## NATIONAL ACADEMY OF PUBLIC ADMINISTRATION

for the National Coalition of STD Directors

# The Impact of Sexually Transmitted Diseases on the United States:

Still Hidden, Getting Worse, Can Be Controlled







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The National Academy of Public Administration is an independent, non-profit, and non-partisan organization established in 1967 and chartered by Congress in 1984. It provides expert advice to government leaders in building more effective, efficient, accountable, and transparent organizations. To carry out this mission, the Academy draws on the knowledge and experience of its over 900 Fellows—including former cabinet officers, Members of Congress, governors, mayors, and state legislators, as well as prominent scholars, business executives, and public administrators. The Academy helps public institutions address their most critical governance and management challenges through in-depth studies and analyses, advisory services and technical assistance, congressional testimony, forums and conferences, and online stakeholder engagement. Learn more about the Academy and its work at www.NAPAwash.org.

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A Report by a Panel of the

# NATIONAL ACADEMY OF PUBLIC ADMINISTRATION

December 2018

# The Impact of Sexually Transmitted Diseases on the United States: Still Hidden, Getting Worse, Can Be Controlled

**PANEL OF FELLOWS** 

Georges Benjamin (Chair)\*

Kenneth W. Kizer\*

**Gregg Pane\*** 

William Gimson\*

Shoshanna Sofaer\*

\*Academy Fellow



#### Officers of the Academy

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Norton Bonaparte, Vice Chair

Teresa W. Gerton, President and Chief Executive Officer

Myra Howze Shiplett, Secretary

Jonathan Fiechter, Treasurer

#### **Study Team**

Brenna Isman, Director of Academy Studies

Cynthia Heckmann\*, Project Director

Laurie Ekstrand, Senior Advisor

Richard Pezzella, Research Associate

#### \*Academy Fellow

National Academy of Public Administration 1600 K Street, N.W. Suite 400 Washington, DC 20006

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#### **Foreword**

The National Coalition of STD Directors (NCSD) advocates on behalf of state and local public health entities across the United States to fulfill their vision of, in their words, "a nation without STDs." NCSD represents their members before Capitol Hill and other federal interests; partners with the Centers for Disease Control and Prevention (CDC) on the design and implementation of sexually transmitted disease response grants; provides technical assistance for members participating in CDC grant programs; and offers coordination services between public health groups. The various state and local public health entities that comprise the membership of NCSD carry out the vital, front-line work that contributes to the wellbeing of communities nationwide.

NCSD contracted with the National Academy of Public Administration (the Academy) to undertake a comprehensive study of the present STD landscape in the United States as a first-step in examining the scope of the epidemic, intersecting and complicating factors, public policy solutions and federal programs involved in STD prevention and control.

This report of a Panel of five Academy Fellows provides the results of extensive information collection and analysis based on research and interviews conducted over the period of July to November 2018. It describes the current state of the STD epidemic, the funds and operations of the federal programs that address it, and trends contributing to the ongoing spread of disease. The study leveraged existing research and data to depict in one narrative the general state of affairs as it pertains to the Academy's charge.

As a congressionally chartered non-partisan, non-profit organization with over 900 distinguished Fellows, the Academy brings nationally recognized public administration experts together to help organizations like NCSD address the challenges that define our time. We are pleased to have had the opportunity to work with NCSD and its members to conduct this study and to contribute to their ongoing efforts to end STDs in America. We appreciate the constructive engagement of the various public health professionals, administrative veterans, and health economists that lent their expertise and time to the project.

I extend my thanks to the Academy Panel, all experts who offered their invaluable insight and keen analysis, and to the professional study team that provided critical support throughout the project. I expect this report will contribute to new efforts by the federal government and state and local health departments to tackle the continuing epidemic and bring relief to millions of patients a year.

Teresa W. Gerton
President and Chief Executive Officer,
National Academy of Public Administration

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## **Acronyms, Abbreviations, and Definitions**

| Acronym or<br>Abbreviation | Definition  |  |
|----------------------------|---|--|
| AADDC                      | Assessment, Assurance, Policy Development, and Prevention Strategies, a         |  |
| AAPPS                      | cooperative agreement issued by CDC covering the time period of 2013 – 2018     |  |
| ACA                        | Patient Protection and Affordable Care Act                                      |  |
| AFHSC                      | Armed Forces Health Surveillance Center   |  |
| AIDS                       | Acquired Immunodeficiency Syndrome, the condition caused by HIV                 |  |
| AMR                        | Antimicrobial Resistance  |  |
| ARLN                       | Antimicrobial Regional Laboratory Network                                       |  |
| ASHA                       | American Sexual Health Association  |  |
| ASTDA                      | American Sexually Transmitted Diseases Association                              |  |
| ASTHO                      | Association of State and Territorial Health Officials                           |  |
| CAB                        | Community Advisory Board  |  |
| CARB                       | National Strategy for Combatting Antibiotic Resistant Bacteria                  |  |
| CARS                       | Community Approaches for Reducing STDs  |  |
| CDC                        | Centers for Disease Control and Prevention                                      |  |
| CMS                        | Centers for Medicare and Medicaid Services                                      |  |
|                            | Continuing Resolution, legislation in the form of a joint resolution enacted by |  |
| CR                         | Congress, when the new fiscal year is about to begin or has begun, to provide   |  |
| CK                         | budget authority for federal agencies and programs to continue in operation     |  |
|                            | until the regular appropriations acts are enacted.                              |  |
| CS                         | Congenital syphilis (see Appendix D)  |  |
| CSTE                       | Council of State and Territorial Epidemiologists                                |  |
| DHAP                       | Division of HIV/AIDS Prevention   |  |
| DIS                        | Disease Intervention Specialist(s)  |  |
| DoD                        | United States Department of Defense   |  |
| DOJ                        | United States Department of Justice   |  |
| DSTDP                      | Division of STD Prevention  |  |
| EHR                        | Electronic Health Record(s)   |  |
| EIS                        | Early Intervention Services   |  |
| ELR                        | Electronic Lab Record(s)  |  |
| EPT                        | Expedited Partner Therapy   |  |
| FACA                       | Federal Advisory Committee Act, the legal foundation defining how federal       |  |
| TAGA                       | advisory committees operate   |  |

| Acronym or   | Definition   |  |
|--|--|--|
| Abbreviation   |  |  |
| FBOP   | Federal Bureau of Prisons  |  |
| FDA  | Food and Drug Administration   |  |
| FQHC   | Federally Qualified Health Clinic  |  |
| FTE  | Full-time equivalent   |  |
| FY   | Fiscal Year  |  |
| GAO  | Government Accountability Office   |  |
| GISP, eGISP  | Gonococcal Isolate Surveillance Project, or Enhanced Gonococcal Isolate      |  |
| Surveillance Project   |  |  |
| HHS  | United States Department of Health and Human Services                        |  |
| HIV  | Human Immunodeficiency Virus   |  |
| НМО  | Health Maintenance Organization  |  |
| HPV  | Human Papilloma Virus  |  |
| HRSA   | Health Resources and Services Administration                                 |  |
| IDCRP  | Infectious Diseases Clinical Research Program                                |  |
| IHS  | Indian Health Service  |  |
| LHD  | Local health department(s)   |  |
| MSM  | Men Who Have Sex With Men  |  |
| NACCHO   | National Association of County and City Health Officials                     |  |
| NCBI   | National Center for Biotechnology Information                                |  |
| NCHHSTP  | National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention        |  |
| NCSD   | National Coalition of STD Directors  |  |
| NGO  | Non-Governmental Organization  |  |
| NIAID  | National Institute for Allergy and Infectious Disease                        |  |
| NICHD  | National Institutes of Child Health and Human Development                    |  |
| NIH  | National Institutes of Health  |  |
| NMI  | NNDSS Modernization Initiative   |  |
| NNDSS  | National Notifiable Disease Surveillance System                              |  |
| National Network to Enhance Capacity of State and Locally Transmit |  |  |
| INNECS   | Prevention Program   |  |
| NSF  | National Science Foundation  |  |
|  | Strengthening Sexually Transmitted Disease Prevention and Control for Health |  |
| PCHD   | Departments, a successor program to the AAPPS cooperative agreement, issued  |  |
|  | by CDC beginning in 2019   |  |
| PHIV   | People Living With HIV   |  |
| PID  | Pelvic Inflammatory Disease, a common STD complication predominantly seen    |  |
| TID  | in women   |  |

| Acronym or   | Definition  |  |
|--------------|---|--|
| Abbreviation |   |  |
| PrEP         | Pre Exposure Prophylaxis  |  |
| RTC          | Randomized Control Trials   |  |
| SAMSHA       | Substance Abuse and Mental Health Services Administration                       |  |
| SEE          | Syphilis Elimination Effort, a term used to refer to the 1999 National Plan to  |  |
| SEE          | Eliminate Syphilis from the United States, issued by the CDC                    |  |
| S.P.A.C.E.   | STD Prevention Allocation Consequences Estimator, a spreadsheet tool            |  |
| MONKEY       | developed by the CDC to estimate the impact of funding changes in STD           |  |
| MONKET       | prevention programs   |  |
| SSuN         | STD Surveillance Network  |  |
| STD          | Sexually Transmitted Disease, infections acquired sexually, such as syphilis,   |  |
| 310          | gonorrhea, and chlamydia  |  |
|              | Sexually Transmitted Infection, clinically used term to describe infectious     |  |
| STI          | agents that cause STDs. The terms STI and STD are interchangeably used. This    |  |
| 311          | report principally uses the term "STD" except where applicable and in-context   |  |
|              | (for example, where "STI" is used in an official program name or description).  |  |
|              | Sexually Transmitted Infection Costs Saved, a spreadsheet tool developed by the |  |
| STIC FIGURE  | CDC to estimate direct medical costs incurred and incidental costs saved by STD |  |
|              | prevention programs   |  |
| SURRG        | Strengthening the United States Response to Resistant Gonorrhea                 |  |
| ТВ           | Tuberculosis  |  |
| The Academy  | The National Academy of Public Administration                                   |  |
| USPSTF       | United States Preventive Services Task Force                                    |  |
| VA           | United States Department of Veterans Affairs                                    |  |
| VHA          | Veterans Health Administration  |  |
| WHO          | World Health Organization   |  |

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#### **Executive Summary**

Sexually transmitted diseases (STDs) have existed throughout recorded history, although effective screening and treatment did not become available until the twentieth century. Efforts to address STDs have flowed and ebbed over the years with reductions in the infection rates mirroring the attention and funding provided to address outbreaks.

A 1997 report from the Institute of Medicine (now the National Academy of Medicine of the National Academies of Science, Engineering and Medicine) coined the phrase, "The Hidden Epidemic" to describe the degree of public awareness about STDs. Twenty years later, the phrase still accurately depicts the state of affairs. While the names of STDs—chlamydia, gonorrhea, syphilis, for example—along with how they are transmitted, can generate apprehension, actual knowledge about these diseases by the general public remains limited. Despite the fact that STDs are preventable and treatable, the rates of known infections for the three STDs cited are rising at alarming rates. Since 2013, reported chlamydia rates have increased 22 percent, gonorrhea rates 67 percent, syphilis rates 76 percent, and congenital syphilis rates 154 percent. "Known infection," is perhaps the tip of the iceberg, as testing and treatment covers but a fraction of those who may be infected. Short-run consequences to infected individuals are minimal, but long-term consequences can be severe, potentially life threatening, and costly to the individual and society in general. STDs are a national public health issue.

Against this backdrop, the National Coalition of STD Directors (NCSD) asked the National Academy of Public Administration (the Academy) to investigate and describe the scope and impact in the United States of three major, reportable STDs—specifically, chlamydia, gonorrhea and syphilis—and assess the effectiveness of current prevention and control programs. As the nonprofit organization representing and supporting state STD directors, their staff, and community-based partners, NCSD engages in a wide range of activities to promote effective STD mitigation policies and strategies and to secure sufficient resources to reverse infection trends.

In response to the NCSD request, the Academy formed an expert panel and a professional study team to collect and review available information concerning STD trends and efforts to prevent and control the three STDs noted above. The study focused principally on federally funded intervention programs and current funding. A review of state and local programs, as well as clinical/epidemiological issues, was beyond the scope of this study. By providing a consolidated overview of the current state, this Academy study is intended to help NCSD and the other

stakeholders in the STD community inform a national action strategy for reducing STD transmission rates and improving public health.

The nation's highly fragmented public healthcare system creates major challenges for tackling the rising rates of STDs. Multiple entities are involved including federal, state, and local government agencies, and myriad nongovernmental partners. Vast variations exist across the nation in how the services are provided and funded. Federal funding has been constrained affecting research, evaluation, and support to states and local jurisdictions, while at the same time many states and localities have experienced budget cuts directly affecting their ability to provide services.

The Patient Protection and Affordable Care Act, and in particular, Medicaid expansion, has altered where people get screened and how services are paid for, while also inadvertently and adversely impacting STD prevention and control efforts. Multiple intersecting conditions affect the occurrence of STDs whose treatment is often complicated by social behaviors, such as drug abuse. Moreover, social stigma continues to create barriers to education, screening, and treatment, and is particularly impactful on those individuals at a higher risk for STDs.

With so many entities having a role in efforts to control the spread of STDs, there is a critical need for a comprehensive, unified national strategy to combat STDs. Such a national strategy needs to focus attention and resources on the most effective approaches to achieve STD prevention and control goals. This Academy Panel report provides an important first step towards developing a national strategy by summarizing the current state—trends, current efforts, the stakeholders, promising practices, and the overall prevention and control environment. Based on the Panel and study team's review of studies, trends, and program descriptions, as well as interviews with a wide range of individuals involved in planning and delivery of STD programs and services, the Panel suggests a number of actions to establish a foundation for an effective national strategy to combat STDs in the U.S.

#### **Actions for Consideration**

- Designate a national STD champion to coordinate federal, state, and local efforts and to lead the development and implementation of a national STD strategy. This champion should be empowered with the appropriate authority to align efforts, advocate for funding, and promote research and innovation across sectors. Input from myriad entities will need to be included in developing and implementing a national STD prevention and control strategy, and committed national leadership will be essential to the effort.
- Change the STD narrative. Sexual health is an important dimension of overall health and wellness. STDs cause serious harm to health and are costly to both individuals and society-at-large. Currently, STD-related social stigma prevents some individuals from seeking treatment, some medical professionals from screening for STDs, and some government entities from offering services at needed levels to combat STD infections. As with mental health and drug use conditions, STDs are a health and wellness problem that must be destigmatized to effectively address.
- *Unifying the field is a necessary step.* Chlamydia, gonorrhea and syphilis are but three of many sexually transmitted diseases. Both Human Immunodeficiency Virus (HIV) and Human Papilloma Virus (HPV) have received far more attention and funding, with commendable positive results. All STDs share common modes of transmission, and comorbidity is unavoidable. Unifying the effort to focus across STDs rather than on certain specific infections can enhance the effectiveness of STD prevention and control efforts.
- Better data and more evaluation to learn about what works—and what does not
  work—and to foster implementation of best practices are essential. Inconsistent state
  reporting requirements and an array of technology challenges makes data collection
  complicated. Actions to align data with information needs are critical. Additionally,
  evaluations should be strategic and test interventions systematically, with an eye towards
  implementation of best practices on a broader scale.
- *Education and awareness are needed.* The public has limited information about the potential dangerous long-term consequences of untreated STDs. Tailored awareness campaigns, focused on groups at higher risk—e.g., adolescents, young adults, men who have sex with men (MSM)—would likely result in more screening, testing, and treatment. Again,

the focus should be on sexual health as an important aspect of general health and wellness. Further, medical professionals must be encouraged to screen for STDs as a routine practice.

Expanded funding and resources are necessary given the scale of the STD epidemic.
 With caseloads numbering in the millions and systemic healthcare issues creating obstacles to care and prevention, a resource investment is necessary to bolster nationwide incidence reduction efforts.

In many respects, these suggested strategies echo some of the key messages articulated in the *Hidden Epidemic* report more than twenty years ago. Society has changed in many ways that affect sexual relationships since that time; yet as a nation, there remains, "reluctance of American Society to openly address issues surrounding sexuality and STDs." There is an urgent need for a national STD strategy and most importantly, for a *commitment to execute the strategy*, lest we find twenty years from now the situation has not changed—that is, a clear and present danger to public health remains a hidden epidemic.

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#### Introduction

In 1997, the Institute of Medicine (now the National Academy of Medicine, of the National Academies of Science, Engineering, and Medicine) published a report, *The Hidden Epidemic: Confronting Sexually Transmitted Diseases*. The report noted that, "despite the tremendous health and economic burden of sexually transmitted diseases (STDs), the scope and impact of the STD epidemic are underappreciated . . . and largely hidden from public discourse;" public awareness and knowledge are "dangerously low." The report cited three overarching reasons for why STDs are hidden: 1) STDs are often asymptomatic and as a result, go undetected; 2) major health consequences, such as certain cancers and infertility, may occur years after the initial infection; and 3) the social stigma attached to having an STD creates a barrier to public discussion and education. The report identified a number of contributing factors to this "hidden epidemic" including:

- Susceptibility to STDs among young women and adolescents and the lag time from initial infection to conspicuous symptoms appearing (biological)
- Sexual practices, substance use/abuse, and sexual abuse and violence (behavioral)
- Poverty, inadequate access to healthcare, inadequate education, and social inequity—with
   STDs disproportionately affecting disenfranchised, marginalized groups (social)

Twenty years later, despite concerted efforts and programs to reduce STD rates and to generate public awareness of this health risk, the description presented in the *Hidden Epidemic* is as apt today as it was when it was first published, a fact acknowledged by the Centers for Disease Control and Prevention (CDC), the lead federal agency for addressing STDs. The foreword to CDC's recently released *Sexually Transmitted Disease Surveillance 2017* <sup>2</sup> opens with a reference to the 1997 report, as does the prior year's 2016 report. Tellingly, the concluding statement in the *Hidden Epidemic Summary Report* appears in its entirety in the forewords to the 2010 through 2015 surveillance reports.

<sup>&</sup>lt;sup>1</sup> *The Hidden Epidemic: Confronting Sexually Transmitted Diseases, Institute of Medicine*, Washington, DC: National Academy Press. (1997)

<sup>&</sup>lt;sup>2</sup> **Sexually Transmitted Disease Surveillance 2017**, Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Division of STD Prevention, (September 2018)

While the description of the problem may be current, the circumstances and context of the problem, in fact, have changed. The Patient Protection and Affordable Care Act (ACA)—including Medicaid expansion—has affected where people get screened and treated and how services are paid for; social media and online dating have influenced partner connections; and the use of medical prophylactics such as Pre-Exposure Prophylaxis (PrEP) to address HIV has changed behaviors in the use of condoms, a known effective deterrent to the transmission of the STDs. These are just some of the examples of the changing world of STDs.

#### Why STDs Are Important to Address

STDs are an urgent national public health problem. Today, the United States leads industrialized nations in the incidence of STDs—certainly not an honor a nation would seek. According to CDC, a combined total of nearly 20 million new infections occur each year, while STD cases cost our U.S. healthcare system \$16 billion annually.<sup>3</sup> Concern is also rising about the growing threat of antibiotic resistant gonorrhea—a fact that led to its inclusion in the National Strategy for Combating Antibiotic Resistant Bacteria. The most recent data from CDC's 2017 Surveillance Report, highlighting the extent of federally reportable STDs, paints a grim picture<sup>4</sup>.

Table 1: Reportable STDs by Disease Type, Number of Cases Report, and Percentage of change from since 2013 and 2016

| Disease               | Reported Cases | Increase since 2016 | Increase since 2013 |
|-----------------------|----------------|---------------------|---------------------|
| Chlamydia             | 1,708,569      | 7%                  | 22%                 |
| Gonorrhea             | 555,608        | 19%                 | 67%                 |
| Syphilis <sup>5</sup> | 30,644         | 10%                 | 76%                 |
| Congenital syphilis   | 918            | 46%                 | 154%                |

<sup>&</sup>lt;sup>3</sup> STDs refer to more than 35 infectious organisms transmitted primarily through sex. Examples include chlamydia, gonorrhea, syphilis, chancroid, genital herpes, human papillomavirus, HIV/AIDs.

<sup>&</sup>lt;sup>4</sup> Four STDs are nationally reported—chlamydia, gonorrhea, syphilis, and chancroid.

<sup>&</sup>lt;sup>5</sup> The reported number of cases for syphilis reflects cases of primary and secondary syphilis.

STDs are preventable—and infections are treatable. Without diagnosis and treatment, the long-term health consequences of STDs are significant: infertility, increased cancer risk, pelvic inflammatory disease, disability, or even death, among others, with a disproportionally higher impact affecting women and newborn babies. While the incidence and prevalence of STDs have materially increased in recent years, federal resources to combat the problem have declined. Moreover, budget cuts at the state and local levels—where the action is—have caused some health departments to reduce staff and close clinics, curtailing access to testing and treatment. Unfortunately, the reduction in services particularly affects at risk populations, who are often marginalized from society-at-large.

