 Promote age-appropriate HIV and STI prevention education for all Americans.
- Agencies and schools should ensure that programs for youth are age- and developmentally-appropriate, and culturally competent, including those designed for LGBT youth.
- To impact policies at the local level, concerned community members should engage with the sexual education councils of their local school boards.
- 1.C.4 Expand public outreach, education, and prevention efforts on HIV and intersecting issues, such as IPV.
- Empowering youth with scientifically accurate information about their physical health and social and emotional well-being must continue to be part of a comprehensive approach by governments, faith-based institutions, schools and communities to prevention and responding to HIV and violence; reaching Black and Latina women and girls should be a priority.
- 1.C.**5** Tackle misperceptions, stigma, and discrimination to break down barriers to HIV prevention, testing, and care.
- Federal and state governments should ensure that Federal and state criminal laws reflect current scientific information regarding HIV transmission and prevention.
- Federal agencies should ensure application of anti-stigma civil rights messages in Federal documents and programs, and ensure messages about protections against discrimination and health information privacy rights are incorporated into their educational campaigns.

GOAL 2: INCREASING ACCESS TO CARE AND IMPROVING HEALTH OUTCOMES FOR PEOPLE LIVING WITH HIV

THE OPPORTUNITY

The only way that health outcomes for people living with HIV will improve is to squarely focus on treatment and care. This requires continued focus on the HIV continuum of care, ensuring capacity of the health care workforce and systems, and supporting comprehensive coordinated care for people living with HIV. The Nation has seen great progress in this area, in large part due to scientific advances and scaling up delivery of services.

Activities that have contributed to success in HIV care and treatment include:

- Availability of highly effective antiretroviral therapies that have dramatically reduced the death rate among people living with HIV infection;
- Ongoing bipartisan support for the Ryan White HIV/AIDS Program (RWHAP), which works with cities, states, and local community-based organizations to provide a comprehensive system of care, takes a public health approach to provide medical care and essential support services to people living with HIV who do not have sufficient health care coverage or financial resources to cope with HIV disease, and provides care completion coverage to more than 500,000 people living with HIV;
- Ongoing bipartisan support for the Housing Opportunities for Persons With AIDS (HOPWA) program, through which the Department of Housing and Urban Development (HUD) makes grants to local communities, States, and nonprofit organizations for projects that provide supportive housing to benefit low-income persons living with HIV/AIDS and their families; and
- Enactment of the Affordable Care Act, which put into place reforms to improve affordable health coverage and protect consumers from abusive insurance company practices

Since the National HIV/AIDS Strategy was released, there have been significant scientific advances and major policy shifts. Milestones during this period include:

- Strong **scientific evidence of the benefits** of early treatment from the START study, which showed that starting antiretroviral treatment early significantly reduces the risk that people living with HIV will develop AIDS or other serious illnesses, and from HPTN 052, which showed that antiretroviral treatment reduces the risk of transmitting HIV to uninfected partners. This research supports changes in treatment guidelines that recommend initiating antiretroviral therapy for all people diagnosed with HIV infection. 1, 2
- Enhanced focus on the HIV care continuum to monitor progress in HIV prevention, care, and treatment and the related Executive Order establishing the HIV Care Continuum Initiative that focuses Federal resources on diagnosis, linkage to care, retention, adherence, and viral suppression.^{50, 51}
- Broad implementation of the Affordable Care Act, resulting in increased health care coverage, inability to be denied coverage for pre-existing conditions, and preventive care coverage that includes HIV testing.

To continue this progress and achieve the goal of increasing access to care and improving health outcomes for people living with HIV, the following challenges must be addressed:

- Nationally, too few people living with HIV are retained in care or have achieved viral suppression, particularly youth.⁸
- Although thousands of people living with HIV have benefited from the reforms of the Affordable Care Act,
 the cost sharing (e.g. co-pays, deductibles) in some plans renders care out of reach for many.
- Changes in the HIV workforce and ways that HIV care is delivered increase the need for re-thinking
 practice models and provision of training and education, including cultural competency to better serve
 clients based on their race/ethnicity, gender and gender identity, sexual orientation, or socio-economic
 backgrounds.
- Researchers have documented multiple barriers to engagement in care for women living with HIV, including that about 30 percent of women with HIV currently live with post-traumatic stress disorder.^{52, 53}
- Many people living with HIV have other co-occurring conditions including substance use and mental health disorders, homelessness, other infectious diseases such as STIs or viral hepatitis, and chronic conditions making engagement in HIV care and adherence to treatment more challenging.
- Physical barriers to care, such as access to transportation, still prohibit many from accessing medical and other services, particularly in rural areas.

The Affordable Care Act has strengthened the health care system and extended health care coverage to more than 16 million Americans, including thousands of people living with HIV. An analysis of the impact of the Affordable Care Act on persons living with HIV estimated that of 70,000 persons with HIV who were uninsured in 2009, approximately 47,000 would be newly eligible for Medicaid if all States chose to expand their Medicaid programs and almost 23,000 would qualify for subsidized private coverage in the Health Insurance Marketplace. Indeed, early evaluations suggest that the Affordable Care Act's health insurance expansions, through Medicaid and the Marketplace, are already playing an important role in the lives of many people living with HIV who report gaining new coverage and access to needed services. 55

Even with the Affordable Care Act's reforms, however, the RWHAP remains critical to support a comprehensive system of care, taking a public health approach to improve health outcomes. The RWHAP continues to be a critical source of care and treatment for people living with HIV who remain ineligible for health care coverage. Those who have coverage, but experience gaps or other barriers rely on the RWHAP for premium and cost-

total health care needs; the lifetime cost of treating a person with HIV infection is estimated to be \$250,000 to

The AIDS Drug Assistance Program is another critical component of the RWHAP to support those in need of financial assistance for medications. Finally, the RWHAP is vital for accessing needed HIV services not covered by insurance. The RWHAP touches the lives of about half of all people living with HIV in the United States, supporting the health care system to achieve higher rates of sustained HIV viral suppression. Doing so not only improves the health outcomes for individuals with HIV, it serves the public health benefit of helping to prevent HIV transmission.

People living with HIV may also have other significant challenges. Many people living with HIV have co-occurring conditions, such as heart disease, depression or other mental health problems, or substance use disorders, as well as other STIs and viral hepatitis infections. In addition, poverty, unemployment, intimate partner violence, unstable housing including homelessness, hunger, lack of access to transportation, and other issues can prevent people from accessing health care. There are also differences in health care access and treatment outcomes by race/ethnicity, gender, age, and geography. Continued research is critical to develop safer, less expensive, and more effective treatments and drug regimens, as well as to evaluate new ways to meet HIV treatment needs while also responding to co-occurring conditions or other barriers to care.

Addressing these overlapping issues, requires expansion of approaches to connecting people to services and keeping them in care, which facilitates their achievement of greater holistic health. The development of new models of care—especially those that integrate HIV prevention, care, and supportive services—is needed.

SUMMARY OF STEPS

It is vital to pursue a concerted national effort to engage people living with HIV in care. The following steps are critical to achieving success:

STEP 2.A

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Establish seamless systems to link people to care immediately after diagnosis and support retention in care to achieve viral suppression that can maximize the benefits of early treatment and reduce transmission risk.

STEP 2.B

Take deliberate steps to increase the capacity of systems as well as the number and diversity of available providers of clinical care and related services for people living with HIV.

STEP 2.C

Support comprehensive, coordinated patient-centered care for people living with HIV, including addressing HIV-related co-occurring conditions and challenges meeting basic needs, such as housing.

INDICATORS OF PROGRESS

Working together on these critical steps, we aim to meet the following targets by 2020:

| P | INDICATOR 4 | Increase the percentage of newly diagnosed persons linked to HIV medical care within one month of their HIV diagnosis to at least 85 percent . |
|----|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| ** | INDICATOR 5 | Increase the percentage of persons with diagnosed HIV infection who are retained in HIV medical care to at least 90 percent . |
| | INDICATOR 6 | Increase the percentage of persons with diagnosed HIV infection who are virally suppressed to at least 80 percent . |
| | INDICATOR 7 | Reduce the percentage of persons in HIV medical care who are homeless to no more than 5 percent . |
| • | INDICATOR 8 | Reduce the death rate among persons with diagnosed HIV infection by at least 33 percent . |

POLICY AND ACTION



Establish seamless systems to link people to care immediately after diagnosis and support retention in care to achieve viral suppression that can maximize the benefits of early treatment and reduce transmission risk.