#### **Study Scope**

The National Coalition of STD Directors (NCSD) contracted with the National Academy of Public Administration (the Academy) to document the scope and impact of STD infection in the United States and to assess the effectiveness of current prevention and control programs. NCSD is a nonprofit, non-partisan public health membership organization dedicated to the prevention of sexually transmitted diseases. Founded in 1996, NCSD represents health department STD directors, their support staff and community-based partners in programs across the fifty states, seven large cities/counties<sup>6</sup> including the District of Columbia, and eight U.S. territories<sup>7</sup> that CDC directly funds. On behalf of its members, NCSD advocates for effective policies, strategies, and sufficient resources for STD programs to reduce STD rates and endeavors to increase public awareness of the serious health and social impact of STDs.

The Academy's charge was to conduct a comprehensive review of relevant documents addressing 1) the current state and impact of three major reportable STDs—syphilis, gonorrhea, and chlamydia; 2) the effectiveness of current federally funded prevention and control programs and approaches (including outreach and education); 3) promising prevention and control practices, and 4) funding streams and funding models.

<sup>&</sup>lt;sup>6</sup> New York City, Los Angeles County, Chicago, Washington, D.C., Philadelphia, San Francisco, and Baltimore

<sup>&</sup>lt;sup>7</sup> Puerto Rico, U.S. Virgin Islands, and U.S. Affiliated Pacific Islands jurisdictions including American Samoa, Guam, the Marshall Islands, the Federated States of Micronesia, Northern Mariana Islands, and Palau

In reviewing STD programs, the study team principally examined federally funded intervention programs supported by the lead federal agency for STD prevention, CDC, and its work with partner agencies and organizations, and on the models it has developed to estimate funding requirements. A detailed review of state and local STD prevention and control programs was outside the scope of this effort. The end goal was to provide evidence to help inform a national action strategy for reducing STD transmission rates and improving public health through a unified vision and coordinated prevention and control programs and services.

#### **Results in Brief**

Addressing STDs requires a unified, coordinated and collaborative approach that is a challenge given the nation's highly fragmented public healthcare system. While CDC is the principal federal funder of STD prevention and control programs, it does not provide direct services. That responsibility lies with the states and local jurisdictions, many of whom—but not all—provide additional funding to support STD programs. As a result, there is wide variation across states and localities in how they address and fund efforts. While CDC collects and reports on STD rates via its annual surveillance report, legal authority for gathering and reporting the data rests with the states. In addition, numerous other federal agencies and nongovernmental partners have a role in STD prevention and control, rendering collaboration across these partners essential.

A host of issues exist related to data collection and analysis affecting the reporting of incidents/cases and associated costs. The national data are only as good as the data from the states—and the quality of the data varies widely. Limitations with the data also make it difficult to predict with certainly the impact of changes in funding, albeit CDC and other studies have demonstrated that cuts in funding affect STD programs and services, which in turn likely affects STD rates.

In recent years, federal funding for CDC has held reasonably steady. However, when adjusted for inflation, the funding equates to a significant reduction—about 40 percent in purchasing power—at the same time that STD rates are rising. Continuing resolutions that delay funding and often result in hiring freezes that suspend the filling of staff vacancies directly affect program initiatives and staff capacity to carry out program activities. Additionally, state and local jurisdictions have suffered budget cuts affecting staffing, clinic operations, and the delivery of services overall.

By expanding insurance coverage, the ACA—in particular, Medicaid expansion—has had a major impact on where individuals get screened and treated. Since more individuals are insured, there has been a shift in screening with more done by private providers than in public health STD clinics.

This has significantly changed the landscape of STD service delivery. It has also resulted in changes in the insurance marketplace and in the payment of services. The healthcare landscape continues to evolve as changes to the ACA are implemented.

A number of challenges confront the program administration of STD prevention and control activities. Included among these is a wide range of technology challenges, particularly with respect to linking electronic health records. Examples include incompatibility across systems, complications from systems originally built for billing rather than health, and the lack of technology staff capacity at all governmental levels.

Finally, the social stigma associated with STDs continues to complicate STD prevention and treatment efforts. Access to care and social equity often factor in to approaches to reach groups at higher risk for contracting STDs, including racial and ethnic minorities and men who have sex with men, as well as women and infants, adolescents and young adults.

These issues are not likely to go away any time soon, making the need to educate the public and healthcare professionals even more important. It is not simply an individual health issue and responsibility—it is a public health problem with broad ramifications.

Currently, a clearly identified, national champion for addressing the STD epidemic is lacking. There is also a need to personalize—to put a face—to the issue as was done successfully with the Ryan White HIV/Acquired Immunodeficiency Syndrome (AIDS) program. Viewing STDs through the lens of maternal and child health, especially in terms of preventing infant deaths, may be a way to help personalize the impacts of STDs.

Today, a number of different strategies and action plans help to inform STD priorities (e.g., National Prevention Strategy, Healthy People, and National HIV/AIDS). CDC has an important national role, but its strategic plan is appropriately a plan of action for CDC itself. Very recently, an effort commenced in the Office of the Assistant Secretary for Health to begin strategizing and developing a national STD action plan. This is a positive step. As this planning effort gets fully underway, it is essential that it include all the responsible levers—federal, state, local and nongovernmental partners/stakeholders—involved in STD prevention and control and that the resultant plan articulate a comprehensive national strategy with actionable steps to stem the tide of STDs.

#### Methodology

The Academy assembled a five-member expert Panel to direct and oversee the study. The Panel represents prominent medical, scientific, and management leaders with expertise in public health, epidemiology and biostatistics, and clinical medicine, as well as knowledge and experience with key federal agencies including CDC, the National Institutes of Health, Veterans Affairs and Department of Defense, state and local government entities, and relevant nonprofits and academic institutions. The Panel held two in-person meetings and provided ongoing guidance to the professional study team of three, who carried out the review based on a structured methodology. <u>Appendix A</u> contains a brief biographical sketch of each Panel member.

The study team performed extensive research in the form of both primary and secondary data collection and analysis, gathering information through structured interviews with a range of knowledgeable individuals in the STD prevention and control space, and reviewing a wide variety of government documents—studies, grants, strategic/action plans, funding models, surveillance data, and the like—as well as academic and nonprofit published research. The study team also attended the 2018 Biennial STD Conference in Washington, D.C., organized by CDC, which brought together federal, state, and local public health officials, as well as academic researchers and stakeholders from partner STD and public health associations/interest groups and conducted site visits to CDC in Atlanta, Georgia and to a local STD clinic. In addition, the study team attended STD Engage 2018, the NCSD annual conference in Orlando, Florida, which provided additional opportunity to connect with public health and partner stakeholders. Appendix B includes a list of interviewees, and Appendix C provides a selected bibliography of the documents and published research reviewed.

The study team focused on structure, organization, operational management, planning, program coordination, and the funding/costs of STD prevention and control programs. Clinical and epidemiological issues, beyond the description of reportable STDs—i.e., what they are, the impact on individual and the public at large, how they are transmitted and treated, and current prevalence and incidence rates—were beyond the scope of this review.

#### **Organization of Report**

This report provides a descriptive examination of the state of STDs in the United States with a focus on efforts to prevent and control these infectious diseases and the costs in terms of public health and dollars associated. The report presents the Panel's key findings and concerns based on

document reviews and interviews and offers actions for consideration to address STDs. The report is organized as follows:

- Section 1: State of the State of Three Federally Reportable STDs
- Section 2: Entities with Roles in Stemming the Tide of STDs
- Section 3: Challenges and Barriers to Effective STD Prevention and Control
- Section 4: Promising Prevention and Control Approaches
- Section 5: Actions for Consideration to Address the STD Epidemic

#### Section 1: State of the State of Three Federally Reportable STDs

In 1912, state and territorial health agencies worked with the U.S. Public Health Service to issue the recommendation that local jurisdictions immediately report, by way of telegraph, new cases of five selected infectious diseases; this would be followed by a monthly report of ten other diseases by way of letter<sup>8</sup>. As early as 1944, federal authorities requested reporting of syphilis and gonorrhea. In 1951, a conference of state and territorial epidemiologists issued the first fully documented list of national notifiable diseases following a request from (then) Director of CDC's Bureau of Epidemiology, Alexander Langmuir. Since then, CDC, in conjunction with local health departments and other stakeholders, has maintained the Nationally Notifiable Disease Surveillance System (NNDSS). CDC publishes the incidence data gathered through this system in the *Morbidity and Mortality Weekly Report* and in recent years, has also published the data online through a variety of outlets.

#### **Reporting Requirements**

While CDC maintains the NNDSS, state and territorial entities often have their own reporting requirements. The amount of data and methodology by which these data are collected may vary among jurisdictions, resulting in gaps in information accessible to CDC. Reporting is not mandated by federal law or regulation and is a purely voluntary process, giving CDC little ability to require certain data points be reported, or that the data be reported on a fixed, reliable timetable.

Although not mandated, reporting statistics to CDC is generally accepted as good practice for the betterment of public health interests, and all jurisdictions are, in fact, reporting. Organizations with an integral role in reporting, like the Council of State and Territorial Epidemiologists (CSTE), recommend that members report case information to CDC and other bodies of jurisdiction. Of note, CSTE maintains a list query tool that allows users to search for reporting requirements nationwide on a per-state basis, with filters for different venues (hospitals, laboratories, and healthcare

https://cdn.ymaws.com/www.cste.org/resource/resmgr/PDFs/CSTENotifiableConditionListA.pdf

<sup>8</sup> National Notifiable Diseases Surveillance System; Available at: https://wwwn.cdc.gov/nndss/history.html

<sup>&</sup>lt;sup>9</sup> CSTE Notifiable Condition List; Available at:

providers)<sup>10</sup>. A cursory use of this tool for reporting requirements on syphilis reveals significant disparities in reporting times for different providers, between states.  $\underline{Table\ 2}$  (on the following page) is a sample of the query results.

Table 2: CSTE Query Tool, syphilis reporting requirements for healthcare providers, 2017

| Jurisdiction         | Healthcare Providers |
|----------------------|----------------------|
|                      |                      |
| Alabama              | 5 days               |
| Arkansas             | 24 hours             |
| Arizona              | 5 business days      |
| New York City        | 24 hours             |
| California           | 1 business day       |
| Colorado             | 1 business day       |
| Connecticut          | 12 hours             |
| District of Columbia | 48 hours             |
| Delaware             | 24 hours             |
| Florida              | 1 business day       |
| Georgia              | Immediately          |
| Hawaii               | 3 business days      |
| lowa                 | 3 days               |
| Idaho                | 3 business days      |
| Illinois             | 7 days               |
| Indiana              | 72 hours             |
| Kansas               | 7 days               |
| Kentucky             | 5 business days      |
| Louisiana            | 1 business day       |
| Massachusetts        | 24 hours             |
| Maryland             | 1 business day       |
| Maine                | 48 hours             |
| Michigan             | 24 hours             |
| Minnesota            | 1 business day       |
| Missouri             | 1 day                |
| Mississippi          | 24 hours             |
| Montana              | Immediately          |

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<sup>&</sup>lt;sup>10</sup> Surveillance/Informatics: SRCA Query Tools; Available at: <a href="https://www.cste.org/group/SRCAQueryRes">https://www.cste.org/group/SRCAQueryRes</a>

| Jurisdiction   | Healthcare Providers |
|----------------|----------------------|
| North Carolina | 24 hours             |
| North Dakota   | 7 days               |
| Nebraska       | 7 days               |

As <u>Table 2</u> demonstrates, reporting timeline requirements can vary greatly, from as little as twenty-four hours to seven days, across states. Beyond these timeline requirements, criteria for reporting cases may differ, as well, with some states requiring reporting for confirmed cases only, while others require both confirmed and suspected cases.

CDC officials raised a number of concerns to the study team about the standards for reporting at state and local levels when reporting cases across different entities. Specifically, hospitals, primary care providers, and laboratories may report cases at different phases of illness or be duplicative of each other. Reports may not include incidence data, offering only confirmed cases with no count of tests done in total or negative results. This lack of congruence in data makes it difficult to get a comprehensive view of the morbidity in certain regions.

#### Case Definitions for Reporting

The CSTE issues case definitions as Position Statements, which are vetted by the CSTE Executive Board and can take anywhere from forty-eight hours to thirteen weeks to be processed depending on the urgency of the issue. Once published, case definition updates inform the NNDSS and are hosted on CDC's website. Case definitions can have subtypes: in the case of syphilis, there are six subtypes including primary, secondary, early non-primary non-secondary, congenital, stillbirth, unknown duration, or late cases. Each syphilis subtype has a clinical description that outlines the circumstances under which a diagnosis of syphilis should be reported as that subtype, with comments that provide context or caveats to the description.

<u>Appendix D</u> represents a matrix of the case definitions for the diseases of focus in this study. **Screening Guidelines** 

The United States Preventive Services Task Force (USPSTF)—an independent, voluntary advisory group convened by the Agency for Healthcare Research and Quality—issues evidenced-based STD screening and treatment guidelines, which they update as needs arise. CDC also issues guidelines that enhance the USPSTF's guidelines when a specific public health need for different screening develops. The CDC guidelines are viewed as recommended best practices. Unlike CDC's guidelines, the USPSTF's guidelines are empowered by law for reimbursement purposes.

A number of the USPSTF and CDC guidelines are almost identical. USPSTF, however, grades its recommendations based on efficacy, using a scale of A, B, C, and D to signify the usefulness of a practice and to what degree it should be implemented. For example, an "A" rating signifies substantial benefit to the patient and therefore, the practice should be offered or provided. Conversely, a "D" rating would be a recommendation against providing the service, indicating that there is little benefit or even a risk of harm, as a result of the practice. Section 2713 of the Affordable Care Act, "Coverage of Preventive Health Services," requires that health insurance providers cover services that are rated "A" or "B." <sup>11</sup> Section 4105 requires Medicare to expand preventive services coverage consistent with USPSTF recommendations and gives Medicare the authority to decline payment for services that are graded "D." Medicaid, as with private insurers, is required to cover services graded "A" or "B."

Currently, the screening guidelines for defined populations are at the "A" level for syphilis and for chlamydia and gonorrhea at the "B" level.

#### The Three Diseases

The study team's charge was to assess the impact of the three nationally reportable STDs—chlamydia, gonorrhea, and syphilis. The three diseases, all bacterial, share several similarities but differ radically in severity and both the method and efficacy of treatment.

#### **Chlamydia**

Chlamydia is an STD caused by the bacterium *chlamydia trachomatis*. Symptomatic expression and complications can vary significantly between men and women; but most of those infected are asymptomatic. Just about 10 percent of men and 5-30 percent of women diagnosed with chlamydia develop symptoms, per CDC<sup>12</sup>. Chlamydia is the most frequently reported bacterial STD in the United States, with CDC estimating 2.86 million infections annually.

Symptoms of chlamydial infection can vary in those that present with them but typically display as painful urination, pain with intercourse, lower abdomen pain, penile or vaginal discharge, abnormal

<sup>&</sup>lt;sup>11</sup> Patient Protection and Affordable Care Act, U.S. Code 42 (2010) § 300gg–13

<sup>&</sup>lt;sup>12</sup> Chlamydia - CDC Fact Sheet (Detailed); Available at: <a href="https://www.cdc.gov/std/chlamydia/stdfact-chlamydia-detailed.htm">https://www.cdc.gov/std/chlamydia/stdfact-chlamydia-detailed.htm</a>

vaginal bleeding, or inflammation of the prostate or testes. There is a wide range of potential complications, with females being particularly vulnerable. Pelvic inflammatory disease (PID) may develop in women, which can result in chronic pain or infertility. Pregnant women run the risk of miscarriage, infection of the newborn, chronic pelvic infections or tubal pregnancies that can rupture and cause death.

#### Gonorrhea

Caused by the *Neisseria gonorrhoeae* bacterium, the gonorrhea STD traditionally infects the mucous membranes of the reproductive organs in both sexes. Infections can also occur in the mouth, throat, eyes, and rectum. Gonorrhea is one of the most common infectious diseases in the United States, with CDC estimating around 820,000 new infections each year.<sup>13</sup>

Gonorrhea often presents in men as a urethral discharge, painful urination, or both. It may be delayed in presentation or in 10-15 percent of cases be asymptomatic. In many women, gonorrhea is asymptomatic during the acute phase. Despite being asymptomatic, women often proceed to serious complications from the infection. When symptoms are present, they include vaginal discharge, pain on urination, or abnormal vaginal bleeding. Non-genital infections present as ocular discharges, sore throat, or rectal pain or discharge. If the individual is already on an antibiotic for another condition, he/she may be partially or completed treated and escape detection because of blunted symptoms or false-negative lab cultures. If the person remains asymptomatic, the individual may continue to be infectious and his/her sexual partner could go untreated, and infertility can result. In patients that are immunocompromised, gonorrhea can be life threatening.

Gonorrhea is transmitted by sexual contact, with infection possible even without bodily fluid exchange. Treatment and curative therapy is currently achievable with a dual-therapy regimen of antibiotics. Prevention is aided by the use of condoms.

Antibiotic resistance is a significant, long-term threat for gonorrhea; and treatment guidelines have been updated frequently to match the pace of the development of resistant strains. Several federal initiatives exist to combat the specific threat of antimicrobial resistant (AMR) gonorrhea: the Gonococcal Isolate Surveillance Project (GISP)—with its companion program, the Enhanced

<sup>&</sup>lt;sup>13</sup> Gonorrhea CDC Fact Sheet (Detailed); Available at: <a href="https://www.cdc.gov/std/gonorrhea/stdfact-gonorrhea-detailed.htm">https://www.cdc.gov/std/gonorrhea/stdfact-gonorrhea-detailed.htm</a>

Gonococcal Isolate Surveillance Project (eGISP)—and Strengthening the United States Response to Resistant Gonorrhea (SURRG). These programs are included in the National Strategy to Combat Antibiotic Resistant Bacteria<sup>14</sup>.

#### **Syphilis**

Among the three STDs that comprise the focus of this study, syphilis is, perhaps, the most significant. Caused by the bacterium *Treponema pallidum*, syphilis entails symptoms and potential complications that, if untreated, can result in disability or death. Transmission occurs through contact with infected tissue, whether in the form of sores or bodily fluids. Transmission orally is possible but less common.

Syphilis, at this time, can be treated with penicillin in patients not allergic to the drug. Significant antibiotic resistance has not been observed. Timely diagnosis is critical due to the potential for severe complications and disease transmission. Other infectious diseases such as HIV are transmitted more easily to a sexual partner through open sores called chancres. Immunocompromised individuals are at risk for more severe complications earlier.

Though more severe, syphilis has the lowest number of reported cases of the three subject STDs of this study, with 101,567 reported new cases across all phases of infection in 2017, per CDC.

#### **Phases**

Syphilis, unlike chlamydia and gonorrhea, afflicts patients on a clinical timescale measured in months to years, and rarely (if ever) poses an acute threat. Infections follow the below stages, with complications possible at every step:

- **Primary Stage**: A single sore, known as a "chancre," appears at the site of infection. As that site can be within an orifice or located in an area otherwise hard to see, and is often painless, the infected individual may not notice it. The chancre will heal around a maximum of six weeks after appearance, regardless of treatment.
- **Secondary Stage**: If not stopped at the primary stage, the infection will progress to the second. In this stage, skin rashes or lesions/sores will appear at sensitive membranes, most

<sup>14</sup> Combating the Threat of Antibiotic-Resistant Gonorrhea; Available at: https://www.cdc.gov/std/gonorrhea/arg/CARB\_FACTSHEET-2018.pdf often the mouth, vagina, or anus. This may be concurrent with, or weeks after, the chancre having healed. The rash is not itchy or irritating, and may resemble rashes from other illnesses. In some cases, the rash may be so faint as to not be visible without close inspection. Some patients may develop large gray or white lesions in the groin, mouth, or armpit. In certain, more severe cases, flu-like symptoms, hair loss, and headaches may coincide with the rash. With or without treatment, the symptoms will end.

- **Latent Stage**: In the latent stage, the patient will present with no symptoms. This state can last for years.
- **Tertiary Syphilis:** If untreated or allowed to progress, latent syphilis may result in tertiary syphilis, a life-threatening syndrome. Often occurring ten to thirty years after first infection, tertiary syphilis affects the nervous system (including the brain), eyes, heart, blood vessels, liver, and even bones and joints. Depending on the organs affected, this can leave permanent damage and, in some instances, result in death.

At any stage of infection, neurosyphilis may develop, as may ocular syphilis. Both conditions involve the infection of the nervous system. Neurosyphilis can lead to headaches, altered mental states, dyskinesia, paralysis, and even dementia. With ocular syphilis, the bacterium infects the eyes, resulting in degradation of sight and, potentially, permanent blindness.