Achieving optimal health outcomes requires that people are identified soon after their HIV infection and systems are in place to link them to care immediately. This is particularly important given that an estimated 156,300 people do not know they are living with HIV, and, therefore, are not receiving regular medical care to manage the disease. Current HIV treatment guidelines note that HIV medications benefit all persons diagnosed with HIV, which underscores the benefits of early detection.²⁹ New HIV testing technologies and laboratory diagnostic algorithms allow for earlier detection of HIV, including diagnosis of acute HIV infection, and may help improve health outcomes and reduce transmission.³⁹

The USPSTF recommends that clinicians screen for HIV infection in all adolescents and adults aged 15 to 65 years, and offer repeat testing to those at increased risk.³² People who receive a diagnosis of HIV infection need to be connected to appropriate clinical care, prevention services, and supportive services. It is essential to provide linkage coordination when and where HIV screening services are provided to help overcome barriers to obtaining care as soon as possible after diagnosis. Given the benefits of early treatment, some clinics have adopted programs that link persons to care the same day or within a few days; these programs can be particularly effective when implemented for persons diagnosed with acute infection.⁵⁹

Integrating HIV treatment services with other services that are accessed by people living with HIV can improve diagnosis and treatment for co-occurring conditions such as STIs, viral hepatitis, and substance use

or mental health disorders. 60 For example, SAMHSA has supported integration through co-location of HIV prevention and care services with substance abuse treatment programs and community mental health programs.⁶¹ Integration of services is an important element of a strategy to better meet the HIV prevention and care needs of people living in rural or under-resourced areas. It also enables providers to take a more holistic approach to health, rather than focusing only on HIV. Some of the same behaviors that prevent HIV infection also will prevent STIs and viral hepatitis infections.

It should be noted that being linked to care is not enough: those in care must be supported to stay in care over time. Many of the approaches for linkage to care can be continued to support retention in care. Helping persons to enroll in and navigate health care coverage or medical assistance programs that provide HIV care or cover costs of care and treatment may be needed to support retention in care.

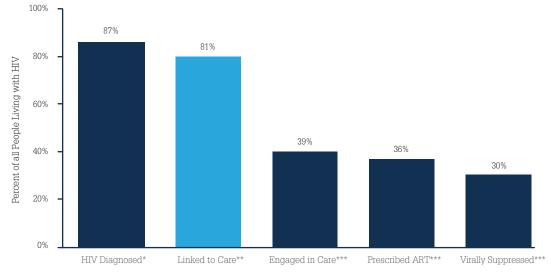
Equally important is the need to re-engage people diagnosed with HIV who have subsequently fallen out of care. In 2012, only 39 percent of all persons living with HIV infection were engaged in care.8 "Data to care" strategies may be applied to identify and re-engage persons in care, and have shown to be effective in improving care continuum outcomes.⁷³ Clinical decision support tools may also be helpful to identify persons out of care. Retention in care is critical for achieving and sustaining viral suppression.

Figure 3 displays the HIV care continuum for 2012. This continuum gives a national snapshot of all people living with HIV infection, meaning those who have been diagnosed and those who have not yet been diagnosed.

DRUG TREATMENT AS PREVENTION

Research has provided evidence that treatment for substance use disorders is an effective HIV prevention intervention. For example, patients receiving methadone for their opiate use disorders were found to significantly reduce the frequency of their opiate use. 62-65 Data suggests that with decreases in opiate use reductions in opiate injection and needle sharing events are also observed. 66-69 Other drugs effective in the treatment of opioid related substance use disorders have also been found to reduce HIVrisk factors. 70 For Buprenorphine, reductions in HIV-risk behaviors were observed. Naltrexone has also shown to reduce significant opiate (heroin) use and HIV-risk behaviors.71 Moreover, medication assisted treatment for opioid use disorders substantially increases the odds of adherence to HIV Highly Active Antiretroviral Therapy (HAART).72

FIGURE 3: The HIV care continuum among persons living with HIV infection in the United States 20128



Diagnosed is a calculated estimate based on data reported to the National HIV Surveillance System, the denominator is the estimated number of persons living with HIV (1.2 million).

Linkage to care is the percentage of persons linked to medical care within 3 months after diagnosis (numerator) among those newly diagnosed in 2012 (denominator). Data are from 28 jurisdictions with complete reporting of CD4 and viral load test results to CDC

^{***} Engaged in care, prescribed ART and virally suppressed data (numerators) come from the Medical Monitoring Project and based on people who had at least one HIV care visit during January to April 2012. The dominator is the estimated number of persons living with HIV (1.2 million)

The particular needs of those in the criminal justice system are challenging for maintaining ongoing HIV care.74 Those who are incarcerated may encounter difficulty accessing HIV medications, especially those in jails or short-term detention. Strong linkages to new health homes and supportive services are needed as part of reentry programs for persons with HIV who are being released from correctional facilities, including enrollment for disability or Medicaid prior to release and referral to substance use and mental health services and medical care. During incarceration, many correctional facilities do not provide medication-assisted treatment for people with opioid dependence, leaving them vulnerable to both overdose and relapse upon re-entry to the community. Facilitating initial appointments post-release and comprehensive case management help ensure better health outcomes related to HIV infection and treatment for substance use disorders.

In addition, people living with HIV need ongoing support to maintain the necessary high levels of adherence to antiretroviral treatment to achieve and maintain viral suppression. Implementation research, to learn how to scale up effective programs and incorporate them into clinical practice, is needed for adherence interventions. Government, academic, and pharmaceutical industry research has provided simpler, more easily tolerated therapies than the initial generation of effective antiretroviral therapies. However: safer, more potent, and more durable treatments are still needed, as is a better understanding of how to manage the clinical complications and consequences of HIV infection and long-term use of antiretroviral drugs.

RECOMMENDED ACTIONS

To establish seamless systems to link people to care immediately after diagnosis, and support retention in care to achieve viral suppression that can maximize the benefits of early treatment and reduce transmission risk, the following actions are needed:

- 2.A.**1** Ensure continuity of high-quality comprehensive health care coverage to support access to HIV care.
- Federal and state governments should ensure access to appropriate HIV treatment by promoting unimpeded coverage of all HIV medications included in the HHS HIV Treatment Guidelines.
- Health care coverage programs should maximize HIV prevention by including the use of antiretrovirals for PrEP.
- People living with HIV should be supported to select the health care coverage that best meets their care and treatment needs.
- 2.A.**2** Ensure linkage to HIV medical care and improve retention in care for people living with HIV.
- HIV resources and efforts from the public and private sectors should be directed to bring to scale evidence-based strategies that ensure immediate linkage to and retention in HIV care.
- Clinical care providers should ensure that all persons with HIV have access to antiretroviral therapy and are retained in care as recommended by the HHS HIV Treatment Guidelines.

- 2. A.**3** Support and strengthen capacity to implement innovative and culturally appropriate models to more effectively deliver care along the care continuum.
- Federal agencies should support the development of new models that effectively diagnose and care for people living with HIV, and support innovation and rigorous evaluation of new delivery models that are responsive to the changing healthcare environment.
- These models should provide culturally and developmentally appropriate services for populations such as gay and bisexual men, youth, older people living with HIV, racial and ethnic minorities, and transgender people.
- Care specific to the needs of women should be offered in HIV primary care service-delivery settings to ensure their retention in HIV care and treatment. Federal agencies should encourage the development and implementation of emerging digital tools and technologies to improve outcomes at all points along the continuum of care.
- 2.A.**4** Prioritize and promote research to fill gaps in knowledge along the care continuum.
- Federal agencies need to develop and test new approaches that are scalable, sustainable, and engage populations at greatest risk of HIV.
- Federal agencies should support new basic scientific research to develop more robust HIV prevention and treatment regimens that are effective and decrease the current burden of adherence.
- 2.A.**5** Provide information, resources, and technical assistance to strengthen the delivery of services along the care continuum, particularly at the State, Tribal, and local levels.
- Federal agencies should extend assistance to state and local partners to help support, scale up, and integrate care continuum improvement efforts that drive change at an accelerated pace.
- The Federal government should support ongoing development and reporting of core HIV quality measures.

POLICY AND ACTION

STEP 2.B

Take deliberate steps to increase the capacity of systems as well as the number and diversity of available providers of clinical care and related services for people living with HIV.

Meaningful improvement in health outcomes requires adoption of policies that will produce a diverse workforce large enough to care for all people living with and at risk for HIV and that has the appropriate training and technical expertise to provide high-quality care consistent with the latest prevention and treatment guidelines. Also needed are health care systems and public health systems that have the capacity to provide care in a non-stigmatizing manner and create relationships of trust with their patients. Efforts to strengthen systems capacity and expand the HIV workforce should focus on the geographic areas where the need is greatest. The Affordable Care Act provides policies and resources to address these issues. In addition, the scope and mission of the AIDS Education and Training Centers, part of the RWHAP, and CDC's HIV Prevention Capacity Building Assistance Centers focus on improving outcomes along the care continuum. 75, 76

For too long, the Nation has suffered from a shortage of primary care health professionals. In addition, the provider workforce of physicians, nurses, and other health professionals who specialize in HIV care is aging, and new recruits are needed to address the impending workforce shortage. The Affordable Care Act, with its investments in the National Health Service Corps, is helping to alleviate primary care workforce shortages in underserved areas. Increased funding to HRSA's Health Center Program also expands the opportunities for

integrating HIV testing, prevention, care, and treatment services into primary care. To be effective, however, these primary care providers need to be experienced HIV providers or have an established source for clinical consultation or referral to assist in managing patients with complex cases.⁷⁷ Training, task shifting, and use of interdisciplinary health teams all can assist in addressing HIV workforce shortages. Many organizations have demonstrated successful models for including peer navigators—who are themselves living with HIV—in clinical and community settings to support engagement in care.78 Regardless of the specific approach, it is critical that the HIV care model meshes seamlessly with the necessary workflow.

Access to substance use treatment for people who inject drugs is also affected by workforce capacity. Many people who inject prescription drugs reside in rural communities without access to evidence-based substance use disorder treatment providers who can provide medication assisted treatment for opioid use disorder.⁷⁹

Health care services that are respectful of and responsive to the health beliefs, practices, and cultural and linguistic needs of diverse patients can also help bring about positive health outcomes. 80 Responsive services will also recognize and support variable and episodic needs across the lifespan for people living with, or at risk for, HIV infection, recognizing that key populations, including heterosexual women, transgender women, youth, older people living with HIV, gay men, and others may have unique or specialized needs that require more tailored approaches. Many people living with HIV come from communities that have historically been poorly served by mainstream health care systems. For example, among some African Americans, there is mistrust of the medical establishment, and it may lead some to question clinical recommendations that are widely accepted by others.⁸¹ Medical providers may not be comfortable taking a sexual history from LGBT patients, which could interfere with appropriate care. Similarly, gay men report being uncomfortable talking with their doctors about their sexual behaviors.82,49

Health care systems are particularly challenged to provide competent care to transgender individuals. There is a dearth of health care staff equipped to provide care with respect for the unique circumstances of their transgender patients. This can result in lower satisfaction with their care providers, less trust, and poorer health outcomes.83

In addition to having HIV expertise, care providers should be culturally competent and able to clearly and effectively communicate to help their patients understand the benefits of following recommended treatment plans. Building pipeline programs into the health care professions for people of color and those in poverty can improve culturally competent care as well as help achieve health equity.

RECOMMENDED ACTIONS

To take deliberate steps to increase the capacity of systems as well as the number and diversity of available providers of clinical care and related services for people living with HIV, the following actions are needed:

- 2.B.**1** Increase the number of available providers of HIV care.
- Federal, State, Tribal, and local agencies should develop strategies for encouraging more clinicians to provide HIV services.
- Federally-supported programs should encourage health care delivery strategies that extend the capacity of the existing workforce of HIV specialists.

Strengthen the current provider workforce to ensure access to and quality of care.

- Federal agencies should engage clinical providers and professional medical societies on the importance of routine HIV screening.
- Federal agencies and health care delivery systems should support the integration of high-quality HIV services into health centers and other primary care settings by providing routine HIV screening, basic HIV care and treatment, referrals for more complex HIV care and treatment, and coordination of care across settings and providers.
- 2.B.3 Support screening for and referral to substance use and mental health services for people living with HIV.
- HIV medical care providers and agencies offering substance use and mental health services should increase collaboration to ensure identification of and treatment for these conditions among persons living with HIV, including increased use of brief screening tools, delivery of medication-assisted treatment, and parity in coverage for mental health and substance use treatment services.

POLICY AND ACTION

STEP 2.C

Support comprehensive, coordinated patient-centered care for people living with HIV, including addressing HIV-related co-occurring conditions and challenges meeting basic needs, such as housing.

To support the provision of quality care for people living with HIV, it is important to reduce barriers that impede access to services. The RWHAP has supported the development of medical homes for people living with HIV for 25 years. This program has valuable experiences to share with other providers, including health centers and private physicians.

Patient-centered care—defined by the Institute of Medicine as health care that establishes a partnership among practitioners, patients, and their families (when appropriate) to ensure that decisions respect patients' wants, needs, and preferences—should be the standard. In addition to ensuring that clinical care services are well-coordinated, non-medical services and assistance to meet basic needs are important supports for achieving optimal clinical outcomes. Access to medical treatment should be supplemented with ongoing case management services to facilitate continuity of care. Basic needs such as housing, education, and employment, and supportive services such as transportation, legal assistance, nutrition services, and child-care are essential for certain populations that face difficulties with everyday needs.

Access to housing is an important precursor to getting many people into a stable treatment regimen. Individuals living with HIV who lack stable housing are more likely to delay HIV care, have poorer access to regular care, are less likely to receive optimal antiretroviral therapy, and are less likely to adhere to therapy. A 2014 HUD white paper, HIV Care Continuum: The Connection between Housing and Improved Outcomes along the HIV Care Continuum, reviewed the evidence for the associations between housing and outcomes along each step of the care continuum that can result in reducing both new HIV infections and homelessness. Additionally, to specifically address distinct needs of vulnerable populations, the DOJ and HUD are collaborating on a project to expressly support transitional housing for low-income persons living with HIV who have experienced domestic violence, dating violence, sexual assault, or stalking.

People have competing demands, including challenges meeting their basic needs for housing, food, and childcare, which often contribute to poorer HIV outcomes. Access to legal services can be important to help

people resolve issues with discrimination, access to public benefits (including health care coverage), and employment and other issues that can create serious barriers to staying in care. Support from social workers or case managers can help with identifying resources. Peer networks among people living with HIV can also be valuable for information sharing and other support. Programs that provide family-centered care can be especially important for women living with HIV. Further, both women and men with HIV can be at risk for intimate partner violence and post-traumatic stress disorder, which can impede adherence and stability in care. The principles of a trauma-informed approach to care, which seek to minimize the chances of re-traumatizing someone who is trying to heal, may be applicable in HIV care settings. 52, 53

In developing ways to improve delivery of care for people with basic needs and with other circumstances affecting care, including people in or transitioning from correctional settings, people living in remote or rural areas, and youth, it will be important to disseminate effective models to enable other providers to better serve those groups and overcome common barriers to care.

RECOMMENDED ACTIONS

To support comprehensive, coordinated, patient-centered care for people living with HIV, including addressing HIV-related co-occurring conditions and challenges meeting basic needs such as housing, the following actions are needed:

- 2.C.1 Address policies to promote access to housing and other basic needs and other supportive services for people living with HIV.
- Federal agencies should consider additional efforts to support housing assistance and other services—such as transportation, childcare, and nutrition—that enable people living with HIV to obtain and adhere to HIV treatment.
- Programs and health care settings should support case management for clinical and non-medical services that contribute to improving health outcomes for people living with HIV, including rehabilitative employment services.
- Federal efforts should be enhanced to address HIV and IPV among homeless and marginally housed women and girls.
- Partnerships between housing programs and other service organizations that provide their clients with HIV testing and linkage to care should be supported at all levels. Housing services and clinical care should be aligned to achieve improved health outcomes.
- 2.C.2 Improve outcomes for women in HIV care by addressing violence and trauma and factors that increase risk of violence for women and girls living with HIV.
- Federal agencies should support research on, and evaluation of, programs that provide trauma-informed care as part of HIV care for women.
- Trauma and violence experienced by young gay and bisexual men and transgender women also should be addressed by research studies and programmatic activities.

GOAL 3: REDUCING HIV-RELATED DISPARITIES AND HEALTH INEQUITIES

THE OPPORTUNITY

Reducing HIV-related health disparities and inequities must be a central priority of the overall Strategy. The Affordable Care Act offers that a group is a health disparity population when "there is a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in the population as compared to the health status of the general population." To address disparities requires focusing on disproportionately affected communities and populations; implementing structural approaches to HIV prevention and care that address conditions such as housing, education, employment, and food security; and reducing stigma and eliminating discrimination associated with HIV infection.

Milestones during the last several years include:

- Implementation of the Affordable Care Act, the broadest Federal effort, to date, to address health inequities, which includes various non-discrimination statutes for treatment and care coverage.
- Changes in state laws to decriminalize behavior like spitting and biting by people living with HIV that are known to pose minimal risk for HIV transmission.
- Enactment of policies that reduce HIV stigma and discrimination, such as lifting of the entry ban to allow people living with HIV the ability to travel to the United States and immigrate without needing a waiver.85
- Elimination of health disparities in some health care settings demonstrates that reducing disparities is achievable.86

Despite many advances—scientific, political, and social—over the last five years, large disparities remain. To achieve the goal of reducing HIV-related disparities and health inequities, the following challenges must be addressed:

- A national response to the HIV epidemic must be mindful of the size and diversity of the country, as well as the needs of the most affected communities.
- Health care systems and social structures that provide varying access to HIV services to different groups who then may achieve varying health outcomes.
- New HIV diagnoses are increasing among gay and bisexual men. Black women account for 64 percent of new diagnoses among women. Differences in diagnosis rates vary considerably by region.¹⁰

 People around the country report that stigma and discrimination, associated with HIV status or receiving HIV-related services, are still rampant, and continue to adversely impact access to care and health outcomes.