Congenital syphilis (CS) refers to a condition present in infants infected with syphilis perinatally or at the time of birth. CS can result in miscarriage, stillbirth, or premature birth, if infection and symptom expression occurs during pregnancy. In 2017, CDC reported that up to 40 percent of babies born to women with an active syphilis infection might be stillborn or die shortly after birth. Some babies born with CS may not display any symptoms at birth, but instead develop symptoms resembling tertiary or neurosyphilis later on in life. These effects can occur anywhere from a few weeks to even years after birth. Deformities and damage caused by CS can be irreversible and result in lifelong disability.

<sup>&</sup>lt;sup>15</sup> Congenital Syphilis CDC Fact Sheet; Available at: <a href="https://www.cdc.gov/std/syphilis/cong-syph-feb-2017-press.pdf">https://www.cdc.gov/std/syphilis/cong-syph-feb-2017-press.pdf</a>

#### **Infection Landscape across America**

In the recently released *Sexually Transmitted Disease Surveillance 2017* report, CDC underscored that reportable STDs in the U.S. have reached record highs, with a total of 2,295,739 cases reported. All three reportable STDs showed an increase in their rates, as did complicating factors, such as congenital syphilis, which although still a relatively small number overall, had a stark 44 percent increase in cases. The increases are not an anomaly—rates have been increasing in recent years as noted in the Introduction. The distribution of rates is uneven across the country, with the highest incidences generally reported in the South.

A total of 1,708,569 cases of chlamydia were reported to CDC, which, the Surveillance Report notes, makes it the, "most common notifiable condition in the United States." With a rate of 528.8 cases per 100,000 people, this represents a 6.9 percent increase in 2016 rates. Rates rose across all regions and all ethnic groups.

Gonorrhea saw an even greater increase in rates, with an 18.6 percent surge over 2016. Rates rose across all regions and ethnic groups, with 555,608 cases reported to CDC. Rates among men increased 19.3 percent; rates among women increased 17.8 percent.<sup>18</sup>

While representing the lowest number of cases, nominally, syphilis has shown a sharp and distressing rise in key areas. In 2017, 30,644 cases of primary and secondary syphilis were reported, a case rate of 9.5 per 100,000 people. This represents a 10.5 percent increase from 2016 to 2017. Rates increased in all demographics and in three-quarters of states and the District of Columbia. Although men accounted for almost 90 percent of all reported cases of primary and secondary syphilis, MSM comprised 68.2 percent of reported primary and secondary syphilis cases

<sup>&</sup>lt;sup>16</sup> Sexually Transmitted Disease Surveillance 2017; Available at: https://www.cdc.gov/std/stats17/default.htm

<sup>&</sup>lt;sup>17</sup> Sexually Transmitted Disease Surveillance (2017) Chlamydia; Available at: <a href="https://www.cdc.gov/std/stats17/chlamydia.htm">https://www.cdc.gov/std/stats17/chlamydia.htm</a>

<sup>&</sup>lt;sup>18</sup> Sexually Transmitted Disease Surveillance (2017) Gonorrhea; Available at: https://www.cdc.gov/std/stats17/Gonorrhea.htm

among men and women who were able to provide information on the sex of their partners.<sup>19</sup> Notably, the case rate for congenital syphilis increased dramatically, from 9.2 cases per 100,000 to 23.3 cases per 100,000 between 2013 and 2017.

Perhaps most alarmingly, the rates of all three diseases are almost certainly understated due to gaps in reporting and the fact that many infections will be mitigated by incidental treatment with antibiotics. Infections may occur and be cured without the individual being aware that he/she was infected.

#### **Health Equity Concerns**

Certain groups are uniquely vulnerable to sexually transmitted infections due to a variety of social and economic factors. Limited access to services, greater likelihood of high risk behaviors, fear or distrust of the healthcare system, and proximity to extant cases (among other conditions), contribute to higher STD rates among certain groups. For example, a 2008 study by CDC's Division of STD Prevention entitled, *Social Determinants and Sexually Transmitted Disease Disparities,* found that the rates of syphilis, HIV/AIDS, chlamydia, and gonorrhea among the black community could range from 5.4 to 17.8 times the rates in white communities<sup>20</sup>.

That same 2008 study identified key disparities in certain populations resulting from geographic segregation, health care provision and use, and socioeconomic status. For example, despite the fact that segregation is illegal in the U.S., the study found that segregation which may occur geographically by neighborhood can be a principal driver of disparity in healthcare access. Citing 2000 Census data that indicates 60 percent of "all census blocks" being racially homogenous, the study asserts that hindrances to healthcare access within those communities may result in disproportionate morbidity from STDs; poverty, lack of insurance, and underemployment are all factors correlated with higher STD rates, which, in turn, fuel those same factors<sup>21</sup>. STDs are amplified notably by these factors known as Social Determinants of Health. Although the data cited

<sup>&</sup>lt;sup>19</sup> Sexually Transmitted Disease Surveillance (2017) Syphilis; Available at: <a href="https://www.cdc.gov/std/stats17/Syphilis.htm">https://www.cdc.gov/std/stats17/Syphilis.htm</a>

<sup>&</sup>lt;sup>20</sup> NCBI Resources: *Social determinants and sexually transmitted disease disparities*; Available at: <a href="https://www.ncbi.nlm.nih.gov/pubmed/18936725">https://www.ncbi.nlm.nih.gov/pubmed/18936725</a>

<sup>&</sup>lt;sup>21</sup> Ibid, S14

here are dated, the patterns identified are not likely to have changed to such a degree as to nullify these conditions.

## **Emerging Drug Resistance**

Concerns about antimicrobial resistant bacteria (AMR) are burgeoning globally. Recent reports of AMR gonorrhea have garnered media and scientific attention, with assertions of "Super Gonorrhea" being just on the horizon<sup>22</sup>. In March 2018, a case of gonorrhea identified in the United Kingdom was reportedly fully resistant to the recommended first-line dual drug therapy<sup>23</sup>.

In the United States, there has been a concerted federal effort to address AMR threats, with gonorrhea included in the focus of anti-AMR efforts. The 2013 CDC report, *Antibiotic Resistance Threats in the United States*, named antibiotic resistant gonorrhea among, "the three most urgent threads of its kind."<sup>24</sup> Following this report, authored with the guidance of the President's Council of Advisors on Science and Technology, the White House issued the *National Strategy to Combat Antibiotic Resistant Bacteria* (CARB). In 2015, the White House published its five-year *National Action Plan for CARB*. Under this action plan, existing AMR programs were joined by new efforts and administratively organized under CDC's Division of STD Prevention.

#### **CDC AMR Gonorrhea Programs**

Historically, CDC has maintained multiple programs to monitor and address drug resistant strains. As noted earlier, two major surveillance programs are currently in operation: 1) GISP with its companion, eGISP, and 2) SURRG.

 $\frac{https://www.theguardian.com/commentisfree/2018/mar/30/super-gonorrhoea-antibiotic-crisis-drug-resistant-bugs$ 

https://www.cnn.com/2018/03/28/health/uk-man-multidrug-resistant-gonorrhea-intl/index.html

https://www.cdc.gov/drugresistance/biggest threats.html?CDC AA refVal=https%3A%2F%2Fwww.cdc.gov%2Fdrugresistance%2Fthreat-report-2013%2Findex.html

<sup>&</sup>lt;sup>22</sup> Opinion Medical Research: *Highly drug-resistant bugs are no longer a future problem. After decades of complacency, urgency is needed*; Available at:

<sup>&</sup>lt;sup>23</sup> CNN: First case of super-resistant gonorrhea reported; Available at:

<sup>&</sup>lt;sup>24</sup> CDC: Biggest Threats and Data; Available at:

• GISP was created in 1986 to monitor antimicrobial resistance in gonorrhea bacteria in the United States. Selected clinics, and state and local public health entities were joined with regional laboratories and CDC to collect and assess resistance information to detect resistant strains and treat them with the appropriate antibiotics. GISP operates by collecting gonorrhea specimens from the first twenty-five men diagnosed with urethral gonorrhea, who seek treatment at selected STD clinics around the country.<sup>25</sup> These samples are then tested against the antibiotics traditionally used to treat the infection. Launched in 2017, eGISP augments GISP capacity by expanding sample collection to women and extragenital sites in both sexes.

 Created, and launched in 2016 with goals of enhancing infrastructure and surveillance for detection of resistant strains, SURRG expands rapid detection and response capacity and promotes advanced field investigations into outbreaks of resistant strains. As of January 2018, nine jurisdictions were participating in this program<sup>26</sup>.

In addition to the two surveillance programs, CDC operates two networks of partner organizations:

1) the STD Surveillance Network (SSuN)—a coalition of state and local health departments that receive CDC funding to conduct sentinel and enhanced surveillance, and 2) the Antimicrobial Regional Laboratory Network (ARLN), a group of public health laboratories, equipped to handle AMR laboratory challenges.

Resistance is defined as significantly decreased susceptibility to a given antibiotic, meaning that increased dosages of that antibiotic would be needed to stop its growth. Currently, ceftriaxone is the drug-of-choice for gonorrhea treatment (in combination with oral azithromycin). CDC guidelines ask and recommend that clinicians report observed ceftriaxone resistance or treatment failures, as well as the collection of isolates for analysis from resistant cases. CDC has updated treatment guidelines to match evolving resistance abilities of *N. gonorrhoeae*, with the most recent

<sup>&</sup>lt;sup>25</sup> Appendix G lists GISP sites.

<sup>&</sup>lt;sup>26</sup> CDC: Combatting the Threat of Gonorrhea; Available at: https://www.cdc.gov/std/gonorrhea/arg/carb.htm

update in 2015 revising the previous dual-therapy solution. Susceptibility to azithromycin, however, decreased from 2013 to  $2016^{27}$ .

# **Intersecting Epidemics**

Related or intersecting conditions and challenges across the nation complicate efforts to address the STD epidemic. Concurrent and continuing outbreaks of other diseases such as HIV/AIDS, as well as shifting and rising substance abuse conditions such as opioid addiction, increase the risk factors for exposure among certain population groups. Shared risk behaviors, contact between so-called "bridge groups," and the added health effects of the complications in question, can have an amplifying effect on STD outbreaks.

#### HIV/AIDS

HIV presents with significant epidemiological and clinical connections to other STDs. Generally, rates of HIV infection have slowed in recent years.<sup>28</sup> This runs counter to the trend for those conventional STDs, which are increasing in number as described earlier in this report.

A 2018 study by Kenneth Mayer and Henry de Vries found that advances in the treatment and prevention of HIV has resulted in the adoption of risk behaviors that would previously effect HIV transmission, but now, facilitates the spread of traditional STDs.<sup>29</sup> Mayer and de Vries suggest the use of HAART and PrEP, the standard treatment and medical prophylactic measures for HIV, respectively, reduced the risk of HIV transmission to such a degree that high risk behaviors previously avoided are now readily practiced, describing the phenomenon as "antiretroviral optimism." <sup>30</sup> This newfound optimism, they went on to say, had the additional effect of epidemiologically uncoupling HIV from other sexually transmitted infections, as the same behaviors would no longer result in the same result: someone with HIV and syphilis could transmit syphilis

<sup>&</sup>lt;sup>27</sup> CDC: Antibiotic-Resistant Gonorrhea Basic Information; Available at: https://www.cdc.gov/std/gonorrhea/arg/basic.htm

<sup>&</sup>lt;sup>28</sup> HIV.gov: New HIV Infections Drop 18 Percent in Six Years; Available at: <a href="https://www.hiv.gov/blog/new-hiv-infections-drop-18-percent-in-six-years">https://www.hiv.gov/blog/new-hiv-infections-drop-18-percent-in-six-years</a>

<sup>&</sup>lt;sup>29</sup> HIV and STIs: The New Normal

<sup>&</sup>lt;sup>30</sup> Ibid, <sup>1</sup>

but not HIV during unprotected sex. Because of this decoupling, two intersecting-but-separate epidemics, known as a syndemic, have emerged.

With the fear of HIV transmission no longer as pronounced as it once was, and alternative therapies and medical prophylactic measures available to prevent exposure and infection with the virus, sexually risky behaviors, among key groups, are more readily practiced. For example, CDC's *National HIV Behavioral Surveillance* indicates that condom use among MSM declined 20 percent between 2005 and 2011.<sup>31</sup> The decreased use of condoms may be a contributing factor to the overall increase in STD transmission, particularly among MSM and associated groups.

#### **Drug Use**

Drug abuse has a noted relationship with STDs. A 2017 New York Times article<sup>32</sup> documented an ongoing outbreak of syphilis in Oklahoma fueled, in part, by drug use. Other jurisdictions beyond Oklahoma including Minnesota have reported syphilis outbreaks and increased rates in drug users.<sup>33</sup> A 2016 study followed participants in a community engagement program in North Central Florida, finding that participants who reported illicit drug use were as much as 4.12 times as likely to report one or more STDs compared to participants who did not report drug use.<sup>34</sup> A 2006 study, which found that methamphetamine use correlates with several high-risk sexual behaviors among high-risk communities, noted a relationship between methamphetamine usage and STD transmission, as well as

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<sup>&</sup>lt;sup>31</sup> NCBI Resources: *Trends in condom use among MSM in the United States: the role of antiretroviral therapy and seroadaptive strategies*; Available at: <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5838316/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5838316/</a>

<sup>&</sup>lt;sup>32</sup> New York Times: *Hunting a Killer: Sex, Drugs and the Return of Syphilis;* Available at: <a href="https://www.nytimes.com/2017/08/24/health/syphilis-std-united-states.html">https://www.nytimes.com/2017/08/24/health/syphilis-std-united-states.html</a>

<sup>&</sup>lt;sup>33</sup> Minnesota Department of Health Advisory: *Syphilis on the Rise, Outbreak in Drug Users;* Available at: <a href="http://www.health.state.mn.us/han/2017/feb27syphilis.pdf">http://www.health.state.mn.us/han/2017/feb27syphilis.pdf</a>

<sup>&</sup>lt;sup>34</sup> NCBI Resources: Prescription opioid use, illicit drug use, and sexually transmitted infections among participants from a community engagement program in North Central Florida; Available at: <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5836499/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5836499/</a>

<sup>&</sup>lt;sup>35</sup> NCBI Resources: *CDC Consultation on Methamphetamine Use and Sexual Risk Behavior for HIV/STD Infection: Summary and Suggestions;* Available at: <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1525267/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1525267/</a>

overlapping social determinants of health, communities need to be aware of STD outbreaks as potential sentinels of drug abuse, including opioids whose use has recently burgeoned to crisis levels.

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# Section 2: Entities with Roles in Stemming the Tide of STDs

STD prevention and control activities involve myriad entities ranging from Federal programs that provide funding, set national guidelines for disease prevention, conduct basic research, promote education and, for certain populations, provide direct services (e.g., the military, veterans, Native Americans) to state and local programs that carry out STD programs and services (and also provide funding) and to public and private health care providers who deliver clinical services. Federal efforts, alone, cut across numerous federal agencies.

# **Federal Agency Efforts**

# Centers for Disease Control and Prevention (CDC)

Among federal agencies, CDC in the Department of Health and Human Services (HHS) is the lead agency providing funding directly to states, localities, and territories to monitor, prevent, and control STDs. CDC provides national leadership, research, policy assessment and evidence-based scientific information about STDs to the medical community and the public. It publishes national STD guidelines and recommendations for screening and supports training and education of health and medical professionals involved in STD screening and treatment.

Organizationally located within the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), the Division of STD Prevention (DSTDP) is responsible for CDC's STD programs. The Division's primary focus is on assessment, assurance, policy development and prevention strategies.

- <u>Surveillance</u>: CDC assesses the burden and outcomes of reportable STDs to monitor trends, improve program management and resource allocation, and estimate costs associated with STDs.
- Prevention and control programs: CDC funds STD activities and staff, including disease investigators, in states, certain local jurisdictions, and territories. The primary funding vehicle is the cooperative agreement. The current cooperative agreement, referred to by DSTDP as CDC's "flagship program," is the "Assessment, Assurance, Policy Development, and Prevention Strategies (AAPPS)." AAPPS began in 2014 and ends on December 31, 2018.36

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<sup>&</sup>lt;sup>36</sup> AAPPS had two components: Part A focused on the core public health functions of assessment, assurance, and policy development and focusing on key STD prevention program activities and Part B—Gonococcal

The FY 2019 successor agreement, "Strengthening STD Prevention and Control for Health Departments (PCHD)," begins on January 1, 2019, and runs for five years. PCHD agreements will focus on conducting surveillance; supporting disease investigation and intervention; promoting screening, diagnosis, treatment, and prevention; and analyzing and using data. Evaluation of the results of the AAPPS cooperative agreement informed this successor PCHD cooperative agreement. (See <u>Appendix E</u> for the PCHD announcement).

- Internal and external workforce development and capacity building: CDC supports partnerships and funds, for example, the National Network of STD Clinical Prevention Training Centers open to public and private health providers; the STD/HIV Disease Intervention Services Training Centers; and the DIS Certification Program.
- Research and evaluation: Examples of current research priorities include efforts targeted to populations with the highest burdens of disease—adolescents and young adults, men who have sex with men (MSM) and transgender and pregnant women; and promoting the development of vaccines, therapeutics, and point of care diagnostic tests.

The Division's work is guided by its strategic plan. CDC has issued a number of strategic plans over the years to identify priorities for addressing STD prevention and control. The current STD Division plan, with performance measures, covers the period of 2017-2022. The division's plan aligns with the NCCHSTP's Plan with several STD objectives and performance measures mirrored in each plan.

The DSTDP strategic plan aspires to build the foundation for decreasing STD morbidity, health disparities from STDs, and the incidence of STDs. DSTDP has developed a roadmap for preventing and controlling the rising rates of chlamydia, gonorrhea and syphilis with four key strategies:

#### • Enhance surveillance

Isolate Surveillance Project (GISP), was a collaborative project involving CDC, regional GISP laboratories and local or state STD programs and their affiliated STD clinics and local public health laboratories. The goal was to establish a scientific base for the selection of treatment options and allow changes in treatment recommendations and practices before widespread treatment failures occur due to drug resistance. In addition, a supplemental funding announcement was released in 2017, "Supplemental Funding for Enhanced Congenital Syphilis Response," to strengthen capacity to address congenital syphilis and build upon activities undertaken in the original AAPPS. The supplemental funding targeted a select set of project areas with high rates of congenital syphilis.

- Promote cost-effective STD interventions (e.g., outbreak investigations, testing and treatment, partner services, and linkage to care)
- Increase uptake of CDC screening and treatment recommendations
- Strengthen evidence for STD prevention and control

The plan's overarching goals are to:

- Eliminate congenital syphilis
- Prevent primary and secondary syphilis
- Prevent antimicrobial resistant gonorrhea
- Prevent STD-related pelvic inflammatory disease, ectopic pregnancy, and infertility

The CDC/DSTDP website<sup>37</sup> hosts a wealth of information on STDs geared toward different audiences, including the general public. The information is easily accessible and reader friendly. For example, the CDC AtlasPlus data tool<sup>38</sup> allows users to build custom reports (charts, tables or maps) culled from surveillance files by disease and broken out by geography, year (data are currently available for the years 2000-2016), or by national, state, or county. Age and race are not broken out—"all ages" and "all races" are the current definers. Program operations guides are also available for public health personnel and others involved in managing STD prevention programs. The guides, developed originally, in part, in response to the Institute of Medicine's *Hidden Epidemic* report provide guidance and techniques for developing STD prevention and control programs and systems.

DSTDP coordinates internally within CDC, for example, with the Center for Surveillance and National Center for Health Statistics on surveillance and data related issues and within NCHHSTP, it works closely with the Division of HIV/AIDS and the Division of Adolescent Health on STD related initiatives. Externally, DSTDP coordinates and collaborates with other HHS agencies and with other federal agencies, state and local partners, and a wide variety of nongovernmental groups and

<sup>&</sup>lt;sup>37</sup> CDC: About the Division of STD Prevention; Available at: <a href="https://www.cdc.gov/std/dstdp/default.htm">https://www.cdc.gov/std/dstdp/default.htm</a>

<sup>&</sup>lt;sup>38</sup> CDC: NCHHSTP AtlasPlus; Available at: <a href="https://www.cdc.gov/nchhstp/atlas/index.htm?s-cid=bb-od-atlasplus\_002">https://www.cdc.gov/nchhstp/atlas/index.htm?s-cid=bb-od-atlasplus\_002</a>

associations such as the National Coalition of STD Directors (NCSD), the National Association of County and City Health Officials (NACCHO), the Association of State and Territorial Health Officials (ASTHO), among others, to carry out its core functions and activities. CDC relies on its partner organizations to provide technical assistance to states and localities and will tap their help in surveying their constituencies on issues. For example, NACCHO is conducting surveys to assess the level of publicly funded STD services offered at the state and at the local levels per a request and funding from CDC.