SUMMARY OF STEPS

A concerted national effort to increase the capacity of all communities to prevent HIV and support community members living with HIV is needed. The following steps are critical to achieve success:

STEP 3.A Reduce HIV-related disparities in communities at high risk for HIV infection.

STEP 3.B Adopt structural approaches to reduce HIV infections and improve health outcomes in high-risk communities.

STEP 3.C Reduce stigma and eliminate discrimination associated with HIV status.

INDICATORS OF PROGRESS

Working together on these critical steps, we aim to meet the following targets by 2020:

| iii | INDICATOR 9 | Reduce disparities in the rate of new diagnoses by at least 15 percent in the following groups: gay and bisexual men, young Black gay and bisexual men, Black females, and persons living in the Southern United States. |
|-----|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | INDICATOR 10 | Increase the percentage of youth and persons who inject drugs with diagnosed HIV infection who are virally suppressed to at least 80 percent . |

POLICY AND ACTION

STEP 3.A

Reduce HIV-related disparities in communities at high risk for HIV infection.

Significant racial disparities in HIV infection exist in the United States (see Figure 4). There are also racial/ethnic disparities along the care continuum and in premature death. According to the most recent HIV care continuum data, Blacks had lower percentages than Whites of HIV diagnosis and successful viral suppression. Disparities along the HIV care continuum and in rates of death might reflect differences in access to and use of health care and treatment. Efforts to address underlying social determinants of health, such as increased access to health care and supportive services, could increase timely HIV diagnosis, retention in care, treatment, and viral suppression. Increasing the number of people living with HIV in heavily affected communities who achieve and maintain viral suppression may reduce disparities in HIV infection rates and mortality in these groups.

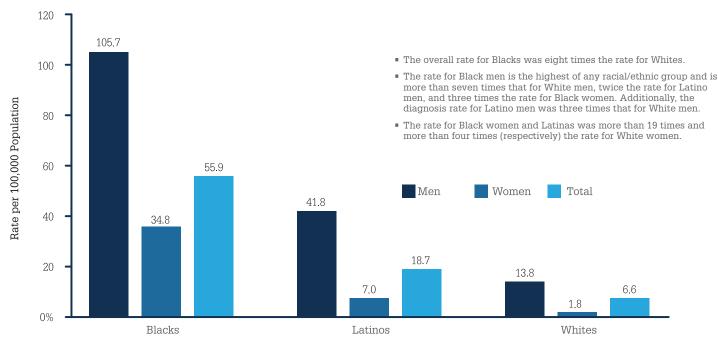


FIGURE 4: Rates of diagnoses of HIV Infection among adults and adolescents by race/ethnicity, 2013 — United States¹⁰

Even though deaths among persons with HIV have been declining since the availability of effective antiretroviral medications, the death rate per 1,000 persons living with HIV in 2012 among Blacks (20.5) was higher than the rate for Whites (18.1) and the rate for Latinos (13.9).87 Racial disparities in death rates among gay men with HIV also exist, with higher death rates among Black and Latino gay men compared to White men.88 Death rates also vary by state, with many of the highest rates concentrated in the Southern U.S.87

RECOMMENDED ACTIONS

To reduce HIV-related disparities in communities at high risk for HIV infection, the following actions are needed:

3.A.1 Expand services to reduce HIV-related disparities experienced by gay and bisexual men (especially young Black gay and bisexual men), Black women, and persons living in the Southern United States.

- Communities must be supported by the public and private sectors to ensure that groups at highest risk receive HIV testing, and that those diagnosed with HIV are linked to and retained in care to achieve viral suppression, and that those testing negative are linked to ongoing prevention services, such as PrEP.
- The Federal government should develop and support initiatives, including demonstration projects funded by the HHS SMAIF, designed to foster and facilitate collaborative linkages between researchers, service providers, and Black women and girls at-risk for or living with HIV to address critical social determinants of health such as poverty, violence, mental health and substance use issues which make women vulnerable to HIV and adversely impact the survival rates of women living with HIV. These factors also contribute to disparities seen among gay and bisexual men and persons living in the Southern United States.

3.A.2 Support engagement in care for groups with low levels of viral suppression, including youth and persons who inject drugs.

- Communities should engage all sectors to ensure consumers and providers are aware of opportunities and structures available in health care delivery and financing to address HIV risk and improve health outcomes.
- The Federal government should support implementation research as critical to improving health outcomes by adopting effective models of care and ensuring those models are culturally appropriate to reach groups at highest risk.

POLICY AND ACTION

STEP 3.B

Adopt structural approaches to reduce HIV infections and improve health outcomes in high-risk communities.

To reduce disparities among groups, effective approaches are required to reduce the risk of HIV transmission not only at the individual level, but also at the community and societal levels as well. HIV is often only one of many conditions that adversely affects communities at greater risk for HIV infection. In many cases, it is not possible to effectively address HIV transmission or care without also addressing structural factors and social determinants of health, such as poverty, lack of education, unemployment, homelessness and other issues. 89, 90 Because of these many co-occurring issues, it is important to employ a biopsychosocial approach to HIV prevention and care that extends beyond an individual's risk behaviors. Factors such as HIV and STI rates in sexual and drug use networks, and joblessness or homelessness that can increase risk for infection or suboptimal access to care must be addressed. Although there have been some successful efforts in this regard, there are too few proven models associated with reducing HIV incidence or increasing access to care that have a focus on broader social determinants and structural factors that influence health outcomes.

Comprehensive sexual education for school-aged youth, an important example of a structural intervention, has not been brought to scale across the country, with only some jurisdictions providing fundamental and essential health and risk-behavior education to their students. To improve outcomes for youth along the HIV care continuum, young people must understand the benefits of early diagnosis as well as staying engaged in care and adhering to treatment.

RECOMMENDED ACTIONS

To adopt structural approaches to reduce HIV infections and improve health outcomes in high-risk communities, the following actions are needed:

- 3.B.1 Scale up effective, evidence-based programs that address social determinants of health.
- Federal agencies should support research and implementation of structural interventions that reduce the risk of infection in high-prevalence communities. Such programs must address the broader context of people's lives that increases their risk for HIV infection and puts those living with HIV at risk for poor health outcomes, with a particular need among young, Black gay and bisexual men.
- 3.B.**2** Support research to better understand the scope of the intersection of HIV and violence against women and girls, and develop effective interventions.
- To effectively address this intersection, it is imperative that governments support efforts to better quantify the degree to which violence is independently contributing to new HIV infections and poor care outcomes among women and girls.

POLICY AND ACTION

STEP 3.C

Reduce stigma and eliminate discrimination associated with HIV status.

Stigma is an attitude of disapproval and discontent towards an individual or group from other individuals or community and public institutions because of the presence of an attribute perceived as undesirable. Stigma can factor into individual interactions and affect larger societal and institutional forces. Discrimination can be a consequence of stigma and may occur when unfair actions are made against individuals on the basis of their belonging to a particular stigmatized group. HIV-related stigma can be confounded with or made more complicated by stigma related to substance use, mental health, sexual orientation, gender identity, race/ethnicity, or sex work. Stigma can lead to many negative consequences for people living with HIV. It is imperative that all levels of government recognize these various biases exist and work to combat stigma and discrimination in order to reduce new infections and improve health outcomes for people living with HIV.

More than 30 years after the first cases of AIDS were identified, people living with HIV still face discrimination in many areas of life including employment, housing, provision of health care services, and public accommodations. This discrimination undermines efforts to encourage all people to learn their HIV status, and makes it harder for people to disclose their HIV status to their medical providers, their sex and needle-sharing partners, and even clergy and others whom they may turn to for understanding and support.

Many people feel shame and embarrassment when they are diagnosed with HIV infection. And, there is still too much social stigma assigning blame to people who acquire HIV, and even for those who are actively seeking to prevent themselves from becoming infected. Creating safe spaces where all individuals feel accepted and respected will enable more individuals to get tested for HIV, enter and stay in care when diagnosed, adhere to medication regimens, and adopt prevention measures, including disclosing their HIV status. Reducing stigma for other conditions common among persons at risk for or living with HIV—such as substance use, mental health problems, and homelessness—and addressing homophobia are also important efforts to improve health outcomes. However, promotion of disclosure of HIV status must be accompanied by protections for people living with HIV. This calls for a continued commitment to civil rights enforcement.