CDC's PCHD cooperative agreement also promotes partnerships with HIV and maternal child health surveillance counterparts and emphasizes an important cross-cutting aspect of comprehensive, effective STD prevention and control, particularly given overlapping epidemics, key populations, and intervention strategies. HIV, in particular, is called out as STD programs are inherently involved in high impact HIV prevention, and HIV programs are involved in STD prevention.

According to CDC officials, building relationships is particularly key to effective coordination across the federal agencies given time and resource constraints. Moreover, coordination is critical given the number of federal agencies (highlighted below) that deal with STD issues and provide grants and program services related to STD prevention and control to states and localities.

A Federal Advisory Committee Act (FACA) committee—the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis, and STD Prevention and Treatment— is in place at the Health Resources and Services Administration (HRSA). The committee's charge is quite broad with HIV and most recently the state of opioids taking up a large part of the agenda. However, an example of a recent (2018) STD-related effort is an STD workgroup drawn from the larger committee that provided comments on the draft DSTDP/CDC clinical guidelines for STD care. CDC is incorporating the input into the planned update to the 2015 guidelines scheduled for release in 2019. Finally, language inserted into the FY 2019 HHS Appropriation Committee Report, supports and encourages collaboration between CDC and HRSA, and between CDC and the Centers for Medicare and Medicaid (CMS). As well, the prior FY 2018 Committee Report called out coordination between CDC and the National Institutes of Health (NIH),<sup>39</sup> and highlighted the recognition that coordination and collaboration across federal agencies is necessary in order to address the rising STD rates.

<sup>&</sup>lt;sup>39</sup> 115<sup>th</sup> Congress Conference Committee from the House (115-862) and Senate (115-289) Reports, 2<sup>nd</sup> Session, Department of Labor, Health and Human Services and Related Agencies Appropriations Bill, 2019

## Other Federal Agencies with a role in STD Prevention and Control

Given the mission and expanse of HHS, it is not surprising that a number of other HHS agencies, in addition to CDC, have a role in STD prevention and control—some of more significance or size than others. Still other federal agencies such as the Department of Defense, the Department of Veterans Affairs, and the Department of Justice's Federal Bureau of Prisons have roles, as well. So, while CDC has the lead role, there are many federal players across the STD space. Below is a snapshot of those agencies.

#### U.S. Department of Health and Human Services Agencies

#### **Health Resources and Services Administration (HRSA)**

HRSA supports health programs and services targeting the underserved and at-risk populations and promotes improvements in healthcare access and quality. HRSA has a key, collaborative role with CDC in STD prevention and control, through the following bureaus/offices.

- Bureau of Primary Health: The Bureau administers the Health Center Program, Section 330 of the Public Health Service Act,<sup>40</sup> providing primary and related care health services. These services include voluntary family planning, as a component of reproductive healthcare and screening and treatment of STIs (sexually transmitted infections). The health centers, known as Federally Qualified Health Centers (FQHCs), provide affordable and accessible primary care to patients regardless of their ability to pay. They play an important role as community-based health centers on the front line, providing STD screening and treatment services, particularly in communities where STD clinics have shuttered due to state and local budget cuts.
- *HIV/AIDs Bureau:* The Bureau administers the Ryan White HIV/AIDS program, which funds direct healthcare and support services for individuals living with HIV. The program coordinates with states, cities, and local clinics, or community-based organizations to

and the Senate Report (115-150), 1st Session, Department of Labor, Health and Human Services and Related Agencies Appropriations, 2018

<sup>&</sup>lt;sup>40</sup> National Association of Community Health Centers: 330 Statute and Program Requirements; Available at: <a href="http://www.nachc.org/policy-matters/regulatory-issues/330-program-requirements/">http://www.nachc.org/policy-matters/regulatory-issues/330-program-requirements/</a>

deliver HIV care, treatment, and support to low-income people living with HIV. Ryan White is a payer of last resort, paying for services not covered by other federal or state programs or private insurance.<sup>41</sup> The program allows recipients to use HIV/AIDS funds to help support STD services. (Please see, <u>STD Funding</u> in Section 3.)

- In January 2018, the Bureau posted a notice of funding opportunity for a cooperative agreement supporting a three-year demonstration project—"Improving Sexually Transmitted Infection Screening and Treatment among People Living with or at Risk for HIV." Its purpose was to fund a single entity that will work with HRSA to promote and evaluate clinical service and system-level interventions to improve the screening and treatment of STIs among low-income people living with HIV or at risk of HIV. The recipient would identify three service jurisdictions and fund between three and five intervention sites within the jurisdictions to implement the interventions. In August 2018, the cooperative agreement was awarded to Rutgers School of Nursing; it will run from September 30, 2018 through September 29, 2021. Clinical and systems-level institutions in Washington, D.C., northern Florida and the Florida panhandle, and southern Louisiana will partner to implement, evaluate and disseminate results and best practices identified during the course of the interventions.
- *Maternal and Child Health Bureau*. The Bureau administers the Maternal and Child Health Program, a block grant program aimed at improving the health of mothers, children, and their families, especially for those with low incomes or limited availability of care. Reducing infant mortality and providing prenatal, delivery, and postnatal care to women, especially at risk and low income women, are key strategies. The Bureau collaborates with CDC/DSTDP on congenital syphilis.

<sup>&</sup>lt;sup>41</sup> The Ryan White Program comprises five parts: Part A—targets cities disproportionately affected by HIV; Part B—assists states and territories; Part C—focuses on quality primary care services with intervention, planning, and development grants; Part D targets women, infants, children, youth, and their families; and Part F funds the AIDS Education and Training Centers for healthcare providers.

• *Office of Women's Health.* The Office leads women's health-related activities across HRSA; and in that role, oversees the Women's Preventive Services Guidelines,<sup>42</sup> which include the recommendation for directed behavioral counseling by a healthcare provider or appropriately trained individual for sexually active adolescents and adult women at an increased risk for STIs.

#### **National Institutes of Health (NIH)**

At NIH, two institutes have major roles in STD prevention and control:

- The National Institute of Allergy and Infectious Diseases (NIAID) funds and conducts both basic and clinical research on STDs. A current key focus is on antibiotic drug resistant gonorrhea and vaccine development. NIAID also funds and conducts collaborative infectious and STD clinical research with the Department of Defense's Infectious Disease Clinical Research Program (IDCRP) to reduce the impact of the diseases on the military.
- The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) funds clinical research including STD related research. The focus is on women and children. One example of a completed study noted on the NICHD website is "Preventing Congenital Syphilis."

#### **Centers of Medicare and Medicaid (CMS)**

CMS oversees the Medicare and Medicaid programs, which finance clinical care, including STD screening and treatment for covered populations. Medicare is a federal program for seniors (65 years and older) and certain persons with severe disabilities and end stage renal disease. Medicaid is a joint federal and state program administered by the states that set eligibility requirements, within broad federal guidelines. It is a means-tested program, intended for the persons meeting income eligibility requirements, based on the federally established poverty level. Both programs serve as the payer for covered medical services that a wide range of clinical care providers may provide.

<sup>&</sup>lt;sup>42</sup> The Women's Preventive Services Guidelines were developed in concert with the National Academies of Sciences, Engineering and Medicine (formerly, the Institute of Medicine) report, *Clinical Preventive Services for Women: Closing the Gap*, to guide clinicians on services they should routinely offer to patients.

CMS also administers large portions of the Patient Protection and Affordable Care Act, which established a set of essential health benefits—e.g., preventive services, including the screening of STDs—that public and private health insurers are expected to cover. These services do not require a patient co-pay. (Section 4 discusses the challenges related to these programs.)

#### **Substance Abuse and Mental Health Services Administration (SAMSHA)**

The SAMSHA leads efforts to advance the nation's behavioral health. Its goal, working with partner agencies, is to reduce the impact of substance abuse and mental health on communities. SAMSHA collaborates with CDC on co-occurring conditions for individuals with STDs and publishes best practice guidance, known as TIPs<sup>43</sup>—Treatment Improvement Protocols—that crosscut co-occurring conditions such as substance abuse with the homeless, and HIV and STDs.

#### **Indian Health Service (IHS)**

IHS is the federal health program for American Indians and Alaska Natives. IHS provides comprehensive healthcare services and collaborates with CDC and its partners on STD prevention and control screening, treatment, outreach and educational approaches, adapting them for its constituency. IHS also conducts surveillance and in concert with CDC publishes an Indian Health Surveillance Report every two years.

#### **Food and Drug Administration (FDA)**

FDA has oversight responsibility for insuring the safety of pharmaceuticals and diagnostic tests used in the prevention and treatment of STDs and funds research to support its regulatory responsibilities and to advance health.

#### Office of the Assistant Secretary for Health

Two offices, in particular, in the Office of the Assistant Secretary for Health play a role in STD prevention.

Substance Abuse and Mental Health Services Administration Pu

<sup>&</sup>lt;sup>43</sup> Substance Abuse and Mental Health Services Administration Publications, Treatment Improvement Protocols (TIPS); Available at: https://store.samhsa.gov/series

- Office of Population Affairs—administers Title X of the Public Health Service Act<sup>44</sup>, the Family Planning Program. The program is the only domestic program devoted solely to family planning and related preventive health services. Title X-funded clinical services include contraceptive services and supplies, STD screening and treatment, and preconception healthcare. These services are confidential and must be available to low-income individuals on a sliding fee scale. The program funds grants to providers rather than direct reimbursement for services.
- *Office of Adolescent Health*—provides links to resources on adolescent health and STDs and administers the Teen Pregnancy Initiative<sup>45</sup>, which focuses on preventing teen pregnancy and educating teens on STDs and HIV prevention.

# Other Federal Agencies

#### **Department of Defense (DoD)**

Healthcare for active service members is provided by DoD. Within DoD, the Armed Forces Health Surveillance Center (AFHSC) monitors and evaluates surveillance data, including STD infections occurring across the military, through the Defense Medical Surveillance System. A Medical Surveillance Monthly Report provides evidence-based estimates of incidence, distribution, impact, and trends of health-related conditions among service members. An Infectious Diseases Clinical Research Program (IDCRP), created under an interagency agreement between the Uniformed Services University of the Health Services and NIAID, supports clinical research, including STD-related studies, with the military health system. STIs are a special focus; IDCRP has established a goal to support DoD STI prevention, diagnosis, and treatment among active-duty members and beneficiaries. Examples of IDCRP initiatives include the GC (Gonorrhea) Resistance Study and Repository and the Sexual and Social Network Study.

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<sup>&</sup>lt;sup>44</sup> Title X – Population Research and Voluntary Family Planning Programs; Available at: <a href="https://www.hhs.gov/opa/sites/default/files/title-x-statute-attachment-a-0.pdf">https://www.hhs.gov/opa/sites/default/files/title-x-statute-attachment-a-0.pdf</a>

<sup>&</sup>lt;sup>45</sup> Office of Adolescent Health, Teen Pregnancy Prevention Program; Available at: https://www.hhs.gov/ash/oah/grant-programs/teen-pregnancy-prevention-program-tpp/about/index.html

#### **Department of Veterans Affairs (VA)**

VA provides clinical care services to veterans through its hospital and outpatient clinic systems, administered by the Veterans Health Administration (VHA). Within VHA, the National Center for Health Promotion and Disease Prevention promotes "healthy living" with educational materials and guides addressing STIs.

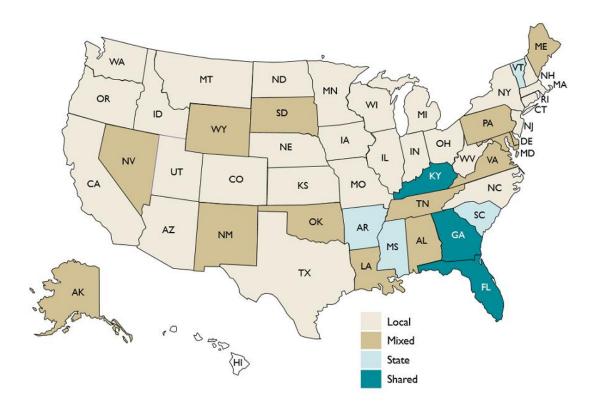
#### **Department of Justice—Federal Bureau of Prisons (FBOP)**

FBOP provides clinical services—screening and treatment—for individuals incarcerated in the federal prison system. FBOP developed clinical guidance, adapted from the CDC, to medically manage exposure to and to treat STDs within the prison setting.

#### **State and Local Efforts**

States and local jurisdictions are the primary providers of public health STD prevention and control services. Essentially, they are where the action is. How these states and localities structure and fund STD programs and services are very much a function of state and local laws and regulations, local customs/cultures, and demographics, as well as morbidity rates. As a result, wide variation exists across the nation in state and local programs. The actual provision of services takes place at the local level, but the responsibility for program administration varies. In more than half the states, public health is a state program but administered locally; in some, it is fully state administered; and in others, there is a shared or mixed governance (i.e. more than one governance type). Figure 1, on the following page, is a map of the United States that depicts in which manner public health is administered by each state, respectively.

Figure 1: NACCHO Forces of Change Profile Study 2015; Public Health Program Governance



Irrespective of their size and structure, there are six core functions performed by state and local programs. $^{46}$ 

Table 3 – Six core functions performed by state and local programs

| Core Function                 | Description   |  |  |  |  |
|-------------------------------|---|--|--|--|--|
| Public Health Surveillance    | State health departments collect and report on STD cases to CDC for national tracking to identify patterns, trends, and outbreaks and respond locally to outbreaks. |  |  |  |  |
| Testing                       | State and local programs help make screening services accessible—particularly for uninsured high risk individuals and individuals with known exposure to an STD.    |  |  |  |  |
| Treatment and Linkage to Care | Disease intervention specialists (DIS) help infected persons get treatment and help link partners to testing and treatment.   |  |  |  |  |
| Contact Tracing               | DIS perform outreach going into communities to find STD cases and prevent future cases.   |  |  |  |  |
| Behavioral Counseling         | STD program staff work one-on-one with patients to determine risk, set goals, and develop plans.  |  |  |  |  |
| Education                     | Program staffs host workshops, provide educational materials, collaborate with schools and community groups, and share information with healthcare providers.       |  |  |  |  |

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 $<sup>^{46}</sup>$  CDC website: STD Spotlight on STD Prevention and Control Programs

As noted in the recent CDC PCHD notice of funding opportunity, "Strengthening STD Prevention and Control for Health Departments," it is the state and local health departments that have the "boots on the ground" ability to monitor and understand local trends through case-based surveillance and to respond to emerging threats.<sup>47</sup> Most importantly, they have the authority to conduct disease investigation activities. With most STDs now reportedly diagnosed outside public STD clinics, they must also work with primary and other healthcare providers and organizations to promote STD screening, treatment, and other services.<sup>48</sup>

State and local programs depend on federal funding for STD initiatives, as well as technical assistance and education. At times, in the case of outbreaks and disease intervention, DSTDP's Field Office staff will augment these state and local public health staff and assist in outbreak response. In addition to publicly provided support, a number of non-governmental organizations (NGOs) provide important assistance to state and local public health departments, often in concert with federal STD programs. There are many groups—but some of the more prominent include:

- National Association of State STD Directors (NCSD)
- National Association of County and City Health Officials (NACCHO)
- Association of State and Territorial Health Officials (ASTHO)
- American Sexually Transmitted Diseases Association (ASTDA)
- American Sexual Health Association (ASHA)

The NGO groups advocate for their constituencies and provide critical support in technical assistance, policy development, and education. ASTDA, whose mission is the control and study of STDs, publishes a scientific journal dedicated to STDs.

<sup>48</sup> Centers for Disease Control and Prevention, Sexually Transmitted Diseases Treatment Guidelines, MMWR Recommendations and Reports 2015;64(3)

<sup>&</sup>lt;sup>47</sup> Centers for Disease Control and Prevention, National Center for HIV-AIDS, Viral Hepatitis, STD and TB Prevention, "Strengthening STD Prevention and Control for Health Departments," (STD-PCHD), CDC-RFA-PS19-1901,2018

States and local public health departments also collaborate with the other programs noted earlier, such as the Title X-Family Planning, to advance STD prevention and control activities. In fact, CDC-funded programs require program collaboration. For example, CDC expects recipients of the upcoming PCHD cooperative agreement to work with:

- regional centers for STD clinical training and education through the National Network of STD Clinical Prevention Training Centers to promote quality and identify healthcare providers and organizations to target for clinical training and education; and
- the National Network to Enhance Capacity of State and Locally Transmitted Disease Prevention Program (NNECS) to strengthen policy development, communication, and collaboration, and to address STD technical issues. (Note: The sponsor of this study, NCSD is the current contractor for NNECS.)

CDC also expect recipients to seek partnerships with clinical providers and healthcare organizations such as FQHCs, school-based health centers, correctional facilities, Medicaid programs, large health plans, professional medical and nursing organizations, and academic institutions.

Some states and local public health departments have integrated their STD and HIV programs to provide combined service delivery. As noted earlier, HRSA's Ryan White HIV/AIDS program money may be used to help support some STD services. CDC's PCHD cooperative agreement also requires recipients to work closely with CDC-funded HIV surveillance and prevention programs operating in their area; STD-related HIV prevention is a cross-cutting strategy.

Challenges confronting states and local public health departments include the lack of predictability in funding and constrained resources at the federal, state, and local levels even in the face of burgeoning rates of STDs. Staffing capacity and the ability to influence other organizations are barriers to implementing STD initiatives.<sup>49</sup> Section 3: Challenges and Barriers to Effective STD Prevention and Control, discusses these issues in greater detail.

#### **National Plans to Address STDs**

 $<sup>^{</sup>m 49}$  The Interim Assessment of STD AAPPS, Summary of Key Findings, CDC/DSTDP, 2017

Over the years, there have been a number of national strategies and action plans to address individual sexually transmitted diseases and crosscutting health and wellness plans that call out STDs as an urgent and major public health problem.

Examples of broad-based plans within the past twenty years include:

- *National Prevention Strategy* (June 2011)
- Healthy People 2010 and Healthy People 2020
- The Surgeon General's Call to Action to Promote Sexual Health and Responsible Sexual Behavior (July 2001)

These plans specifically cite STDs as a significant health risk and establish strategies or action steps for addressing STDs in the overarching context of health and wellness. The *National Prevention Strategy* emanated from the National Prevention Council,<sup>50</sup> which was created by the Patient Protection and Affordable Care Act; the Surgeon General is the chair. *Healthy People* began as a Surgeon General initiative in 1979. The first *Healthy People* plan was issued in 1990; it has been updated and issued every decade since. "Healthy People 2030," is currently under development. And, as its name implies, *the Surgeon General's Call to Action to Promote Sexual Health* was also a Surgeon General initiative.

Examples of disease specific plans include:

- National Strategy for Combating Antibiotic Resistant Bacteria (September 2014)
- National HIV/AIDS Strategy for the U.S. Updated to 2020 (July 2015)
- National Viral Hepatitis Action Plan (January 2017)

The *National Strategy for Combating Antibiotic Resistant Bacteria* emanated from the White House and informed by the work of the President's Council of Advisors on Science and Technology. The White House Office of National AIDS Policy released the first National AIDS Strategy in 2010.

<sup>&</sup>lt;sup>50</sup> The National Prevention Council is a separate entity from the U.S. Preventive Services Task Force (USPSTF). USPSTF, created in 1984, is an independent volunteer panel of experts in prevention and evidence-based medicine that issues recommendations for patient care. A recent example is the recommendation for syphilis screening for in pregnant women issued in September 2018. It is unclear whether the National Prevention Council is currently active; the last annual report is dated 2014.

Planning is currently underway, led by the HHS Office of the Assistant Secretary of Health, to update the plan along with the *National Viral Hepatitis Action Plan*, first released in 2011. As noted in the description of the latter plan,<sup>51</sup> these are national plans—not federal agency plans.

This list is illustrative only—and not intended to be all encompassing of the many plans and initiatives that have been established as national health priorities emerge. However, a similar national plan addressing the reportable STDs is currently not in place.

In 1999, CDC issued the *National Plan to Eliminate Syphilis from the United States*, commonly referred to as SEE—the Syphilis Elimination Effort. It was a collaborative effort between CDC and a wide range of partners, both public and private, at the national, state, and local levels.<sup>52</sup> While "national" in name, it focused on geographic areas with high morbidity. At the time of its launch, the data suggested that it was possible to eliminate syphilis as rates were close to their nadir nationally.<sup>53</sup> Rates in the targeted areas did see drops in the number of cases; but by 2002, rates were increasing among certain populations. In May 2006, CDC issued an updated plan, adjusting the elimination goal and refocusing the effort. The program ended in 2013; and, while it achieved some early successes, it is not considered a success overall, as syphilis rates have increased steadily since. In addition, as an unintended consequence, those initial successes contributed to reductions in funding at both the federal and state, and local levels, in turn affecting prevention and control efforts. Essentially, monies were shifted to other priorities—not an uncommon occurrence for programs competing for the same pools of available, but often limited, funding.