The Americans with Disabilities Act (ADA), whose twenty-fifth anniversary occurred in 2015, is the landmark civil rights law that has proven so vital to the protection of people with disabilities, including HIV. To be free of discrimination on the basis of HIV status is both a human and a civil right. Proactive enforcement of the ADA, the Fair Housing Act, the Rehabilitation Act of 1973, and other civil rights laws is vital to establishing an environment where people will feel safe to get tested and seek treatment. People are encouraged to file an ADA complaint if they experience disability discrimination, including any complaint alleging violations against people living with HIV, against a State, Tribal, or local government or a place of public accommodation. When people do seek coverage and treatment, provisions of the Affordable Care Act also guard against discrimination based on pre-existing conditions and promote parity in mental health and substance use treatment.

Laws and policies across the Nation should reflect current public health best practices for preventing and treating HIV. State laws that criminalize behaviors like spitting and biting that are known to pose minimal

RECOMMENDED ACTIONS

To reduce stigma and eliminate discrimination associated with HIV status, the following actions are needed:

3.C.1 Promote evidence-based public health approaches to HIV prevention and care.

- State legislatures should review HIV-specific criminal statutes to ensure that they are consistent with current scientific knowledge of HIV transmission and support public health approaches to preventing and treating HIV.
- Federal agencies, local health departments, and community-based efforts should be coordinated and strengthened to dismantle discrimination in clinical settings.
- Broad-based efforts to reduce stigma of common co-occurring conditions for people at risk for and living with HIV, such as substance use and mental health disorders, viral hepatitis, and sexually transmitted infections, should be enhanced.
- 3.C.2 Strengthen enforcement of civil rights laws, and assist States in protecting people living with HIV from violence, retaliation, and discrimination associated with HIV status.
- DOJ and other Federal agencies must prioritize enforcement of Federal antidiscrimination laws that protect people based on HIV status, and should proactively outreach to localities around the country where discrimination, blatant or subtle, may exist against people living with HIV.
- Federal and State governments must also protect against discrimination in drug pricing and insurance coverage for persons living with HIV.
- 3.C.3 Mobilize communities to reduce HIV-related stigma.
- Governments at all levels must support efforts to increase community mobilization, especially to address HIV among LGBT people, including within faith-based communities.
- Federal agencies should support research to better measure and address stigma in the community and health care systems.
- 3.C.4 Promote public leadership of people living with HIV.
- Governments and other institutions (including HIV prevention community planning groups and Ryan White planning councils and consortia) should work with networks of people living with HIV, service organizations, and other institutions to actively promote public leadership by people living with HIV, including women, gay and bisexual men, racial/ethnic minorities, transgender people, and youth.

GOAL 4: ACHIEVING A MORE COORDINATED NATIONAL RESPONSE TO THE HIV EPIDEMIC

THE OPPORTUNITY

More than three decades into the HIV epidemic, Americans have witnessed increased coordination across all sectors—government agencies, non-governmental organizations, the private sector—in responding to the HIV epidemic. These coordinated efforts have helped move the Nation closer to the Strategy goals of reducing HIV infection rates, improving access to care and improving health outcomes, and reducing disparities. Activities that contributed to successful coordination include:

- Persistent advocacy from people living with HIV and their allies, pressing all sectors to do more, better, and faster.
- Engagement of affected communities and mobilization of broad sectors of society to take action against
 a condition that is highly stigmatized and associated with sexuality, substance use, and other issues that
 magnify cultural divides.
- Innovations in prevention and care programs that reflect a strong consumer perspective and incorporate
 multi-disciplinary approaches.
- Focused and sustained efforts to understand and respect differences in culture, language, and values across multiple populations and various disciplines.
- Increasing reliance on outcomes to drive a Federal domestic HIV investment that has risen to more than
 \$23 billion per year.

The release of the Strategy spurred considerable efforts to increase coordination, particularly across Federal agencies. Milestones during this period include:

- Establishing a Federal Interagency Working Group on HIV comprised of representatives from multiple departments and many HHS agencies that oversaw specific actions undertaken in response to the Strategy's Federal Implementation Plan.
- Developing and implementing a core set of HIV program indicators used across HHS to support data sharing and promote increased transparency.⁹⁵
- Formulating recommendations for the **HIV Care Continuum Initiative** and significant accomplishments within and between agencies. 50-51, 96

- Collaboration between DOJ and CDC to publish a comprehensive examination of HIV-specific criminal laws and a best practices guide to help States reform these laws.⁹³
- Establishing a Federal Interagency Workgroup on the intersection of HIV and violence against women that resulted in more than 15 new initiatives within two years.⁹⁷

To meet the goal of achieving a more coordinated response to the epidemic, the following challenges must be addressed:

- Cascading the successful experience of coordination at the Federal level to the State, Tribal, and local levels
 as well as outward to partners including the health care system. Similarly, lessons from these areas can
 inform ongoing Federal efforts to improve coordination.
- Maintaining accountability for Federal funds while encouraging jurisdictions to engage in coordinated planning that integrates all funding sources with the added benefit of streamlining and reducing reporting burden.

With dispersed responsibility for responding to HIV, there is a need for a clearer understanding of roles and increased accountability. The many Federal agencies that operate critical HIV programs do so under their own statutory authority as established by Congress. It is not possible or desirable to merge all HIV programs under one roof. At the same time, while acknowledging improved coordination since the release of the Strategy, even greater coordination is possible and essential as the Federal response improves to ensure that agencies work in closer collaboration. More effort needs to be directed toward identifying, learning from and replicating global, state, Tribal, and local successes.

SUMMARY OF STEPS

A concerted national effort to achieve a more coordinated national response to HIV is needed. The following steps are critical to achieve success:

STEP 4.A

Increase the coordination of HIV programs across the Federal government and between Federal agencies and State, territorial, Tribal, and local governments.

STEP 4.B

Develop improved mechanisms to monitor and report on progress toward achieving national goals.

POLICY AND ACTION

STEP 4.A

Increase the coordination of HIV programs across the Federal government and between Federal agencies and State, territorial, Tribal, and local governments.

Funding for HIV services is spread across multiple departments, including HHS, HUD, DOJ, Veterans Affairs, and Defense. Within HHS, in particular, responsibility for HIV programs is spread across multiple agencies including the Centers for Medicare & Medicaid Services (CMS), HRSA, CDC, SAMHSA, the Indian Health Service, the Food and Drug Administration (FDA), the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP), the Office of Minority Health, and others. Responsibility for HIV research is primarily owned by the National Institutes of Health (NIH); in addition, CDC, VA, Defense, and the United States Agency for

International Development also support research initiatives. This distribution of responsibility is appropriate, as each agency has its own expertise, and different agencies operate different programs with varying purposes and with unique histories.

Spreading HIV programs and services across the Federal government has helped to ensure a multi-faceted response, but has resulted in challenges to optimal coordination. Within HHS, the Office of the Assistant Secretary for Health, working through OHAIDP, plays a critical role in promoting consistent policies across HHS. This level of coordination helps to ensure that operating divisions within HHS implement policies that foster coordinated planning across agency and budget lines; align program reporting cycles; adopt common, interoperable data metrics and outcome measures; and adequately reflect the priorities of the Strategy within funding opportunity announcements and other relevant policy documents.

Active coordination also benefits from the exchange of ideas and strategies between leaders with common goals who face similar challenges. This is particularly important in areas with high burden, where campaigns to end AIDS urgently require local political will and concerted resource allocation.

RECOMMENDED ACTIONS

To increase the coordination of HIV programs across the Federal government and between Federal agencies and State, territorial, Tribal, and local governments, the following actions are needed:

- 4.A.1 Streamline reporting requirements for Federal grantees.
- The Federal government should continue to simplify grant administration activities, including work to standardize report formats, consolidate funding announcements, and optimize the frequency of grantee reporting requirements for Federal HIV programs, while maintaining the ability to assess performance standards.
- 4.A.2 Strengthen coordination across data systems, and the use of data to improve health outcomes and monitor use of Federal funds.
- Federal and state agencies should support and encourage appropriate sharing and use of data to improve continuity of prevention and care services, including monitoring outcomes along the HIV care continuum at the State level, and foster data sharing collaborations among institutions that serve communities at the local level.
- 4.A.3 Ensure coordinated program planning and administration.
- The Federal government should continue to increase its focus on coordinated planning for HIV programs and services across agencies.
- Federal agencies should encourage leadership at state and local levels to coordinate planning, prioritizing, and implementation of HIV prevention and care services.
- The Federal government will support States to implement integrated planning according to CDC and HRSA guidance; comprehensive HIV prevention plans that are inclusive of all funding resources are encouraged.
- The Federal government should develop a cross-governmental HIV research agenda for the Nation that spans basic science to implementation science in support of the Strategy goals.
- 4.A.4 Promote resource allocation that has the greatest impact on achieving the Strategy goals.
- The Federal government should review the methods used to distribute Federal HIV funds and take steps to ensure that resources go to the States and localities with the greatest burden of disease.
- Federal and State programs should use data from resource allocation modeling to prioritize and select effective, scalable, cost-efficient programs for reaching populations where the impact will be the greatest.