CDC conducted a number of evaluations of the 2006 SEE program, and the lessons learned are instructive for future plans. Dr. Gail Bolan, the DSTDP Director and her colleague Jo Valentine, the DSTDP Director of the Office of Health Equity, recently published an article<sup>54</sup> highlighting key lessons learned from the SEE experience. They grouped the lessons into five essential program components:

<sup>&</sup>lt;sup>51</sup> National Viral Hepatitis Action Plan 2017-2020, Department of Health and Human Services, January 2017

<sup>&</sup>lt;sup>52</sup> The National Plan to Eliminate Syphilis from the United States

<sup>&</sup>lt;sup>53</sup> "Syphilis Elimination: Lessons Learned Again," Jo A. Valentine, MSW and Gail A. Bolan, MD, *Sexually Transmitted Diseases*, Volume 45, Number 95, September 2018

<sup>&</sup>lt;sup>54</sup> Ibid.

- 1) *Access to care is essential*—Financial, structural, personal, and interpersonal barriers can limit access to STD healthcare services.
- 2) *Expanded partnerships are critical*—The wellness context requires engagement of new partners to incorporate evolving conceptual frameworks such as those addressing equity and sexual health.
- 3) *Diverse epidemics require tailored interventions*—Public health programs do not evolve as quickly as STD epidemics (i.e., delays occur between outbreak and programmatic responses.)
- 4) *Effective program evaluation is critical*—More robust, rigorous program evaluation is needed to help insure how best to use limited resources. (The authors further note here that the diversity of the syphilis high morbidity areas made national evaluation impractical.)
- 5) *It takes more than money*—The SEE campaign did not receive funding at the requested level, but successful programs can adapt to limited resources by partnering with others.

The DSTDP Strategic Plan, together with the NCHHSTP Strategic Plan, establishes *CDC* strategies and *CDC* action plans, a point division staff quickly to note. While national in scope, the plans and strategies address only what is within CDC's purview. They do not, and cannot, extend beyond its purview. Moreover, CDC cannot realistically be held to a performance standard of disease elimination, when it does not control the provision of services. However, it can advocate, influence, and support partners through policy, funding, technical assistance and the like, which, in turn, can affect a reduction of STDs.

A national STD action plan may be on the horizon. The Office of the Assistant Secretary for Health is spearheading a planning effort to strategize and develop such a plan. The effort is in its nascent stages, but the goal is to finalize a national STD action plan by early 2020, a relatively aggressive timetable. An interagency working group is being formed and listening sessions, as well as direct outreach to stakeholders including state and local entities and NGOs, is planned. To develop a truly national STD plan, planning must include all partners—federal, state, local, and territorial agencies/jurisdictions, nonprofits, academic institutions, and the like, and the plan itself must be actionable. The efforts outlined by the Office of the Assistant Secretary for Health appear both appropriate and timely—and a very important step in addressing the STD epidemic.

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# Section 3: Challenges and Barriers to Effective STD Prevention and Control

A number of significant challenges and barriers confront STD program staff, public health providers, and their partners in their efforts to effect change and help reduce incidence of STDs. First, the complex and often-changing system for delivering and paying for healthcare is a challenge for users to comprehend, let alone navigate. For CDC, challenges include the fragmentation of funds across programs—both the programs it funds and those related programs funded in other ways—together with the challenges of coordinating efforts; the limited control of spending by states, territories, and cities; and the inverse relationship between the growth in STDs and funding levels. Further, data to understand the economic impact of STDs and the effects of changes to funding on future economic impact are in short supply. Technology also poses an additional challenge. The collection of basic surveillance data involves solving substantial interoperability problems across jurisdictions. Finally, evaluation is hindered by inherent data and design issues and funding challenges, which present barriers to developing the kinds of studies that can advance program effectiveness. These challenges are discussed in more detail below.

#### **Provision of Healthcare Services**

#### A Fragmented System at All Levels

The United States healthcare system is like a multi-dimensional puzzle with many moving parts. The federal, state, and local governments and the territories can, and do, make laws and regulations concerning aspects of access to the healthcare system. Payment for healthcare services comes via the government, through for example, Medicare for seniors and individuals with specified disabilities (as noted in <u>Section 2</u>), and Medicaid for low income families and individuals.<sup>55</sup> Separate systems provide active duty military and veterans their medical care that delivers many health

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<sup>&</sup>lt;sup>55</sup> Although these are the two largest healthcare programs, others also exist such as Children's Health Insurance Program (CHIP), and the Ryan White program which offer insurance coverage and/or services to specific groups of beneficiaries. Further prison populations receive care through the Federal Bureau of Prisons for federal facilities and separate provider entities in each of the 50 states. The Indian Health Service (IHS) provides healthcare to Native Americans living on reservations and those living in some urban areas.

services directly to those covered. Private insurance coverage typically provided through employers and less often purchased directly by individuals, covers large numbers of families and individuals across the nation. The number covered by private health plans has grown since implementation of the Patient Protection and Affordable Care Act (ACA) which made private plans available on federal and state marketplaces. Finally, millions of Americans have no healthcare coverage at all. In short, the United States really does not have a single healthcare system. Rather, the "system" is different both across and within states.

With the implementation of the ACA in 2014, the already complex landscape of federal, state, and territory laws and regulations became even more complex. Major provisions of ACA included:

- Requiring that insurers accept all applicants, regardless of pre-existing condition or sex, and charge the same rate without regard to either pre-existing condition or sex
- Requiring everyone to have insurance, with a penalty for remaining uninsured that would take effect in 2016—two years after implementation of the law<sup>56</sup>
- Offering the financing for Medicaid expansion to the states, so that Medicaid could be offered to an increased number of their low-income residents<sup>57</sup>
- Allowing children to remain on their parents' health insurance until age twenty-six
- Offering premium subsidies to households with earnings from 100 percent to 400 percent of the federal poverty line to make coverage more affordable
- Requiring that insurance cover essential health benefits, including preventive care.

As intended, the ACA has substantially reduced the number of uninsured in the years since implementation. However, it has not achieved its full promise for a number of reasons. First, nineteen states are not Medicaid expansion states, leaving many of the poor in those states without

<sup>&</sup>lt;sup>56</sup> This requirement, rescinded by the 2017 Tax Cuts and Jobs Act, is no longer in effect as of January 1, 2019.

<sup>&</sup>lt;sup>57</sup> Originally, a requirement, Medicaid expansion is optional, because of the June 28, 2012, ruling on ACA. In participating states, eligibility for Medicaid is increased for those with income up to 133 percent of that states' poverty level, and for initial years, the federal government pays 100 percent of the cost.

coverage.<sup>58</sup> These states still have the basic Medicaid that insures those below a certain poverty line. In addition, although many buyers receive subsidized premiums, these premiums are still unaffordable to a substantial portion of those needing coverage. Moreover, for those with insurance, high deductibles and co-pays may limit their access to care. Finally, others may remain uninsured because they find the requirements to apply for insurance too challenging or they objected to mandated coverage and preferred to pay a penalty for abstaining from coverage. The penalty for not maintaining healthcare coverage, however, disappears in 2019, as a result of the Tax Cuts and Jobs Act signed into law in December 2017.

In some cases, provisions of the ACA may have had an unintended consequence that affects STD treatment options. Believing that ACA extended insurance coverage to more Americans (which it did)<sup>59</sup>, some government-supported public healthcare alternatives such as STD clinics were closed anticipating a reduction in need.<sup>60</sup> However, although ACA did, in fact, expand coverage, there are still millions of people not covered by insurance or other healthcare programs. This means that their STD testing options became more limited. As STD clinics closed, the available alternative for those in certain medically underserved communities was a Federally Qualified Health Clinic (FQHC). But these clinics often lacked capacity to add large numbers of additional patients to their workload. In addition, these clinics may not be staffed with the disease intervention specialists (DIS) personnel needed to do both counseling of those who test positive for STDs and contact tracing of partners to ensure that they also receive treatment.

<sup>&</sup>lt;sup>58</sup> Virginia becomes an expansion state on January 1, 2019. In addition, 2018 election results will increase the number of participating states. Voters in three states—Idaho, Nebraska, and Utah—approved referendums to adopt the expanded program; and in Maine, where voters had earlier approved expansion, but the current governor had halted its implementation, the newly elected incoming governor plans to proceed with implementation.

<sup>&</sup>lt;sup>59</sup> From a 2013 baseline (pre-ACA) of 57 million covered by Medicaid, coverage grew to 73 million in June 2018. The bulk of the growth came in the thirty-one Medicaid Expansion states (about 15 million people) compared to those states that did not adopt Medicaid Expansion (about 3 million people)

<sup>&</sup>lt;sup>60</sup> Funding cuts unrelated to ACA no doubt also contributed to closing clinic facilities that served the uninsured population. Public health facilities, including STD clinics, were closing prior to implementation of ACA.

In addition, a very popular provision of ACA extends young adults' insurance coverage on parents' policies until the age of twenty-six. The positive consequence in terms of potential testing and treatment for STDs is that treatment is available to them through insurance-related providers. The downside, however, is that these insurance providers send the person holding the policy—the parent—an "Explanation of Benefits." This means that parents will be informed of any STD testing and treatment—an outcome that young adults may want to avoid. According to a National Center for Health Statistics Data Brief (2016), 7 percent of youth between the ages of fifteen and twenty-five would not seek sexual or reproductive healthcare because of concerns that their parents would find out. For the youngest cohort in this survey, 17 percent of youth age fifteen to seventeen years old would avoid this type of healthcare because of concerns related to parents finding out.<sup>61</sup>

In addition to a fragmented array of laws and regulations and a variety of sources of payment for healthcare, the delivery of healthcare services is also fragmented. Those seeking healthcare could potentially receive care at public health clinics including FQHCs, specialty clinics that care for those with a specific medical issue, such as STD clinics, health maintenance organization (HMO) medical facilities, private practice physicians' offices, urgent care clinics, military and veterans care facilities, emergency rooms, jails and prisons, and college campus facilities, among other locations. The decision about where to seek treatment depends on a variety of factors including the patient's type of healthcare coverage, which providers accept that coverage, the type of illness or injury, and convenience. In the case of STDs, social stigma could drive individuals to seek privacy for testing and treatment. They may, and often do, choose to seek care at somewhere other than their usual provider. The vast mix of coverage and settings can lead to confusion for individuals about who will pay for testing and where to go for testing. Uncertainty can lead to foregoing or delaying testing, and thus, could result in exposure of more partners to STDs and higher risk of sequelae.

Multiple potential settings can also lead to inconsistency in screening and treatment among healthcare providers both in public and private settings. For example, some providers may be diligent in asking appropriate screening questions to particularly vulnerable groups such as young adults or men who have sex with men (MSM). They may assess the need for appropriate STD testing, follow through with the testing and treatment when needed, and properly submit surveillance data. Others, however, may not. According to data from a nationally representative

<sup>&</sup>lt;sup>61</sup> National Center for Health Statistics, Data Brief No. 266, December 2016.

survey of men and women age fifteen to forty-four, the National Survey of Family Growth, only 47 percent of women and 23 percent of men with recent sexual activity received a sexual risk assessment from a doctor or other medical care provider in the past year."<sup>62</sup> This means that even just asking the questions that could lead to testing is not happening in large numbers of cases. As a result, some who should receive testing and treatment may not be receiving it. Given the serious consequences of untreated STDs, the long-term effects of failing to test and treat are both financially and medically substantial.

As discussed in an earlier section of this report, STDs are more prevalent in some segments of the population than in others. Lack of, and limited, healthcare coverage, is correlated with higher STD rates. Similarly, those at the poverty level have higher rates of STDs and are less likely to have insurance. While Medicaid does cover many millions of low income individuals, additional millions are still without coverage. Most of the states that did not opt-in for Medicaid expansion are southern states. These states have disproportionately high incidence rates for STDs, which means access to healthcare may be lacking for some who need it the most in relation to sexual health.

The fragmented nature of the testing and treatment environment also leads to issues with collecting the surveillance data that is of vital importance in planning STD control strategies. Timely information, for example, about clusters of cases, can lead to a focused strategy to control the spread of infection. Accurate numbers are also important for overall budget planning and for national strategies to reduce prevalence.

#### STD Funding—Amounts and Funding Streams

As noted earlier, CDC is the only federal agency that funds state, territorial, and local public health departments to monitor, prevent, and control the spread of STDs. Section 318 of the Public Health Service Act<sup>63</sup> authorizes STD funding for public health departments, academic institutions, and public health organizations. The states, localities, and territories provide the clinical services. CDC officials and partner groups note that the fact that CDC does not directly pay for services can, at times, complicate interactions with lawmakers who tend to be more familiar with the structure of the Ryan White HIV program, which does fund direct services, particularly when the CDC prioritizes

<sup>62</sup> National Center for Health Statistics, National Health Statistics Report, Number 110, March 29, 2018.

<sup>63</sup> Section 318 (a)(b)(c) of the Public Health Service Act [42 U.S.C. Section 247c (a)(b) and (c)] as amended

funding requests for surveillance. According to CDC officials, the STD landscape is not well known to appropriators—and making a case for surveillance activities can be a harder sell than treatment, particularly given competing priorities for limited dollars. Because STD programs are state and local programs, with wide variations, CDC cannot always explain fully how states use STD funding. Still Congress has supported the STD program and held fairly firm against proposals to cut the program. The recently enacted fiscal year (FY) 2019 appropriation is \$5 million above the President's FY 2019 budget proposal.

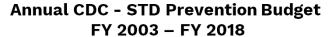
Over the past few years, the CDC's DSTDP funding has held reasonably steady, with a slight reduction in FY 2017.

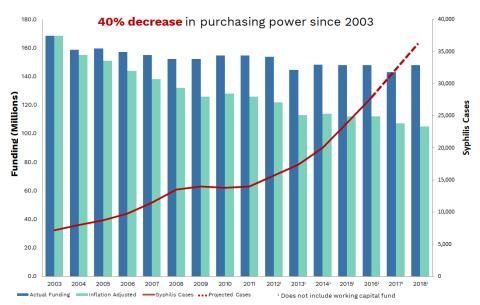
Table 4 - DSTDP Funding by Fiscal Year

| Fiscal Year         | FY 2014 | FY 2015 | FY 2016 | FY 2017 | FY 2018 | FY 2019 |
|---------------------|---------|---------|---------|---------|---------|---------|
| Funding in millions | \$157.3 | \$157.3 | \$157.3 | \$152.3 | \$157.3 | \$157.3 |

These numbers are actual dollars and are not adjusted for inflation. In terms of purchasing power, the division has experienced a 40 percent decrease since 2003. The chart on the following page provides a snapshot of actual and inflation adjusted funding.

Figure 2 - Snapshot of Actual and Inflation Adjusted DSTDP Funding<sup>64</sup>





The FY 2019 appropriation is the first time in twenty-two years that the CDC has not been under a continuing resolution (CR) for the start of a new fiscal year. While certainly not unique to CDC, CRs have a major impact on the agency's ability to fund states and localities, delaying the release of funds and underscoring the uncertainty of final funding—with the ripple effect occurring at the state and local levels in terms of what funding they can expect and when. In addition, there is no certainty that once enacted, the approved funding amounts will remain stable. Program cuts can be directed after an appropriation is approved. For example, in late FY 2018, \$558,000 was transferred from the STD program to fund another HHS priority,65 and the President just recently directed that all agencies take a 5 percent reduction in their FY 2019 budgets in response to current budget deficit estimates. How the cuts will be translated across agencies and programs is not known at this time. However, the across-the-board budget cut approach—where the same

<sup>64</sup> Source of information for Figure 2 provided by the NCSD and CDC

<sup>&</sup>lt;sup>65</sup> Under the authority of the Secretary of the Department of Health and Human Services, \$558,000 provided in the annual appropriations was transferred from the STD program to the Unaccompanied Alien Children's Program; no Congressional approval was required.

percentage cut is applied across all programs rather than distinguishing priority programs and applying the cuts differentially—is not an uncommon practice.

The FY 2019 HHS budget request asked for \$40 million to support a crosscutting Infectious Diseases Elimination Initiative to support efforts to decrease the prevalence of HIV, hepatitis B and C, STIs (sexually transmitted infections), and tuberculosis in select states and jurisdictions at high risk for these diseases and with high rates of opioid-related transmission. Congress did not adopt the request in the final appropriations conference report. Instead, Congress approved a new initiative for \$5 million targeting the infectious disease consequences of the opioid epidemic and directed the CDC to focus efforts on improving surveillance, treatment, and education efforts around hepatitis B and C and HIV. STIs were not included.

Domestic HIV/AIDS Prevention and Research receives the lion's share of funding within the CDC's Center for HIV/AIDS, Viral Hepatitis, STI, and TB Prevention. The FY 2019 appropriation provides \$755.6 million for HIV/AIDS programs out of a total \$1.132 billion for the Center. As noted above, Congress funded the STD program at \$157.3, which is roughly 21 percent of the HIV program funding and 13 percent of the Center total.

In terms of staffing, the Center is projected to have a Full-time Equivalent (FTE) level of 983 for FY 2019 (down from 1,023 in FY 2018). According to DSTDP officials, the DSTDP FTE approved count is 292, with actual on board strength at 235, again, indicative of the smaller number of resources assigned to STDs and suggesting a lower priority for STDs versus HIV.

CDC's STD funding is not designated by a specific line item. Funding within CDC is allocated at the division level; the Director's office makes decisions based on prior commitments and upcoming priorities and initiatives.<sup>66</sup> The current breakdown of DSTDP's budget plan for FY 2019 appears in the table and chart on the following page.

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<sup>&</sup>lt;sup>66</sup> Note: This annual appropriation also funds benefits to survivors of Tuskegee.

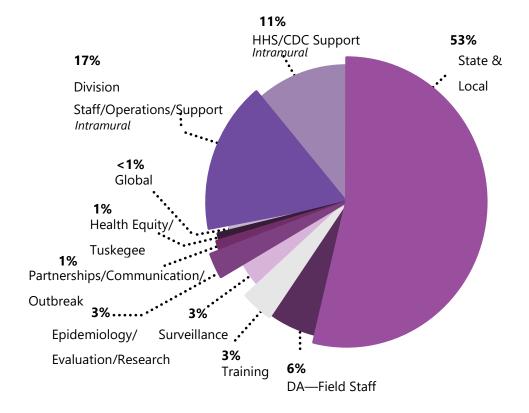
# **DSTDP FY 19 Planning Budget**

DSTDP FY 19 Planning Budget

| Program Name                                     | Budget            | %    |
|--|-------------------|------|
| State/Local Programs <sup>¥</sup>                | \$<br>84,006,291  | 53%  |
| DAField Staff <sup>¥</sup>                       | \$<br>9,705,010   | 6%   |
| Training <sup>¥</sup>                            | \$<br>5,175,018   | 3%   |
| Surveillance <sup>¥</sup>                        | \$<br>4,847,868   | 3%   |
| Epidemiology/Evaluation/Research <sup>¥</sup>    | \$<br>5,000,000   | 3%   |
| Partnerships/Communication/Outbreak <sup>¥</sup> | \$<br>1,535,000   | 1%   |
| Health Equity/Tuskegee <sup>¥</sup>              | \$<br>2,163,262   | 1%   |
| Global Activities <sup>¥</sup>                   | \$<br>647,945     | <1%  |
| Division Staff/Operations/Support*               | \$<br>27,117,945  | 17%  |
| HHS/CDC Support*                                 | \$<br>17,111,647  | 11%  |
| Total  | \$<br>157,309,986 | 100% |

<sup>\*</sup>Extramural / \*Intramural

Figure 3- DSTDP FY 19 Planning Budget Breakdown by Percent



HIV funding from the CDC's Division of HIV/AIDS Prevention (DHAP) provides about 10.6 percent of the funding to state and local STD programs, not reflected in the pie chart above. Additionally, DHAP funding is provided for other projects, such as SSUN and Training Centers.

In recent years, hiring freezes leading to savings resulting from staff vacancies, as well as some unobligated state/local funds from grants, have freed up monies that CDC/DSTDP then redirects to fund new demonstration research projects to the extent possible. For example, unobligated monies have been reprogrammed to 1) fund STD prevention intervention evaluation projects in California, New York, Baltimore, and Pennsylvania aimed at increasing chlamydia screening, and in California and Washington to evaluate different ways STD DIS support HIV outcomes; 2) provide a supplemental funding opportunity for strengthening congenital syphilis response; and 3) infrastructure upgrades and STD clinic surveys, among others.<sup>67</sup>

The funding to states and localities is principally through the cooperative agreement vehicle noted earlier:

- Assessment, Assurance, Policy Development, and Prevention Strategies—STD AAPPS FY 2014 through FY 2018 (targeted funding: \$550 million for Part A, and 1.5 million for Part B); and
- Strengthening STD Prevention and Control for Health Departments, STD PCHD FY 2019-2023 (targeted funding: \$475 million over the performance period).

In the past, funding allocations were based on historical data. However, in more recent years with the AAPPS and PCHD cooperative agreements a revised funding allocation formula was put in place to align available funding with the greatest needs based on a project area's population and STD morbidity. In addition, parameters were set to ensure that each jurisdiction previously funded would continue to get some funding under the new formula approach—essentially, a hold harmless provision for those jurisdictions that would experience reductions over time based on the data. CDC has since revised the AAPPS formula in the current PCHD, based on experience and recipient feedback. There is no requirement for any matching funds from the states.

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<sup>&</sup>lt;sup>67</sup> Presentation, "CDC Division of STD Prevention Town Hall: Questions from the Field," Gail Bolan, M.D., (November 16, 2017).

The current funding formula and estimated funding for each jurisdiction appears in Appendix F. It includes a floor amount (\$300,000) and any reduction from prior years capped at 5 percent. The PHCD cooperative agreement also delineates funding restrictions specific to the cooperative agreement. For example, recipients may conduct STD-related HIV activities, but they should not exceed 10 percent of the program effort or allocation. They may also provide assistance, without CDC approval, of no more than 10 percent of the overall amount to not-for-profit or government clinics that can document their ability to provide safety-net clinical preventive services per CDC guidance.

Despite these guidelines, CDC cannot guarantee that the money distributed to states will always be used/distributed, as intended. States make the decisions on how the money is distributed with the exception of those large cities directly funded by CDC (e.g., NYC). Moreover, CDC/DSTDP staffs do not readily know how much money the states contribute.

Funding for STD clinical research rests in the National Institutes of Health (NIH); the specific line item is Sexually Transmitted Diseases/Herpes Research. Research funding is split across multiple institutes including National Institute for Allergy and Infectious Diseases' (NIAID's) Office of STD Research and the Office of AIDS Research and the National Institutes of Child Health and Human Development (NICHD) for congenital syphilis. The Office of STD Research funds both investigator-initiated research grants and NIAID solicited proposals, typically funded through cooperative agreements. Funding for STD research has been essentially flat over the last decade. An area that has seen some influx of funds through set-aside cross-cutting Institutes is antibiotic resistance, which includes research on gonorrhea. According to program officials, the threat of potentially untreatable STDs has created a sense of urgency to fund the research for new drugs and potential vaccines.

Some STD funding for prevention, screening and treatment, research, education/outreach, and/or mental health related services is also contained in other HHS agencies noted earlier in Section 3.68

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<sup>&</sup>lt;sup>68</sup> HHS agencies include HRSA's Bureau of Primary Healthcare (FQHC), HIV/Aids Bureau (Ryan White HIV/AIDS program), and Maternal and Child Health (Women's Preventive Services Program); CMS; Assistant Secretary for Health, Office of Adolescent Health (Teen Pregnancy Initiative); Office of Population Affairs (Title X Family Planning); SAMHSA Administration for Children and Families; IHS; and FDA. Other agencies include the DOD, VA, and the Department of Justice (DOJ) FBOP.

Perhaps, not surprisingly, there is no one source of information for what is spent on STD efforts—federal, state and local—at the present time.

## State/Local Funding

States and local health departments leverage different funding streams within their control to provide core services and activities on the front line. As noted earlier, the total amount spent and from what source is not captured in a consolidated, systematic way. Jurisdictions may also combine HIV and STD programs, comingling program funds. There are no requirements to report the total amount spent on STD prevention and control; and many jurisdictions face challenges in trying to identify the original source of dollars spent according to a survey conducted by the National Coalition of STD Directors (NCSD).<sup>69</sup> Local health departments, in particular, may not know where their funding originated. In that same survey, NCSD found that 45 percent of the forty states responding—for example, Arkansas, Massachusetts, Idaho, Missouri, and Nevada—do not provide state funding to local health departments. They rely solely on federal funds. While not a scientific survey—the response rate for states was 80 percent and 83 percent for directly funded cities and some problems were evident with data submitted, indicating potential conflating of federal and state dollars—it does underscore the challenges in trying to identify STD funding.

Given the intersection of STDs and HIV, it is important to note here that Ryan White HIV/AIDS program funds (Part B) can be used by states to help support STD services through ambulatory or outpatient care for HIV+ individuals and through the Early Intervention Services (EIS) program, which includes targeted testing, referral services, and linkage to care, education, and outreach. EIS programs can also support testing for individuals, as well as DIS and partner services. In addition, the Ryan White Program has a drug rebate program—the AIDS Drug Assistance Program—where drug manufacturers' rebates can be used to support partner services, disease investigation, and PrEP programs.<sup>70</sup>

<sup>&</sup>lt;sup>69</sup> NCSD, Reduced U.S. Funding would Force Cutbacks to Core Public Health Services: A Survey of State and Local STD Directors, (2018).

<sup>&</sup>lt;sup>70</sup> The FY 2019 appropriations funded the Ryan White HIV/AIDs Program at \$2.34 billion in grants to cities, counties, states, and local community based organizations.

Many of the states and local jurisdictions that do provide funding in addition to federal funds have faced and reported cuts in their budgets. The National Association of County and City Health Officials (NACCHO) queried its HIV, STI and Viral Hepatitis Sentinel Network<sup>71</sup> in October 2017 to assess the impact of existing or potential budget cuts. Of the 62 percent responding—representing varying jurisdictional sizes, geographic locations and settings—the query found that most local health departments (LHDs) reported stagnant or declining funds for HIV, STIs, and viral hepatitis services. While not nationally representative, those LHDs reporting funding cuts noted that the services they reduced were most likely to affect disease surveillance and STI partner services (along with HIV testing and Hepatitis B vaccination). And, 43 percent reported reductions in HIV, STIs, and/or viral hepatitis program staffing levels. Of positions eliminated or reduced—the greatest loss was public health nurses, followed by outreach and education staff, other nursing/clinical staff, DIS, and case managers. In another broader study—NACCHO's 2017 Forces of Change Survey—nearly one-third of the LHDs reported anticipating future cuts in the upcoming fiscal year. That report concluded that the combination of budget cuts and workforce reductions occurring since 2008 jeopardize the basic services that LHDs provide and on which communities rely.

CDC conducted an analysis of the impact of budget cuts on programmatic activities in state and local health departments with staffing reductions in FY 2012.<sup>72</sup> CDC used data collected from a 2013-2014 survey of health departments and concluded that funding cuts to STD programs may result in higher STD rates. In addition, LHDs with funding reductions were more likely to reduce staff, partner services and clinical services than those LHDs without funding reductions.

Another CDC study in partnership with NACCHO and NCSD using the same 2013-2014 survey data found of that 33 percent of STD programs reported at least one negative impact due to budget cuts.<sup>73</sup> The most common responses were reduced clinic hours, reduced routine screenings, and

<sup>&</sup>lt;sup>71</sup> The Sentinel Network comprises more than 100 LHDs from over 40 states and the District of Columbia.

<sup>&</sup>lt;sup>72</sup> Gift, Thomas, Kendra M. Cuffee, and Jami S. Leichliter. CDC/DSDP: *The Impact of Budget Cuts on STD Programmatic Activities in State and Local Health Departments with Staffing Reductions in Fiscal Year 2012.* (2013)

<sup>&</sup>lt;sup>73</sup> Gift, T, K. Heyer, A. Benedetti, K.A. Brookmeyer, and Pang S. Hoover. CDC, NACCHO, and NCSD: *Current Public STD Prevention Services and Recent Changes: Results from a 2013-14 Survey*. (2014).

reduced partner services for STDs other that early syphilis. Because the data is dated, CDC is currently funding separate NACCHO surveys of state and local health departments to assess their programs and services including the impact of budget cuts. Not surprisingly, budget cutbacks appear to have a significant impact on local capacity to provide services. Updated data will be helpful in documenting the impact and making the case for additional resources.

#### The Challenge of Assessing Costs and Estimating Funding Needs

As decision makers weigh competing demands for scarce resources, cost is a highly important factor in deliberations. Yet measuring cost is complex and often inexact. In the health area, including in the STD health arena, multiple factors add to the complexity. Some of these factors are conceptual in nature—what do we want to measure—and others relate to the difficulties of actual measurement.

First, the definition of "cost" needs to be clear. Is the measure prevalent cost—the cost related to all STD cases in a given year—or cost per case over the lifetime of the disease? Further, does the cost include just direct costs—those related to the services of healthcare providers, hospitalizations, tests, drugs, home care and other actual expenses—or does it also include indirect costs such as lost wages of the individual who is ill with STDs and lost productivity? In addition, is cost sufficient information, or should benefits, such as reduction in spread of STDs, be measured as well to balance the picture? Finally, what effects do changes in available funds—i.e., the money available to fund direct costs—have on change in disease prevalence?

All of these cost configurations rely on the same underlying data related to number of cases of STDs, by type, and estimates of the cost of treatment. If indirect costs are also in the equation, then costs related to lost productivity and other indirect costs must be assessed. All of this is extremely complex and affected by a wide range of variables.

CDC estimates of cost have focused on costs related to the number of cases reported to CDC. What is available are counts of the number of individuals who test positive for chlamydia, gonorrhea, and syphilis. Although cases of all three of these infections are required to be reported to CDC, not all positive cases are reported. Some cases fall through the cracks and are not reported. Additionally, some "new" cases are over-reported. For example, someone who tests positive for chlamydia on one visit and prescribed an antibiotic to treat the disease, at a later date can be retested, and test positive again. This could be a new case, or if the patient never took the medication, it could still be the original infection. Thus, the same case could actually be counted twice, or more times, if this same pattern continues. As in almost all data sets, there is some degree of error related to issues,

such as lags in reporting and coding issues. So, the first challenge in assessing cost relates to the count of cases. The case count collected by CDC appears a reasonably accurate count of cases albeit not exact.

A second challenge in assessing cost is that treatment need, and consequently the treatment, varies, and different treatment results in different costs. For example, when diagnosed early enough, chlamydia infections can be effectively treated with an antibiotic, for low cost. However, if untreated, chlamydia can lead to pelvic inflammatory disease (PID), in female patients and is far more costly.

Treatment of gonorrhea and syphilis can be effective when diagnosed early; but when left untreated, the disease can lead to greater medical problems requiring far more costly treatment. Perhaps the most extreme consequence of failure to treat one of the reportable STDs relates to syphilis. As noted earlier, pregnant women with untreated syphilis can give birth to babies with congenital syphilis. This sometimes leads to stillbirth, or the birth of a child that requires lifelong care. The next challenge, or really set of challenges, is estimating the treatment scenarios of those receiving treatment and those who may seek treatment. Estimating treatment scenarios is also only one facet of the problem. The other is assessing cost of testing and treatment.

STD testing and treatment can occur in a wide variety of medical settings and each setting can result in a different costs. These settings include correctional institutions, STD clinics, public health clinics, managed care health providers, and private physician offices. Each of these can vary in cost. Although somewhat dated, a 2004 review of prior research studies reported diagnostic and treatment of a single case of acute gonorrhea ranging from \$36 to \$69 depending on treatment setting.<sup>74</sup> Both inflation and availability of a wider range of treatment options, especially an increase in treatment by private physicians resulting from implementation of the ACA, have most likely increased both the average diagnostic and treatment costs since this earlier work.

#### Past Efforts Assessing Costs

Despite the substantial challenges of assessing cost associated with STDs, there have been four such efforts since 1997. The most recent (published in 2013) utilized data from CDC surveillance records

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<sup>&</sup>lt;sup>74</sup> Chesson, Harrell W., John M. Blandford, Thomas L. Gift, Guoyu Tao, and Kathleen L. Irwin. "The Estimated Direct Medical Cost of Sexually Transmitted Diseases Among American Youth, 2000." *Perspectives on Sexual and Reproductive Health*, Vol. 36. No. 1. ( January/February 2004)

for 2008, which means that these data are now 10 years old.<sup>75</sup> Owusu-Edusei, et. al., report estimates, as shown in Table 6 below.

Table 6: Estimates of Lifetime Costs of Three Reportable STDs using Data for Newly Diagnosed Cases from 2008

| Sexually transmitted | Total lifetime direct medical cost | Lower estimate of cost        | Higher estimate of cost |
|----------------------|------------------------------------|-------------------------------|-------------------------|
| disease              | estimate                           | range                         | range                   |
| Chlamydia            | \$516.7 million                    | \$258.3 million <sup>76</sup> | \$775. million          |
| Gonorrhea            | \$162.1 million                    | \$88.1 million                | \$243.2 million         |
| Syphilis             | \$39.3 million                     | \$19.6 million                | \$58.9 million          |
| Total                | \$718.1 million                    | \$366 million                 | \$1,077.1 million       |

The authors of this work crafted these figures based on estimates using:

- diagnosis and treatment costs by setting of treatment from earlier work,
- proportion of cases in each treatment setting from the national STI surveillance data for 2008,
- costs of sequelae (primarily PID in women and epididymitis in men) from previously published estimates,
- proportions of cases symptomatic and asymptomatic from previously published estimates,
- proportions of "cases treated" estimates from previously published work, and
- proportions of cases that developed PID in women and epididymitis in men estimated in previously published work.

<sup>&</sup>lt;sup>75</sup> Owusu-Edusei, Kwame Jr., Harrell W. Chesson, Thomas L. Gift, Guoyu Tao, Renna Mahajan, Ocfemia Banez, Cheryl Marie, and Charlotte K. Kent. "The Estimated Direct Medical Cost of Selected Sexually Transmitted Infections in the United States 2008." *Sexually Transmitted Diseases*, Vol. 40, No. 3. (March 2013). This work includes estimates for eight STDs. We report data for the three that are the focus of this study.

<sup>&</sup>lt;sup>76</sup> Ranges were created by calculating plus or minus 50 percent of the cost estimate. They were not estimated bases on empirical data related to treatment costs of these three STDs.

Costs for gonorrhea were calculated using similar previous estimates from other studies. However, because there was no prior reliable work on sequelae rates and costs for gonorrhea, the authors used rates for chlamydia in their calculations. Costs related to syphilis relied primarily on two earlier rate and cost estimates.<sup>77</sup> The two earlier studies themselves relied on estimates from yet other prior work.

Out of necessity, as shown above, the authors developed their cost models based on prior work, and much of this prior work relied on assumptions to develop the estimates. The use of estimates and assumptions for most of the basic variables in the model lead to a conclusion that the total lifetime cost figures provided are not definitive. The authors' broad range provided to the cost estimate seems to be an acknowledgment of the tentative nature of their findings. However, the use in many cases of lower ranges in selecting aspects of the estimates may lead to the conclusion that the midpoint may be in a reasonable range of accurate, if not lower than actual, costs. This work underscores the lack of data for more definitive calculations of STD costs. Given the age of foundational data for the 2013 study (2008) and the even older prior work used to build the calculations, it is clear that the cost estimates are dated.

Major changes have occurred since 2008 that no doubt affect costs associated with these three STDs. First, the reported number of reportable STD cases has risen dramatically with chlamydia, gonorrhea, and primary and secondary syphilis cases increasing by 41 percent, 65 percent, and 127 percent respectively from 2008 to 2017. Simply multiplying the 2008 cost figures by the percent increase for each of the three STDs shows that based solely on the change in case counts, the lifetime cost of new cases is escalating at a substantial pace. The new figures based only on increases in the number of cases jump to \$728.5 million for chlamydia, \$267.5 million for gonorrhea, and \$89.2 million for syphilis. These are *extremely rough* calculations based on the 2008 cost-per-case figures, and do not account for multiple other potential changes in the cost of

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<sup>&</sup>lt;sup>77</sup> Owusu-Edusei K. Jr, K.W. Hoover, and G. Tao. "Estimating the direct outpatient medical cost per episode of primary and secondary syphilis in the United States: Insured population perspective, 2003-2007, Sexual Transmitted Disease 2011;" 38:175-179. Chesson H.W., J.M. Blandford, T. L. Gift, et al. "The estimated Direct Medical Cost of Sexually Transmitted Diseases among American Youth." *Perspective Sexual Reproductive Health.* 36: 1-19. (2000)

care. The calculations should be considered as a basic demonstration of the potential of the effects change in case numbers on costs rather than an accurate estimate of the costs.

Changes in the healthcare system, including implementation of the ACA in 2014 resulted in a higher proportion of cases being treated by private physicians and at HMOs—a more expensive setting, than being treated at STD clinics and public health facilities where treatment is less costly. Finally, inflation in the cost of medical care—a rate far higher than the general inflation rate increased the cost of all healthcare, including testing and treatment of STDs. According to the Bureau of Labor Statistics, medical inflation from 2008 to 2018 was 31.89 percent.

While the cost figures reported in the 2013 study, (using 2008 data) are dependent on multiple estimates, the obvious conclusion is that direct costs for STDs are significant. The combination of 1) the substantial increase in the number of STD cases reported in the years since 2013; 2) the move to more testing and screening at private physicians and HMOs (a more expensive option than STD clinics and other health clinics); and 3) the rise in medical inflation, all lead to a conclusion that were this same analysis completed today, the resulting estimated costs would be substantially higher.

#### Effects of Changes in Funding Level on Incidence of STDs

While it is important to know the direct cost of STDs, it is also important to understand the impact of changes in funding on STD rates. This is especially important in an era when budget reductions or flat year-to-year budgets for STD programs are common. Given medical inflation, flat funding is, in essence, a reduction in funding. A number of studies between 1980 and 2017 demonstrated a link between resources allocated for the prevention of sexually transmitted diseases and the incidence of STDs at the population level. While several of these studies have focused on a single STD, a pattern of change in funding and change in subsequent incidence level is evident. Less funding means less screening, less testing, less treatment, less partner services, and less outreach. All of which leads to increases in STD incidence as disease spreads without interventions.

The most recent work to examine the relationship between funding levels and STD rates in the out years (when the effects of the funding reduction would have an impact) was published in 2018.<sup>78</sup> The intent of this work was to provide information about the basis for two models developed for health departments to use to predict the impacts of funding cuts. According to the authors, the models (discussed below), are intended to generate, "a general approximation of how a change in STD prevention funding might affect the level of STD services provided, STD incidence rates, and the direct medical cost burden of STDs."<sup>79</sup>

The authors offer two approaches 1) an historical formula approach based on the observed relationship between state level gonorrhea case rates and STD prevention funding over an eighteen-year period, and 2) the DIS approach which is based on the observed association between DIS activities and subsequent gonorrhea case rates at the population-level in several settings. Notable is that both of these analyses are centered on information concerning gonorrhea and the same results are applied to chlamydia and syphilis, as well.

The historical formula approach first calculates the dollar amount of change in budget per capita and the subsequent change in gonorrhea rates using data from a study documenting rates from 1981 to 1998. As indicated above, the results are then applied to assess incidence of chlamydia and syphilis, as well. The DIS approach relies on a decade of data of reported gonorrhea cases in New York State and change in the level of DIS services. The focus is on the DIS because these are the workers who do patient interviews and arrange treatment for partners of those who have tested positive. Less of these services would lead to fewer treated cases and thus, allow more disease to spread in the community. The assumption is that a reduction in budget would lead to fewer DIS on staff, and thus, fewer patient interviews and partner services.

The authors then calculated the direct medical costs associated with a change in STD incidence. Utilizing the results of the earlier calculation of change in incident rates, they applied these rates to average lifetime cost figures generated in the 2013 study discussed above. The overall intent of this

<sup>&</sup>lt;sup>78</sup> Chesson, Harrell W., Jennifer A. Ludovic, Andres A. Berruti, and Thomas L. Gift. "Methods for Sexually Transmitted Disease Prevention Programs to Estimate the Health and Medical Cost Impact of Changes in Their Budget." *Sexually Transmitted Diseases*. Vol. 45, No. 1. (January 2018).

<sup>&</sup>lt;sup>79</sup> Ibid, page 1.

article is to provide STD programs with details on how the two estimation models were developed, as well as methods they can use to estimate the potential effects of changes in funding of their STD prevention budgets. No doubt, because of the need for estimates of multiple variables in these equations, the authors term the results a "general approximation." This work again demonstrates the need for data to generate more definitive information about the relationship between investment in prevention and outcome<sup>80</sup>.

Two products based on the methodology that were subsequently published in the study described above were developed to help STD programs assess the impacts of budget changes. One, STD Prevention Allocation Consequences Estimator (S.P.A.C.E. MONKEY 1.1) is a spreadsheet tool, which offers step-by-step directions for developing the estimates using an Excel program. The authors clearly acknowledge "considerable uncertainty" in potential results.