STEP 4.B

Develop improved mechanisms to monitor and report on progress toward achieving national goals.

HIV prevention and care in America requires a bold public health response. Annual deaths have declined, but the number of new infections has been static and the number of people living with HIV is growing. The Nation must:

- Critically evaluate current efforts to maximize impact.
- Measure the results of efforts to reduce new infections and improve health outcomes to chart progress nationally, and refine the response to this public health problem over time.
- Ensure that funds are allocated according to current burden of disease and that the most effective prevention and care strategies are targeted to achieve maximal results.
- Ensure that program goals are clearly stated and performance is monitored.

This requires a monitoring plan that evaluates the implementation of the Strategy, its progress, and the impact of the Strategy efforts. A system of regular public reporting will help to sustain public attention and support at the national level.

At the state level, monitoring and progress reports should reflect integrated planning. Such planning encompasses a joint comprehensive needs assessment, information and data sharing, cross-representation on prevention and care planning bodies, coordinated or combined projects, combined meetings, and fully merged planning bodies. Community engagement is an essential component for planning comprehensive, effective HIV prevention and care programs in the United States.

To understand the epidemic the American people face and how it is changing requires an effective HIV surveillance system. The National HIV Surveillance System is the primary source of data used to monitor the epidemic in the U.S, including most of the Strategy indicators.^{8, 51, 98}

HIV surveillance data are used extensively to target and evaluate HIV prevention and care programs. Therefore, comprehensive and timely data are critical, as are continued improvements in electronic laboratory reporting as timely receipt of laboratory data is critical. Surveillance necessitates a complex system of reporting from providers, laboratories, and State and local health departments to coordinate accurate, complete, and timely reporting.

To be able to meet these imperatives, there must be a strong data infrastructure to provide the necessary information, including client-level data in order to measure individual health outcomes. Further, no single data system meets all the data needs for monitoring progress and performance. Data systems such as the National HIV Surveillance System and the client-level data from the Ryan White HIV/AIDS Program Services Report require ongoing investments to ensure ongoing collection, analysis, and dissemination of data to guide policy decisions and resource allocation. 99 This includes support for adopting new analytic methods and approaches to increasing the timeliness of data to enhance the ability to describe the burden of HIV across the Nation

and allocate resources to achieve the greatest impact, as well as provide support for local analysis and use of local data. In addition, supplementary data sources such as health care payer databases, surveys, and linkages to electronic health records will ensure robust information to guide decision-making, including the development of Strategy indicators to measure stigma, uptake of PrEP, and HIV diagnoses among transgender women. In addition, STD and viral hepatitis surveillance, as well as data related to substance use (e.g., arrests, hospitalizations, and overdose) can provide early warning signs of emerging or potential HIV outbreaks. 100

RECOMMENDED ACTIONS

To develop improved mechanisms to monitor and report on progress toward achieving national goals, the following actions are needed:

4.B.**1** Strengthen the timely availability and use of data.

- Federal agencies and State, Tribal, and local jurisdictions should ensure
 use of surveillance, program, and health care data for public health action,
 characterizing burden of disease, resource allocation, performance monitoring,
 and progress reporting.
- Federal agencies should sustain and enhance data systems to promote collection and timely dissemination of data to monitor program performance and progress reports for the National HIV/AIDS Strategy, and ensure measures used at the national level can be replicated at the State level.
- Federal and local agencies should develop and implement new data elements and systems or analytic methods, as appropriate, to address gaps. These agencies should leverage health information technology—including electronic health records and electronic laboratory reporting—to increase efficiency and coordination of public health data systems.

4.B.**2** Provide regular public reporting on Strategy goals.

- Progress in reaching Strategy goals will be reported by the Federal government through an annual report at the end of each year, released by ONAP in conjunction with other White House offices and Federal agencies.
- Federal agencies should support appropriate public access to data systems and disseminate evaluation findings through multiple channels.
- States should monitor their progress towards the goals of the updated Strategy by measuring the National HIV/AIDS Strategy indicators where feasible.

4.B.3 Enhance program accountability.

- Governments at all levels should hold themselves and recipients of public funds accountable for achieving results.
- Funding announcements should clearly state performance goals and funders should actively monitor progress, provide technical assistance or take corrective action, as needed, and explore mechanisms to reward success to ensure Federal funds have the greatest impact.
- Progress reports should be made available to the public.

APPENDIX 1

INDICATOR DEVELOPMENT AND PROGRESS

As part of the Update process, a work group comprised of Federal agency representatives was charged with developing recommendations for indicators, measures, and targets to monitor progress toward achieving the Strategy goals. The work group established criteria (see box) for reviewing existing, and developing new, indicators; selecting data sources; and evaluating measures and targets. The work group reviewed surveillance data and pertinent published literature; and conducted focused consultations with stakeholders from the Federal government, academia, clinical care, and advocacy. Many of the indicators from the 2010 Strategy were retained, but measures or data sources were changed to reflect current science, practice, and the indicator criteria. Table A1 shows a comparison of the original indicators through 2015 and the updated indicators through 2020, noting indicators that have been changed, are new, or were dropped. Specific changes are described below. The work group sought to develop updated indicators with ambitious, yet feasible, targets that would inspire action and maintain progress toward meeting the Strategy's HIV prevention, treatment, and care outcomes.

Three key issues were designated to be "developmental indicators," meaning that data sources, measures, and targets will be identified and progress monitored thereafter. These three issues are PrEP, stigma, and HIV among transgender persons. Data and measures exist for all three but do not currently meet the indicator criteria. Working with stakeholders, the Federal government will develop indicators for these three issues during the next five years.

CRITERIA FOR THE INDICATORS

Establishing criteria for the indicators allowed the work group to adhere to a systematic process that ensured consistency and efficiency in developing recommendations for up to 12 indicators. The criteria it used were as follows:

Indicators: All indicators were required to have a direct relationship to one or more of the Strategy goals. In addition, each indicator needed to reflect current HIV science, policy, and practice; represent measurable outcomes or impacts rather than processes; and be derived from quantitative data from an appropriate source.

Data Sources: In evaluating data sources, the work group considered favorably those that were nationally representative; provided data on a timely, routine basis; expected that the data would be comparable across years; had data that were amenable to stratification by age, geographic region, race/ethnicity, sex, and transmission category to monitor disparities; and retained sufficient flexibility to adapt definitions, as needed, in response to changes in guidelines or clinical practice. A priority was placed on data sources that would allow States to monitor progress toward Strategy goals in their jurisdictions.

Measures: The measure for each indicator needed to demonstrate face validity, in that it appeared to assess what was intended. In addition, measures needed to be simple and easy to communicate to a range of audiences.

PROGRESS REPORT, 2010 - 2013

The indicators, baseline and annual data, and progress assessments are included in Table A2. Each indicator and its progress is described briefly below; more detailed specifications for the indicators, including data sources and measures, will be available on the ONAP website. The baseline year was set at 2010 for all indicators to reflect the ongoing Strategy work. The year for reaching the final targets is 2020. After careful consideration, the work group decided to set annual targets by allocating the total amount of change needed between the 2010 baseline and the 2020 target as follows: five percent of the total change is expected for each of the initial three years (2011–2013), ten percent is expected for each of the subsequent four years (2014–2017), and fifteen percent of the total change is expected for each of the final three years (2018–2020). This allows for implementation activities begun after the 2010 release of the Strategy to take hold and their effects to accelerate over time, rather than expecting slow advances year by year.

Progress was assessed by comparing the most recent year of data to the annual target for that year. For the indicators with preliminary data shown in Table A2, progress was assessed for the most recent year that the data were not preliminary.

Overall, there is a mixed picture of progress. Important gains are underway toward increasing the percentage of persons living with HIV who know their status, are linked to care, and have achieved viral suppression. Progress also is being made in reducing the number of new diagnoses and the death rate. More work is needed to reach the targets for other indicators. Concerted action for 2016-2020 will be necessary to meet the accelerated annual targets for all indicators. This Update and the bold targets it has set offer new opportunities to reinvigorate the combined national effort to reduce new infections, improve access to and outcomes of HIV care, and reduce health disparities.

INDICATOR 1

Increase the percentage of people living with HIV who know their serostatus to at least 90 percent, from the baseline of 85.7 percent.