A second product, "Sexually Transmitted Infection Costs Saved Version 1.1" (beta test version), "STIC FIGURE," provides a spreadsheet to estimate the direct medical costs and indirect costs (lost productivity) saved by sexually transmitted disease prevention programs. The authors acknowledge up front that, "estimating the costs saved through STD prevention is not an exact science." This tool requires a number of assumptions by users. For example, it calls for estimating the number of partners treated for each patient provided with therapy for his or her partner(s). This number could actually vary from none to a large number depending on number of partners, number given the therapy, and number who actually used the therapy. The authors suggest putting "one" as the number treated is, perhaps, a conservative choice.

Despite the shortcomings involved in measuring the costs associated with screening, testing, and treating STDs, it is clear that direct costs are substantial. By adding indirect costs into the picture—those costs related to lost productivity—the total becomes substantially greater. Considering the significant increases in the number of diagnosed cases of STDs in recent years; the move away from

<sup>&</sup>lt;sup>80</sup> A new study (which was not available for review at the time of this study) is forthcoming entitled, "The Estimated Impact of Federal STD Prevention Funding on Reported STD Rates: An Analysis of State-Level Data from 1981 to 2016. The authors are CDC's Austin Williams, PhD and Harrell Chesson, PhD. The conclusion from the abstract asserts that: 1) Federal STD prevention funding allocated by CDC was significantly correlated with reductions in gonorrhea and chlamydia rates and 2) some of the recent increases in STD incidence may be related to recent decreases in funding levels.

STD screening, testing, and treatment in the public clinic settings to the private physician offices and facilities (in part as a result of ACA); and the high level of medical inflation, it is reasonable to presume the costs can only be rising at a substantial rate.

#### **Data Collection and Program Evaluations**

To say that efforts to stem to tide of STDs are difficult to measure or evaluate would be a major understatement. Indeed, just measuring the size of the problem—the incidence of STDs in the population—is problematic. How does one measure incidence of a disease when those who suffer from it may not be aware they are harboring a serious infection? Without reliable, valid incidence information, how does one measure program effectiveness? A step in the right direction is to collect more data nationally that can be analyzed; another is to conduct evaluations of various types to fill gaps in information. A number of data collection and evaluation efforts and their findings are discussed throughout this report, but several additional endeavors are worth noting.

#### STD Surveillance Network (SSuN)

A major effort underway to gather and analyze more detailed information concerning the population diagnosed with STDs is SSuN. Initiated in 2005, SSuN is a collaboration between CDC and competitively selected state, county, and city health departments. Sixteen health departments are currently involved in SSuN Part A under a cooperative agreement, which lasts through the end of 2018. SSuN Part B includes four health departments.

Part A of the SSuN initiative involves specific data collection by health departments for a random sample of reported gonorrhea cases. These data include information about the clinical presentation, as well as additional information from patient interviews. Both demographic and behavioral characteristics of patients are collected taking appropriate steps to ensure patient anonymity. SSuN funded health departments also conduct facility-based sentinel surveillance on STD clinics and other clinics that provide reproductive health services. Information collected for patients included patient visit dates, tests performed at visit, diagnoses received, and demographic and behavioral characteristics. The data offers the opportunity to assess trends in patients seeking care, in provider testing practices, and the numbers and proportion of patients diagnosed with STDs.

SSuN Part B funds four health departments to collaborate with local healthcare providers to obtain electronic health data to monitor STD prevention, measure clinical services delivered, and assess STD-related health outcomes. This work spans a wide variety of provider settings and data sources. These data allow an assessment of trend data not available through other means.

#### Community Approaches for Reducing STDs (CARS)

From 2011 to 2014, CDC's Division of STD Prevention conducted a demonstration program, Community Approaches for Reducing STDs (CARS), in four sites across the country. CDC selected sites through a competitive process and funded them through cooperative agreements. The purpose of the project was to implement and evaluate community engagement methods for designing and implementing STD prevention programs through community-based activities and interdisciplinary interventions. The focus was on at-risk populations. The primary goals of the program were to 1) reduce STD disparities, 2) promote sexual health, and 3) advance community wellness. Community Advisory Boards (CABs) were established to reflect the community at-risk and play a significant role in guiding selection and implementation of activities. Selected sites were located in Los Angeles, California, Philadelphia, Pennsylvania, San Antonio, Texas, and Richmond, Virginia.

Activities included recruiting residents from site communities to participate in CABs, train them on skills needed to work as a team to prioritize needs and plan strategies to meet those needs. Activities selected for implementation were intended to fit the specific community and integrate with services to offer comprehensive assistance, including screening and treatment for STDs. For example, the Philadelphia site, in addition to testing and treatment, offered GED classes and resume development workshops.

The evaluation of the demonstration projects focuses primarily on implementation issues, such as CAB member satisfaction with participation, and partner commitment in interventions implementation. It also documented output measures such as STD screening rates and positivity rates. The evaluation reports offer a substantial list of lessons learned, and highlight that as information was collected from sites, adjustments were made to improve performance and try to ensure maintenance of the effort after the end of the demonstration period. The evaluation was intended as a reference tool for future efforts utilizing similar models of community-based STD prevention programs.

#### A Collection of Evaluations of Successful Interventions

The American Sexually Transmitted Diseases Association Journal published a special issue entitled, "Effective Interventions to Reduce Sexually Transmitted Diseases" in February 2016. The issue

comprises a number of articles reporting evaluation results from a wide variety of interventions to curb sexually transmitted diseases.<sup>81</sup> The intent is to highlight evidence of effectiveness of various interventions to control STDs. (Several of the articles from this journal are cited in other portions of this report as evidence of effectiveness). The authors are forthcoming about shortcomings of the evaluation research, noting that limited cost information is provided while the rigor of the studies varies. The issue includes three overview articles synthesizing studies related to assessment, program evaluation, and predicting the impact of interventions.

#### **Evaluation Challenges**

As alluded to earlier, STD-related programs are difficult to evaluate. The lack of awareness of infection by individuals in the population is only one of the challenges. Solid evaluation requires far more control of the subjects, the treatment, and the environment than is often feasible. In most cases, where these three factors can be controlled and a measure can be taken of effectiveness, then generalizability becomes a concern. The follow-on question is—if it works, can the treatment be applied to different subjects; and, in a different environment, will it still have the same effect? Is the treatment feasible in different situations? Are resources and expertise available to implement it on a broader scale? Finally, is the situation changing so quickly that what worked two years ago is no longer likely to work?

Good evaluation costs money, and CDC's recent budgets for evaluation related to reportable STDs represents about 1 to 3 percent of its total budget. While there are other efforts underway to collect data and implement evaluations in the STD arena, they are relatively small. Evaluation may be limited by standard data collection issues, such as poor survey response rates, limited access to interviews, poor program data, lack of baselines, and lack of integrity of the treatment to be assessed. Nonetheless, well thought out data collection and carefully designed evaluations can be powerful tools to affect policy and practice.

The examples discussed above highlight some of the specific efforts that have been undertaken to collect more information in order to assess program process and output. They are not the only efforts, but they represent some of the most focused in relation to understanding what works.

<sup>&</sup>lt;sup>81</sup> Peterman, Thomas A., and Marion W. Carter. "Effective Interventions to Reduce Sexually Transmitted Disease: Introduction to the Special Issue." *Sexually Transmitted Diseases*, Vol. 43, Supplement 1. (February 2016).

## **Technology Changes Help Reporting but also, Prove Challenging**

Technology is almost always both a solution and a problem. As technology evolves and is adopted, the learning curve can be steep; and the price for new, more advanced equipment, can be high. Over the years that STDs have been reportable, information on paper has given way to electronic collection and transfer of information. People are still required to record information initially into an electronic format; then, they are responsible for transferring the information across systems, and for the analysis of the information. Consequently, a high level of technical expertise of those who operate data collection and transfer is essential.

While the challenges related to any new technology are extensive, they become even more arduous when one digital system has to seamlessly exchange data with another. Interoperability occurs when information held in one electronic health record (EHR) system transfers information through a standardized wire format to a separate EHR in such a way that the information exchanged proves to be machine readable by the accepting EHR. The issue, however, is that the EHR systems, or electronic lab records (ELR) systems may use different formats, different vocabulary, different timeframes, etc., that impede interoperability. Unraveling these differences and developing new solutions to achieve interoperability requires both time and expertise.

While EHRs are no longer "really new," they have changed medical data collection. During patient visits, doctors, or other medical professionals, record information directly into the patient's medical record on a computer that maintains the patient record over time. Interaction with labs or other providers can all be handled electronically. Labs send information on reportable disease tests back to medical professionals and to states and territory health departments, which in turn, report the information to CDC. State and territory public health systems, HMOs, private physicians, and other medical providers, including labs, have been free to select EHR systems that they deem appropriate. With all of these separate actors involved with many different EHRs or ELRs, the challenges of achieving interoperability are considerable. Fifty-seven separate entities—fifty states, two cities, and five territories—provide data to CDC on reportable diseases, including STDs.

Some electronic medical records systems were originally developed to facilitate billing. Collection of data for surveillance or medical research was not the priority; however, these systems are evolving, offering more functionality. Multiple competing vendors create and sell EHR and ELR software to the medical community. In most cases, reportable disease data now comes from the labs that do the testing. While this offers some efficiency gains in information collection, the down side is that lab information is very limited on each case. Age, sex, location and, in some cases, race

may be all that is available. From an STD research standpoint additional information, such as sexual orientation and partner history would be helpful.

As noted in Section I, states and territories are responsible for setting the requirements concerning the reporting of reportable disease incidence information. Differences across states and territories in health data standards, privacy rules including those for sharing information across providers, and timeliness of submissions are all factors that result in differences across the entities reporting incidence information to CDC.

CDC is currently involved in a major program to upgrade the National Notifiable Disease Surveillance System (NNDSS). This system collects information from states and territories for all notifiable diseases, including STDs. The project, the NNDSS Modernization Initiative (NMI), is intended to strengthen and modernize the infrastructure and create systems that are both more efficient for those providing data to the system and more functional for putting data to use. This multi-year project will require states and territories to make changes to their systems. Given competing demands at the jurisdiction level, focus on the needed upgrades could take several years. To facilitate jurisdictional involvement, periodic conference calls have been set up to share ideas, and help one another. These calls are attracting large numbers of participants.

CDC also has ongoing work to make STD screening and treatment guidelines available electronically in real-time. The strategy is to ensure that when medical personnel see a patient, screening and treatment guidelines will be readily accessible in their EHRs to guide their actions in selecting the appropriate treatment. CDC is planning to pilot the concept with gonorrhea screening and treatment at one clinic location during the first half of FY 2019.

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## **Section 4: Promising STD Prevention and Control Approaches**

Despite budget cuts, the ever-changing healthcare delivery environment, and other challenges, STD services providers are using an array of tools and strategies to reduce the incidence of STDs in their communities. Some of these tools and strategies have been employed longer than others, and many of them have, at least to some extent, been evaluated to assess effectiveness.

# Disease Intervention Specialists Play an Important Role in Reducing STD Infection Rates

An important role at both STD clinics and other public health clinics that screen, test, and treat STDs is that of the Disease Intervention Specialist (DIS). As noted earlier in Section 2, disease investigation is a core public health function. DIS staffs are key to contacting partners of those individuals receiving treatment for STDs, to notify them of possible infection and encourage them to be tested and treated. The DIS role is not unique to the fight against STDs, but is critical in the battle against other infectious diseases such as TB. The National Coalition of STD Directors (NCSD), the National Association of County and City Health Officials (NACCHO), the Public Health Accreditation Board, and CDC Division of STD Prevention are working together to establish a DIS national certification program. The goal is to standardize practices in the field, enhance training, ensure quality and consistency of practice, and recognize the professionalism and importance of DIS work to the healthcare community.

DIS staff often conduct an initial interview with individuals who have tested positive and been treated for an STD and educate them about the risk that their partners may be infected. If their partner(s) is infected and not treated, then the risk is high of re-infection. DIS staff will also contact partners directly to advise them of their risk of infection and direct them to resources for treatment. The goal, of course, is for both partners to be free of disease. The DIS is also frequently involved in outreach and education to the community in general to enhance understanding about the risks of STDs and available treatment. Some DIS staffs are also involved in aspects of data collection and reporting for clinic sites.

The DIS role in relation to reducing the numbers of individuals with STDs is quite clear because it extends beyond the individual who has come for treatment to any number of sexual partners who may not know they are carrying STDs. These partners may, in fact, have additional partners who may also be infected. DIS staffs try to follow that chain of contact to facilitate testing to break the cycle of infection, treatment, and infection again.

One of the two analyses in the 2018 study cited earlier<sup>82</sup> concerning impact of budget reductions on future STD rates focuses on what happens when the number of DIS staffs is reduced. The authors cite a 2007 study showing that a 10 percent increase in DIS activities could reduce gonorrhea rates by 2 to 6 percent.<sup>83</sup> To be conservative, the authors used the 2 percent rate of change. They applied these findings related to gonorrhea to chlamydia and syphilis, as well. Change in the number of DIS was generated by taking an estimate of DIS salary and benefits and dividing that number into the amount of the total budget cut. Thus, the entire value of the cut was deemed to be related to DIS capacity. The analysis indicates that over a ten-year period there is a 3.62 percent increase in numbers of STDs, and substantial additional costs related to treatment.

As the opportunities for screening, testing, and treatment of STDs becomes less frequent in an STD-focused setting and more frequent in private healthcare settings, the role of the DIS in reaching out to partners is reduced. While private physicians may likely counsel those they are treating for STDs to advise partners of their disease status, resources are not generally available to provide the follow up with partners to ensure a greater likelihood of success. Thus, the cycle of treatment and reinfection may be less likely broken.

#### **Expedited Partner Therapy Encourages Treatment for All Partners**

Expedited Partner Therapy (EPT) is a strategy intended to make it easy for partners of infected individuals to be treated. EPT provides individuals who are being treated for a confirmed STD to receive the appropriate medication to give to their partner. The infected individuals receive partner medication at the same time that they are receiving treatment. Thus, the partner does not have to see a medical provider. He or she just takes the medication provided. Several studies have assessed the efficacy of this approach and found it effective in reducing re-infection. These studies include a 2010 evaluation of the effectiveness of EPT across a variety of socio-demographic and behavioral

 $<sup>^{82}</sup>$  Chesson, Harrell W. et.al. (2018 $_{-}$ 

<sup>&</sup>lt;sup>83</sup> Du P., F.P. Coles, T. Gerber, et al. "Effects of Partner Notification on Reducing Gonorrhea Incidence Rate." Sexually Transmitted Disease. 34:189-194. (2007)

subgroups. EPT was shown to be more effective across almost all groups than other modes of informing and treating partners.<sup>84</sup>

This, of course, assumes that the individuals receiving treatment are willing and able to talk to their partner, or partners, about their infection and that the partner is willing to take the medication without seeing a medical professional. While many infected individuals who receive treatment know and are in continued contact with their partner or partners, others may not. With dating connections via social media apps increasing, more patients may not be able, or willing, to identify and contact their partners.

A number of other barriers also make this only partially workable:

- Legal barriers in some states do not allow physicians to prescribe medication without seeing the patient;<sup>85</sup> they cannot prescribe medication for a partner without actually examining the partner.
- If the "medication" is actually a prescription for medication rather than the medication itself, filling the prescription can be an issue related to cost. Insurance may not cover the costs of filling the prescription for the partner.
- CDC does not recommend using EPT for treating men with STDs who have sex with men (MSM)

Thus, EPT seems like a promising strategy to extend treatment beyond the individual patient—but only in some circumstances.

<sup>&</sup>lt;sup>84</sup> Shiely, Frances, Kevin Hayes, Katherine Thomas, Roxanne Kerani, James P. Hughes, William L. Whittington, King K. Holmes, H. Hunter Handsfield, Matthew Hogben, and Matthew R. Golden. "Expedited Partner Therapy: A Robust Intervention," *Sexually Transmitted Diseases*. Vol. 37, Issue 10, p. 602-607. (October 2010)

<sup>&</sup>lt;sup>85</sup> A 2008 study found that about 25 percent of jurisdictions reviewed in 2007 prohibited EPT, in that physicians are not allowed to prescribe medication without seeing the patient. See Hodge, James G, Amy Pulver, Matthew Hogben, Dhrubajyoti Bhattacharya, and Erin Fuse Brown. "Expedited Partner Therapy for Sexually Transmitted Diseases: Assessing the Legal Environment," *American Journal of Public Health*. (February 2008).

#### **Express Clinics Are Intended to Speed Testing and Treatment**

The intention of Express Clinics is to make it easy and fast to get screening and treatment for STDs. Walk-ins are welcome eliminating the need to plan and make an appointment. In some cases, the individual can use the clinic website in advance of the visit to complete any required paperwork, and order specific tests to reduce waiting at the clinic location. Some offer do-it-yourself testing at the clinic rather than having to wait for medical staff to be available. Test results are available within forty-eight to seventy-two hours and a secure link to a website is provided for test result retrieval. Quick turnaround of test results is intended to maintain the contact with the individual who was tested in an immediate way. A prolonged wait for results is positively associated with failure to return for treatment.

Express Clinics, which are generally no or low cost may be an attractive alternative for those who seek privacy about testing. For example, young adults who are covered by their parents' health insurance could use an Express Clinic for free or pay for testing without benefit of insurance to protect their privacy. This would circumvent the divulging of testing by an insurer's "Explanation of Benefits." Teens and young adults are in a high-risk group for STDs, so testing options that confidentially foster testing and treatment are especially important.

## **Behavioral Counseling can be an Effective Prevention Strategy**

Both the U.S. Preventive Services Task Force and the Women's Preventive Services Initiative have recommended behavioral counseling as an important tool in the fight against STDs for certain high risk groups. Counseling is also included in the Patient Protection and Affordable Care Act (ACA). Counseling covers a range of areas including:

- understanding STDs—what they are, how they are spread, and their health consequences;
- overcoming fear and stigma related to testing and treatment;
- safe sex behavior—including the use of condoms;
- routine testing in some cases, and
- coping with STDs—treatment and ensuring that partners are STD-free.

Counseling is particularly important for those in high-risk groups—i.e., adolescents, teens, young adults, MSM, and adults with multiple partners.

An evaluation synthesis of eleven different behavioral counseling interventions (2016) showed promising results, with the exception of the intervention related to MSM. They conclude that, "Counseling is likely to benefit some STD clinic attendees, although unlikely to benefit MSM."<sup>86</sup> In recommending behavioral counseling, the Preventive Services Task Force indicates that it can reduce a person's likelihood of acquiring an STD. Counseling intervention can range from just thirty minutes to two hours or more with positive outcomes, with longer more intense counseling being more effective than shorter interactions. Many successful approaches target the message to the age, sex, and ethnicity of their audience, although not enough evidence was available to the Task Force to measure the effectiveness of targeting.<sup>87</sup>

Counseling can also come in the form of video. A 2016 study reports the results of a controlled trial at three sites to assess the effectiveness of showing a short video, "Safe in the City," in waiting rooms at STD clinics. This short video, depicting couples in situations demonstrating decisions about safe sex, was shown during some periods in STD clinic waiting rooms, and not at other times—with timing controlled by the researchers. Those who visited the clinic during the showing of the video were the treatment group, and the control group included those at the clinic when the video was not shown. Costs of the production of the video and its showing were low. Subsequent testing for STDs in those viewing the video versus those not seeing the video showed a positive effect for viewing.

# Other Innovative Methods are being used to reach the Community in Need of Care

A number of relatively new strategies are being used to make screening, testing, and treatment as comfortable and easy as possible. The goal is towards increasing the number of individuals served by focusing, to some extent, on those who would be less likely to seek help at more traditional STD clinic locations or from private physicians.

To appeal to younger people—adolescents, teens, and young adults—some clinics have altered their business model to be more user-friendly to this age group. For example, they have either changed or extended their hours to increase accessibility (such as having clinic hours available

<sup>&</sup>lt;sup>86</sup> Brookmeyer, Kathryn A., Matthew Hogben, and Jennine Kinsey. "The Role of Behavioral Counseling in STD Prevention Program Settings." *Sexually Transmitted Diseases*, Vol. 43: 102-112. (February 2016).

<sup>&</sup>lt;sup>87</sup> United States Preventive Services Task Force. "Sexually Transmitted Infections: Behavioral Counseling."

outside the typical school hours). They have installed Wi-Fi in their waiting areas, and curtained off the reception desk to allow more privacy in the conversation with the receptionist. Interior decor is designed to appeal to this age group. Bike racks outside of the clinic accommodate a likely mode of transportation for some who are coming for screening.

While it is likely that clinics are staffed with employees who are accepting of all cultures, some clinics are making a special effort to match staff diversity with community diversity. The intention is to ensure that individuals are more comfortable about seeking services. Since racial and ethnic minorities and MSM are at higher risk for STDs, encouraging these groups to seek services is very important.