This indicator retains a focus on increasing serostatus awareness among persons living with HIV infection, as this awareness (i.e., being diagnosed with HIV infection) is necessary to access HIV medical care and support services. In addition, analyses suggest that persons unaware of their HIV infection may account for about one third of new infections, so increasing knowledge of serostatus is central to reducing new infections as well as improving health outcomes. The 90 percent target is the same as the target established by the Joint United Nations Programme on HIV/AIDS for their 2020 indicators. 101

PROGRESS: The percentage of people living with HIV who knew their serostatus in 2012 (87.2 percent) exceeded the annual target (86.1 percent).

INDICATOR 2

Reduce the number of new diagnoses by at least 25 percent, from 43,806 at baseline to 32.855.

This indicator measures progress towards the goal of reducing new infections. This is an ambitious target because it requires and encompasses improvement in all other indicators and in overall prevention, treatment, and care efforts.

Although HIV incidence estimates were used previously as an indicator for the Strategy to measure reductions in new infections, as noted in Table A1, these estimates have not provided a timely and consistent way to monitor progress. The estimated number of new infections has changed, and likely will continue to change over time, due to changes in HIV testing technology and incidence estimation methods. These changes make it difficult to use these data as an indicator to measure progress over time. In contrast, HIV diagnosis data are published in a routine and standardized format and are available for all States. Given these advantages, HIV diagnosis data are used for the indicator in this Update.

Using diagnosis data to track progress in reducing new HIV infections has some challenges. First, these data must be interpreted with consideration for trends in HIV testing, as changes in testing can lead to changes in diagnosis trends that are not related to trends in new infections. For example, if HIV diagnoses decrease, evaluation is required to determine whether this decrease is due to fewer HIV tests being conducted or HIV

tests being performed on persons at lower risk, versus an indication of a decline in new HIV infections. Second, efforts to increase the percentage of people living with HIV who know their HIV status require an increase in diagnoses—meaning that, at least initially, achieving progress toward Indicator 1 may have a negative impact on progress toward Indicator 2. Over the longer term, diagnosing individuals who were previously undiagnosed will ultimately result in increased linkage to and retention in care and treatment, increased viral suppression, and decreased transmission to uninfected partners. This will reduce new infections, which will be reflected in a decrease in the number of new diagnoses.

Because HIV incidence is not being used as an indicator, the 2010 indicator for transmission rate was not included (transmission rate is based on incidence).

PROGRESS: The number of new diagnoses in 2012 (42,616) was lower than the annual target (42,711), exceeding expected progress in reducing the number of new diagnoses.

As noted above, diagnosis trends must be considered in the context of HIV testing trends. Data used to monitor trends in HIV testing come from the Behavioral Risk Factor Surveillance System. Although a statistically significant increase in testing during 2011-2013 was seen, the amount of increase was small (from 42.9 percent ever tested to 43.5 percent). Taken together, decreases in HIV diagnoses in the context of a slight increase in testing is encouraging. Additional years of diagnosis data and additional analyses about testing trends in high risk populations are needed to determine the extent to which these trends may reflect declining incidence in high risk populations.

INDICATOR 3

Reduce the percentage of young gay and bisexual men who have engaged in HIV-risk behaviors by at least 10 percent, from the baseline of 34.1 percent.

This is a new indicator, measuring HIV prevention behaviors in young gay and bisexual men, a group in which HIV infections have increased in recent years. Having an indicator specifically measuring risk for HIV acquisition among young gay and bisexual men reflects the need for effective prevention strategies to achieve the goal of reducing new infections in at-risk groups. The indicator is measured using data from the Youth Risk Behavioral Surveillance System and thus includes males in grades 9-12. Risk behaviors are assessed for the 3 months prior to the interview and include having had multiple (3 or more) partners, not using a condom at last sex, or having ever injected any illegal drug.

PROGRESS: 34.1 percent of young gay and bisexual men had engaged in HIV-risk behaviors. These data were first available in 2013 so progress is not assessed.

INDICATOR 4

Increase the percentage of newly diagnosed persons linked to HIV medical care within one month of diagnosis to at least 85 percent, from the baseline of 70.2 percent.

In recognition of the benefits of early treatment and thus the need for immediate linkage to HIV medical care for all persons newly diagnosed with HIV, this updated indicator measures linkage to care within one month of diagnosis. This is an ambitious new target as the previous indicator called for linkage to care within three months of diagnosis (see Table A1).

PROGRESS: The percentage of newly diagnosed persons linked to HIV medical care within one month of diagnosis in 2013 (72.6 percent) exceeded the annual target (72.4 percent).

INDICATOR 5

Increase the percentage of persons with diagnosed HIV infection who are retained in HIV medical care to at least 90 percent, from the baseline of 50.9 percent.

In order for persons living with HIV infection to realize the full benefit of HIV medical care, they must stay in care over time. Doing so helps to achieve viral suppression that can improve health outcomes, reduce the risk of HIV transmission, and lower the number of new infections.

This indicator differs from the measure of retention used in 2010 (see Table A1). This updated indicator relies on surveillance data, which includes all persons diagnosed with HIV infection, rather than data reported from the HRSA Ryan White HIV/AIDS Program. With this larger pool of persons in the denominator, the baseline level of retention is lower than in the 2010 Strategy. The 2020 target will be difficult to reach, but is a key focus area of the Update. The target of 90 percent is comparable to the indicator used by UNAIDS.¹⁰¹

PROGRESS: The percentage of persons with diagnosed HIV infection who were retained in HIV medical care in 2012 (53.8 percent) did not meet the annual target (54.8 percent), suggesting that additional attention is needed in order to reach this goal. The percentage retained in care in 2012 was higher than the baseline level of 50.9 percent indicating progress in the right direction.

INDICATOR 6

Increase the percentage of persons with diagnosed HIV infection who are virally suppressed to at least 80 percent, from the baseline of 43.4 percent.

Accruing the full clinical and public health benefits of HIV medical care depends upon entry into a robust care continuum that includes early diagnosis, timely linkage to care, consistent access and adherence to HIV medical care and antiretrovirals, and ongoing monitoring to ensure viral suppression. As the endpoint of the continuum of care, it is important that the nation's target for viral suppression is bold and ambitious. This target for the United States aligns with the 90-90-90 goals set by UNAIDS but uses a different denominator.¹⁰¹ That is, 90 percent of those diagnosed are retained and 90 percent of those retained are virally suppressed is approximately the same as 80 percent of those diagnosed being virally suppressed.

This indicator differs from the measures of viral suppression used in 2010 (see Table A1). The updated indicator measures viral suppression among all persons with diagnosed HIV infection, rather than only in specific groups.

PROGRESS: The percentage of persons with diagnosed HIV infection who were virally suppressed in 2012 (50.1 percent) exceeded the annual target (47.1 percent).

INDICATOR 7

Reduce the percentage of persons in HIV medical care who are homeless to no more than 5 percent, from the baseline of 7.7 percent.

Housing status is an important factor affecting access to HIV care and health outcomes. This indicator differs in two ways from the measure of housing status used in 2010 (see Table A1). First, changes were made to allow for measurement of housing status in a broader group of persons in HIV care than those receiving services through the Ryan White HIV/AIDS Program. Second, the updated indicator focuses specifically on homelessness, rather than on the broader category of housing instability. The improved sampling frame was considered an acceptable tradeoff for the narrower focus on homelessness. As the proportion of those who are homeless decreases, it will take considerable effort to reach the small proportion of those still requiring housing assistance.

PROGRESS: The percentage of persons in HIV medical care who were homeless in 2012 (8.3 percent) did not meet the annual target (7.4 percent) and increased, rather than decreased. This trend suggests that additional effort is needed in order to reach this goal. As noted in the 2013 Report on the State of Homelessness in America, the trend may reflect devastating economic climate affecting the nation at the time. ¹⁰³

INDICATOR 8

Reduce the death rate among persons with diagnosed HIV infection by at least 33 percent, from the baseline of 23.5 per 1,000 persons with diagnosed HIV infection to 15.5.

For this Update, a new indicator to monitor all-cause death rates among persons living with HIV was added because reducing mortality is an anticipated outcome of achieving all of the goals of the Strategy. This indicator reflects the overall quality of HIV medical care received, such that sustained delivery of high quality care should lead to greater reductions in death rates for persons living with HIV.

PROGRESS: The death rate per 1,000 persons with diagnosed HIV infection in 2012 (18.1) was lower than the annual target (22.7), exceeding expected progress in reducing the death rate.

INDICATOR 9

Reduce disparities in the rate of new diagnoses by at least 15 percent in the following groups: gay and bisexual men, young Black gay and bisexual men, Black females, and persons living in the Southern United States.

This indicator monitors disparities in diagnosis rates for disproportionately affected groups. It is a new indicator (See Table A1). The indicator measures reductions in the disparity, rather than reductions in the rate for each group by measuring changes in the ratio of the disparity rate for each group and the overall population rate. The ratio provides a measure of the disparity, such that the ratio increases as the difference widens between a selected group and the overall population and decreases as the difference narrows. The choice of measuring diagnosis rates, rather than numbers, was made to standardize measures (i.e., per 100,000 population).

PROGRESS: The disparity ratios for gay and bisexual men and young Black gay and bisexual men in 2012 (21.9 and 112.9, respectively) did not meet the annual targets (20.2 and 107.8, respectively) and were increasing, rather than decreasing. The disparity ratio for Black females in 2012 (1.4) was lower than the annual target (1.7), exceeding expected progress in reducing disparities. In fact, the ratio for 2012 met the 2020 target of 1.4 and achieving the 15 percent reduction in the disparity ratio. It will be important to determine whether the reduction in the disparity is sustained in future years; if so, the disparity target could be revised to be more than a 15 percent reduction. The disparity ratio for persons living in the Southern United States in 2012 (0.33) met the annual target (0.33).

INDICATOR 10

Increase the percentage of youth and persons who inject drugs with diagnosed HIV infection who are virally suppressed to at least 80 percent from the 29.7 percent and 37.6 percent baselines, respectively.

This indicator extends a focus on viral suppression, as measured by Indicator 6, to youth and persons who inject drugs, given data showing important disparities in viral suppression (i.e., lower percentage virally suppressed) for these groups in comparison to the overall. Ensuring that the target for viral suppression in these groups is the same as the overall target reduces the disparity in these groups. This indicator uses a different target and specified groups as compared to the 2010 disparity indicator for viral suppression (see Table A1).

PROGRESS: The percentage of youth who were virally suppressed in 2012 (38.0 percent) exceeded the annual target (34.7 percent). Similarly, the percentage of persons who inject drugs who were virally suppressed in 2012 (42.8 percent) exceeded the annual target (41.9 percent).

TABLE A1: COMPARISON OF NATIONAL HIV/AIDS STRATEGY INDICATORS FOR 2015 AND 2020

| NHAS INDICATORS BY 2015 | NHAS INDICATORS BY 2020 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CHANGED | |
| Lower the annual number of new infections by 25 percent. | Reduce the number of new HIV diagnoses by at least 25 percent. |
| Increase from 79 percent to 90 percent the percentage of people living with HIV who know their serostatus. | Increase the percentage of people living with HIV who know their serostatus to at least 90 percent. |
| Increase the proportion of newly diagnosed patients linked to clinical care within three months of their HIV diagnosis from 65 percent to 85 percent. | Increase the percentage of newly diagnosed persons linked to HIV medical care within one month of their HIV diagnosis to at least 85 percent. |
| Increase the proportion of Ryan White HIV/AIDS Program clients who are in continuous care from 73 percent to 80 percent. | Increase the percentage of persons with diagnosed HIV infection who are retained in HIV medical care to at least 90 percent. |
| Increase the percentage of Ryan White HIV/AIDS Program clients with permanent housing from 82 percent to 86 percent. | Reduce the percentage of persons in HIV medical care who are homeless to no more than 5 percent. |
| ADDED | |
| _ | Reduce the percentage of young gay and bisexual men who have engaged in HIV-risk behaviors by at least 10 percent. |
| _ | Increase the percentage of persons with diagnosed HIV infection who are virally suppressed to at least 80 percent. |
| _ | Reduce the death rate among persons with diagnosed HIV infection by at least 33 percent. |
| _ | Reduce disparities in the rate of new diagnoses by at least 15 percent in the following groups: gay and bisexual men, young Black gay and bisexual men, Black females, and persons living in the Southern United States. |
| | Increase the percentage of youth and persons who inject drugs with diagnosed HIV infection who are virally suppressed to at least 80 percent. |
| DROPPED | |
| Reduce the HIV transmission rate by 30 percent. | |
| Increase the proportion of HIV diagnosed gay and bisexual men with undetectable viral load by 20 percent. | |
| Increase the proportion of HIV diagnosed Blacks with undetectable viral load by 20 percent. | |
| Increase the proportion of HIV diagnosed Latinos with undetectable viral load by 20 percent. | |

Please see the narrative description of each indicator for the reasons for changes, additions, and deletions.

Table A2. Indicators and Progress for the National HIV/AIDS Strategy, Updated to 2020

| idale Artinde de la contra del la contra de la contra de la contra del la contra del la contra del la contra de la contra del la contra de la contra del la contr | | Date | Date by Year | | Targets | Jets | Progress |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------|--------------|-----------|---------|--------|----------|
| Indicator | 2010 Baseline | 2011 | 2012 | 2013 | Annual | 2020 | |
| Increase the percentage of people living with HIV who know their serostatus to at least 90 percent. | 85.7% | 86.4% | 87.2% | | 86.1% | %06 | • |
| Reduce the number of new diagnoses by at least 25 percent. | 43,806 | 42,218 | 42,616 | 42, 018** | 42,711 | 32,855 | • |
| Reduce the percentage of gay and bisexual men who have engaged in HIV-risk behaviors by at least 10 percent. | n/a | n/a | n/a | 34.1% | n/a | 30.7% | n/a |
| Increase the percentage of newly diagnosed persons linked to HIV medical care within one month of diagnosis to at least 85 percent. | 70.2% | 70.4% | 71.4% | 72.6% | 72.4% | 85% | • |
| Increase the percentage of persons with diagnosed HIV infection who are retained in HIV medical care to at least 90 percent. | 20.9% | 51.5% | 53.8% | | 54.8% | %06 | _ |
| Increase the percentage of persons with diagnosed HIV infection who are virally suppressed to at least 80 percent. | 43.4% | 46.8% | 50.1% | | 47.1% | %08 | • |
| Reduce the percentage of persons in HIV medical care who are homeless to no more than 5 percent. | 7.7% | 8.1% | 8.3% | | 7.4% | 2% | • |
| Reduce the death rate among persons with diagnosed HIV infection by at least 33 percent.§ | 23.5 | 20.8 | 18.0 | | 22.7 | 15.5 | • |
| Reduce disparities in the rate of new diagnoses by at least 15 percent among gay and bisexual ment | 20.5 | 21.2 | 21.9 | 22.2** | 20.2 | 17.4 | • |
| Reduce disparities in the rate of new diagnoses by at least 15 percent among young Black gay and bisexual ment | 109.4 | 112.4 | 112.9 | 114.9** | 107.8 | 93.0 | • |
| Reduce disparities in the rate of new diagnoses by at least 15 percent among Black females† | 1.7 | 1.5 | 1.4 | 1.3** | 1.7 | 1.4 | • |
| Reduce disparities in the rate of new diagnoses by at least 15 percent among persons living in the Southern United States† | 0.33 | 0.35 | 0.33 | 0.36** | 0.33 | 0.28 | • |
| Increase the percentage of youth with diagnosed HIV infection who are virally suppressed to at least 80 percent. | 29.7% | 33.7% | 38.0% | | 34.7% | %08 | • |
| Increase the percentage of persons who inject drugs with diagnosed HIV infection who are virally suppressed to at least 80 percent. | 37.6% | 39.2% | 42.8% | | 41.9% | %08 | • |

Note: Progress colors: Green = Annual target met; Yellow = Annual target not met, progress in expected direction; Red = Annual target not met, progress in the opposite direction * Annual targets are for the most recent data year available (does not include data marked "preliminary")

^{**} Preliminary data

^{\$} Death rate is measured per 1,000 persons with diagnosed HIV infection. +Measures shown are ratios of the disparity rate in the specified group to the overall rate.

APPENDIX 2 LIST OF ACRONYMS

ADA Americans with Disabilities Act

ADAP AIDS Drug Assistance Program

AIDS Acquired Immune Deficiency Syndrome

ART Antiretroviral Therapy

CDC Centers for Disease Control and Prevention (HHS)

DOJ U.S. Department of Justice

FDA Food and Drug Administration (HHS)

HHS U.S. Department of Health and Human Services

HOPWA Housing Opportunities for Persons with AIDS (HUD)

HPTN HIV Prevention Trials Network

HRSA Health Resources and Services Administration (HHS)

HIV Human immunodeficiency virus

HUD U.S Department of Housing and Urban Development

IPV Intimate Partner Violence

LGBT Lesbian, Gay, Bisexual, and Transgender

NIH National Institutes of Health (HHS)

OHAIDP Office of HIV/AIDS and Infectious Disease Policy (HHS)

ONAP White House Office of National AIDS Policy

PEP Post-exposure prophylaxis
PrEP Pre-exposure prophylaxis

110 Onpobato propriyanto

RWHAP Ryan White HIV/AIDS Program (HRSA)

SAMHSA Substance Abuse and Mental Health Services Administration (HHS)

SMAIF Secretary's Minority AIDS Initiative

START Strategic Timing of Antiretroviral Therapy

STI Sexually transmitted infection

APPENDIX 3 LIST OF REFERENCES

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