Recognizing that not all of those who may need treatment can easily come in to clinic facilities, some clinics have resorted to the mail for testing. The clinic mails test kits to those who request them, and in turn, the kits are sent back to the facility for analysis and for prescribing medication, if needed. This allows for testing and treatment for those in rural locations, or those without access to transportation to reach a clinic facility.

Reaching both those who require testing and those who have tested positive and now require treatment needs to be via a method that will work. Cell phone calls from unfamiliar numbers, and emails are often ignored, especially by younger people. Text messages are more likely to be received and read; and as discussed earlier, test results can be retrieved from the internet with codes to ensure privacy and speed the notification process. Additionally, websites providing information to the younger population may benefit from being formatted for cell phone viewing rather than for computers. Apps, webinars, and podcasts that focus specifically on the audience they are intended to reach, as opposed to generic presentations, are being utilized to better deliver STD-related messages. Finally, the focused distribution of materials about sexual health and about testing and treatment services are being distributed at specific venues, such as gay pride parades, to reach high-risk groups.

# Section 5: Actions for Consideration to Address the STD Epidemic

The ongoing STD epidemic in the United States is not abating—the number of reported cases continues to rise yearly. Unfortunately, a complex set of challenges currently inhibit the ability of American public health entities from controlling this epidemic. We have described a number of the key challenges including: the fragmented nature of our healthcare landscape; the intersecting diseases; the numerous intergovernmental players and nongovernmental stakeholders who have a role and must collaborate; infrastructure and funding challenges; the need for more research and evaluation and better data; and the need to ensure access to care in terms of education and social equity. The need for public engagement and better messaging to address social stigma barriers is clear, as is the need for a champion who has the authority and clout to marshal the effort. In many respects, this study has only scratched the surface—more data and analysis are necessary, particularly in the area of intergovernmental relations and the state and local issues, policy setting, and innovative practices and models. Below, the Panel offers actions for consideration to move to a more holistic, health-centric approach to STD prevention and control.

## **Need for a Champion**

Unlike antibiotic resistant bacteria, HIV prevention and control, and most recently the opioid epidemic, addressing STDs is not currently a recognized national priority of the White House or the U. S. Congress. With CDC and other federal public health entities lacking the legal authority to mandate compulsory reporting and to exert direct control over the STD field beyond coordination and grant administration, efforts are mostly constrained to working within the existing funding and framework available.

The STD epidemic is not solely a federal problem—it is a cross-jurisdictional, nationwide problem. To achieve significant improvement, an STD champion is needed to spearhead a coordinated national STD prevention and control effort. Past leadership appointments related to disease eradication or control have frequently come in the form of a "czar" whether in name formally or informally. Examples include the AIDS Czar, the Bird Flu Czar, and the Ebola Czar. The Panel is not suggesting an STD czar, but recommends the appointment of an individual with the standing and clout who could unify and harmonize policy across the disparate agencies that play a role in STD prevention and control. This individual should be empowered with the appropriate authorities to align efforts, advocate for funding, and promote research and innovation across sectors. It could reside in the Office of the Assistant Secretary for Health or with another senior Department of

Health and Human Services official who can effectively engage other appropriate agencies and stakeholders.

There is precedent for recent unification efforts involving STDs. The U.S. National Strategy for Combatting Antibiotic Resistant Bacteria (and resultant National Action Plan) issued by the White House gave CDC the expanded authority to coordinate and manage separate antimicrobial resistance (AMR) programs, as well as related laboratory and surveillance networks. One key point articulated in the CARB strategy that is equally as important for a concerted STD offensive: efforts must be coordinated with all parties and stakeholders, not just federal government entities. Buy-in from the diverse array of stakeholders across the nation is necessary. The importance of this is magnified by the nature of an infectious disease—effective control cannot be maintained if there are cracks through which infected individuals may fall and, thus, spread the illness to others that also dwell within those blind spots. Under these circumstances, coordination is made easier by way of a single point of contact.

#### **Focus on Wellness and Health**

### Changing the Narrative

Brushing up against moral and practical concerns, as well as issues of scale, STDs fall into a unique and difficult niche in public perception. The three reportable STDs are not well positioned to generate significant urgency or pressure in the way other diseases may. One need only look at the initial response to HIV to understand the struggle of achieving wide public acceptance of and action towards sexually transmitted disease intervention and control. In 1981, the first cases of what would eventually come to be known as AIDS were identified among men who were having sex with men (MSM) in Los Angeles<sup>88</sup> with five cases of pneumocystis pneumonia, one of the early coinfections associated with HIV.<sup>89</sup> It would not be until 1984 that HIV caught the national spotlight, when a child, Ryan White, was diagnosed with HIV contracted by blood transfusion; and not until a year later, that President Reagan would publicly acknowledge the disease. By this point, the virus had been linked to thousands of deaths.

<sup>&</sup>lt;sup>88</sup> Earlier cases can be traced to as far back as the 1960s in the United States, and as early as the 1920s in Central Africa, where the disease is believed to have originated),

<sup>&</sup>lt;sup>89</sup> CDC: Morbidity and Mortality Weekly Report; Available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/su6004a11.htm

In an era of relative control of HIV and the relatively low awareness and incidence of sequelae from the three reportable STDs, it is a challenge for advocacy groups to make the argument to policymakers that STDs are a priority worth significant investment. The narrative around STDs must be reframed to a consequence of life, as opposed to the punishment of the individual behavior or results of carelessness.

The human papilloma virus (HPV) provides a model for such a reframing. HPV is actually a family of over 100 viruses that are related to each other, of which over forty are capable of infecting the genitals. For most people so infected, the virus will never even produce symptoms; and for those that do develop them, itching and warts are the extent of their experience. The virus tends to clear out of the body naturally, without need for intervention. However, some individuals will develop cancers, because of the infection—approximately 79 percent of cancers found in genitals are likely attributable to HPV, accounting for about 33,737 cases yearly<sup>90</sup>. Due to the relationship between the virus and cancer, HPV could be presented both to policymakers and the public as a cancer-causing disease, rather than a sexually transmitted disease in the traditional sense. This approach was bolstered by the fact that many sexually active individuals will acquire HPV at some point in their life; 45.2 percent of adults aged 18-59 surveyed in 2013-2014 were diagnosed with genital HPV that carries a high risk for cancer<sup>91</sup>. Without total abstinence, it is unlikely for most people to avoid infection.

The CDC website hosts helpful information focused on the HPV and the HPV-cancer relationship; an example is a webpage entitled, "What CDC is doing about HPV and Cancer." By focusing on the life consequences of the disease and the reality that infection is likely, the conversation shifts from that of avoiding illness through behavioral changes to addressing diagnosis and treatment of the illness through practical ones. This is further facilitated by the recent development of mass-market HPV vaccines that address several virus types associated with cancer development, which enables

https://www.cdc.gov/nchs/products/databriefs/db280.htm

https://www.cdc.gov/cancer/hpv/what\_cdc\_is\_doing/index.htm

<sup>90</sup> CDC: HPV and Cancer; Available at: https://www.cdc.gov/cancer/hpv/statistics/cases.htm

 $<sup>^{\</sup>rm 91}$  CDC: National Health Center for Statistics; Available at:

<sup>&</sup>lt;sup>92</sup> CDC: HPV and Cancer; What CDC Is Doing About HPV and Cancer; Available at:

security from the disease at a young age and places the treatment and discussion of it alongside other, less taboo illnesses, such as measles and the mumps.

The three STDs addressed in this study fall into a similar niche as HPV. Contraction is not uncommon, particularly in the case of chlamydia, where an estimated 2.86 million cases per year<sup>93</sup> are reported. Complications from any of the three illnesses can be as severe as infertility, permanent disability, or death. Acquisition of the disease is facilitated by more relaxed attitudes around sex and is something that the average person could encounter given modern trends. While HPV is preventable by way of vaccination, chlamydia, gonorrhea, and syphilis, if caught early, are curable via reasonably easy therapy regimens, requiring as little as one visit to the doctor's office, or no more than the prescription of a standard one-week dose of antibiotic pills.

The story is there: these three STDs are easy to catch, easy to treat, but can be devastating if left to advance further. Several diseases share these attributes: for example, strep throat or the flu (which although incurable is mostly preventable and if topically addressed, usually not fatal). What makes STDs unique relative to them, is the stigma associated with the diseases and the general lack of public awareness of the breadth and depth of the diseases. By shifting the conversation towards these diseases as neglected infections with distressing quality of life and mortality implications, could result in a more effective point for advocacy.

## **Unifying the Field**

The STDs of focus in this study spread similarly to diseases that garner more attention, like HIV. The populations impacted are often the same, with shared risk factors. STDs are infectious diseases by nature, and do not possess a fixed population that is easily predicted and controlled. These STDs can also be comorbidities with HIV.

A common concern raised in nearly all interviews and contact with STD program officials and researchers was the lack of flexibility in funding across programs such as HIV to address STDs. Given that a significant, dedicated STD funding source is not likely in light of budget constraints and competing priorities, interviewees expressed the need for both additional funds and greater flexibility within programs that intersect with the STD field. This would apply broadly to HIV-specific programs, like Ryan White, as much as it would to fertility and family planning programs,

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<sup>&</sup>lt;sup>93</sup> CDC: Chlamydia - CDC Fact Sheet (Detailed); Available at: <a href="https://www.cdc.gov/std/chlamydia/stdfact-chlamydia-detailed.htm">https://www.cdc.gov/std/chlamydia/stdfact-chlamydia-detailed.htm</a>

like Title X grants. Some cross-financial support currently exists in these programs as noted earlier. However, even more flexibility would be helpful and should be considered. Allowing more leeway for grant recipients and others receiving federal funding to apply funds to STDs, within set parameters for accounting/reporting, could promote more granular, targeted efforts to contain local outbreaks and address population-specific needs.

Focusing on a single STD disease is not the most effective use of resources or approach to stemming STDs. For example, even if patients are screened regularly for syphilis, they may not be assessed for gonorrhea or chlamydia. In addition, educating patients is not a guarantee that they will change their risk behavior, which puts the burden upon the healthcare system to manage those cases that can be identified. Prioritizing one disease over the others leaves blind spots from which all three diseases may rebound.

The need to unify STD strategies and approaches seems evident. We noted earlier a number of national plans exist, such as Healthy People 2020, that at least tangentially touch on STDs. Very recently, an effort was launched in the Office of the Assistant Secretary for Health to begin planning and developing a national STD action plan uniting the goals and strategies of agencies and partners with a role in STD prevention and control. This is a positive step. Instead of spreading STD efforts across multiple strategies, a truly unified national STD plan and strategy is needed, clearly defining authorities, roles, and areas of flexibility. Attaching funding resources to specific strategies would also be helpful.

#### **Better Data and Evaluation**

Currently, data standards are not universally applied, nor entirely reliable. STD reporting is dictated by state laws that direct local authorities to report to state public health entities, who then forward the data collected to CDC. It is an unwieldy system that requires CDC to rely on the ability of local entities to report cases. An example of an issue that arises involves "case counts" versus "case rates." When state and local officials report cases to CDC, do they represent the number of cases out of those tested overall or only those with positive test results? Without rate information, incidence is impossible to determine accurately, which makes the targeting of response efforts more difficult. As CDC lacks the authority to mandate the collection of data, they cannot control the quality, timeliness, or form of that data, and must rely on state and local jurisdictions to provide them with usable data.

Potential variations in state and local reporting standards are compounded by inconsistent technology applications. Reporting utilities may vary widely between the various jurisdictions across the nation, adding an extra obstacle towards achieving sufficient surveillance coverage. The

cost of updating case reporting systems to be interoperable with CDC and other jurisdictions may be impossible for certain states and localities to meet given their funding and staffing capacity. As the data reported needs to be standardized, so, too, should the systems by which those data are shared and disseminated strive for greater interoperability across all reporting systems.

Over the years, a number of research studies and program evaluations have focused on various aspects of STD service delivery. Yet, overall, the body of evaluation work is limited. This is partly because of the extremely difficult task of trying to measure prevention. When individuals may not even know they are ill and when screening and testing are not systematic, evaluation options are few. Although randomized control trials (RTC) resolve some control issues in evaluations, generalization from RTCs is often problematic. A well thought out evaluation strategy intended to test interventions systematically, and with an eye towards implementation on a broad scale can elevate understanding about what works. In addition, systematic collection of performance measurement data by programs is invaluable to set baselines from which to assess progress. They can also be invaluable to evaluate efforts intended to assess outcomes associated with changes in programs across multiple program settings. Both RTCs and evaluations that rely on high-quality secondary data can add to the body of knowledge.

Strong evaluations that can guide both policy and programs to achieve positive outcomes are both difficult and costly. The scant amount (roughly 1 to 3 percent) of the budget that currently funds STD evaluation at CDC will not likely allow the level of effort needed for significant evaluation. Without the ability to ensure consistent, meaningful collection of performance measures at the patient care level, and all along the chain of service provision, understanding program performance will be limited. A body of sound, well-constructed evaluations can enhance both efficiency and effectiveness.

#### **Education and Awareness**

Nearly all those interviewed expressed the general sense that STDs still fly under the radar for most people, with at-risk individuals<sup>94</sup> more likely to be unaware of the possibility of infection, or the

<sup>&</sup>lt;sup>94</sup> Women and infants, adolescents and young adults, racial and ethnic minorities, and men who have sex with men

consequences of illness they may suffer. Due to the often generalized or, in some cases, lack of symptoms associated with the three focus STDs of this study, patients may fail to seek treatment, or recognize that treatment is needed to begin with. Due to the lack of insurance with the at-risk communities, there is a lower probability that a patient infected with one of these STDs will be diagnosed or incidentally treated in the course of regular medical checkups or doctors' visits.

Patients must be empowered to be their own advocates, and given the knowledge to know the effective preventive practices to use, and when to seek treatment. This endeavor can take many shapes, from awareness campaigns, to sexual education in schools, and would undoubtedly be interwoven with the effort to reframe STDs as a matter of personal health and wellbeing, as opposed to a stigmatized infection. A focus on wellness must be paramount. The potential ramifications and complications of an STD must be a core component, to make clear to those at risk that contracting gonorrhea, chlamydia, or syphilis can easily go beyond something as mundane as painful urination or a sore.

While educating the public is a critical component of awareness, the other half of the equation—health care practitioners—must also be addressed. During the course of the Study Team's review, it was repeatedly noted that medical school curricula do not provide a suitable amount of education regarding STDs, or sexual health, outside of obstetrics, gynecology, and other fields relevant to diseases like HIV. This lack of emphasis or focus may prevent providers from considering STD screenings for high-risk patients, or discussing risk factors and symptoms with them, contributing to a continued threat of transmission or belated treatment. Providers must be adequately informed on STD symptoms and risk factors and how best to ask about them to be proactive with their patients' health. CDC's planned effort to make the guidelines for STD screening readily available to medical providers through electronic health record applications is positive step for expanding awareness among the medical community.

A redoubled messaging effort is critical to this awareness campaign, and can make use of various new opportunities to reach target audiences. The advent of social media, and, more specifically, mobile phone dating and "hook-up" services like Tinder, Bumble, and Grindr, can provide opportunities for partnerships with key stakeholders that have a direct connection with groups at risk. Due to the very nature of the technology, there are low cost, low-effort interventions that can be tailored to specific populations.

#### **Expanded Funding and Resources**

The general lack of resources available to the STD field is compounded by the ongoing turbulence in the healthcare market. In the lead up to, and following the passage of, the Patient Protection and Affordable Care Act, funding for STD-specific clinics and services was cut, and services reduced, by state and local authorities under the assumption that STD care would be provided for by primary care providers and paid for with private insurance, with Medicaid covering all outlier cases. With Medicaid expansion rendered opt-in rather than compulsory, and with the individual mandate rescinded, the environment for which significant portions of STD infrastructure were designed is different today and continues to evolve. The extent of healthcare coverage is shifting with some reports of uninsured rates rising, 9596 increasing the number of individuals potentially without access to care. This situation will need to be monitored and evaluated.

An expansion of STD services to suit specific needs and emerging trends is necessary, and that can only be achieved with an influx of new, or redirection of existing, funds. Even for those with health services covered by private insurers, there are reasons that may push patients to seek specialized STD clinic services. Among them, anonymity and convenience are paramount; patients may be reluctant to speak with their primary care practitioner, have to fill a prescription at their neighborhood pharmacy, or submit a reimbursement request to their insurer.

While the CDC does not directly fund service provision, funding issued by the agency is, in many instances, the only funding state and local health departments may receive for their STD programs. Given this reliance, and the demonstrated utility of STD-specific services, as well as the drop in purchasing power, it would appear that more resources are needed for the Division of STD Prevention and through them, states and localities. As mentioned earlier, STD/STI programs comprise approximately 13 percent of total funding for the Center for HIV/AIDS, Viral Hepatitis, STI and TB Prevention—certainly, not enough to make a significant improvements and innovations in STD prevention and control programs beyond the current state. More flexibility to use funds across programs, as noted earlier, would also be helpful.

<sup>&</sup>lt;sup>95</sup> Reuters: *U.S. healthcare uninsured rises most in near decade: Gallup;* Available at: https://www.reuters.com/article/us-usa-healthcare-uninsured/u-s-healthcare-uninsured-rises-most-in-near-decade-gallup-idUSKBN1F5230

<sup>&</sup>lt;sup>96</sup> The Commonwealth Fund: First Look at Health Insurance Coverage in 2018 Finds ACA Gains Beginning to Reverse; Available at: <a href="https://www.commonwealthfund.org/blog/2018/first-look-health-insurance-coverage-2018-finds-aca-gains-beginning-reverse">https://www.commonwealthfund.org/blog/2018/first-look-health-insurance-coverage-2018-finds-aca-gains-beginning-reverse</a>

## **Conclusion**

The Hidden Epidemic concluded by noting, "a multifaceted approach is necessary at both the individual and community levels" The report asserted that STDs are public health problems, rooted in "human behavior" and "fundamental societal problems"—the first that must be confronted is the "reluctance of American society to openly address issues surrounding sexuality and STDs." More than two decades later, that assessment rings true.

In its *Global Health Sector Strategy on Sexually Transmitted Infections 2016-2021*, the World Health Organization (WHO) delineates its approach for addressing STDs from a perspective of individual and sexual health. WHO's goal is to promote a "people-centered approach, grounded in principles of human rights, gender equality, and health equity." 98The strategy emphasizes tackling the inequities and underlying social determinants of health that perpetuate STD outbreaks, facilitating patient access to information on STD status, breaking the stigma and accompanying discrimination that comes with STDs and STIs, and expanding the capacity of local healthcare systems to be able to handle outbreaks in their communities. The importance of this method of synergizing and integrating STDs with general health and wellbeing is exemplified by the fact that the report originates from WHO's Department of Reproductive Health and Research, where WHO's sexually transmitted infection programs are housed.

Many of the issues that contribute to the ongoing epidemic have been identified by practitioners and experts in the field for many years, if not decades. While certain new challenges and opportunities have emerged recently, it is clear that the stakeholders in this field—from program officials at CDC, to disease intervention specialists at state and local public health departments, to other partners such as university researchers and advocacy groups—understand the factors at hand. What they need are the resources and authority to address them head on.

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<sup>&</sup>lt;sup>97</sup> The Hidden Epidemic, Institute of Medicine. Washington, D.C.: National Academies Press: 315. (1997)

<sup>&</sup>lt;sup>98</sup> Global Health Sector Strategy on Sexually Transmitted Infections 2016-2021s. Geneva, Switzerland: World Health Organization (2016) Available at: <a href="http://apps.who.int/iris/bitstream/handle/10665/246296/WHO-RHR-16.09-eng.pdf;jsessionid=5071561450AD75E068A4D6E1D091412B?sequence=1">http://apps.who.int/iris/bitstream/handle/10665/246296/WHO-RHR-16.09-eng.pdf;jsessionid=5071561450AD75E068A4D6E1D091412B?sequence=1</a>

The lessons of *The Hidden Epidemic* are as appropriate today as they were at the close of the twentieth century, and the path is clear: efforts must be made to directly and openly address the STD epidemic, with a concerted focus fueled by expanded resources made available to key stakeholders, empowered by new innovations and technologies. By breaking down the social stigma around STDs and sexual health, expanding access to services, and educating the public about the risks, symptoms, and treatments of and for these diseases, rates can be reduced, and people can become healthier.

## **Appendix A: Panel of Fellows and Study Team**

#### **Panel of Fellows**

**Dr. Georges C. Benjamin, M.D. (Chair)\***— A well-known health policy leader, practitioner, and administrator, Dr. Benjamin currently serves as the Executive Director of the American Public Health Association, the nation's oldest and largest organization of public health professionals. He is also a former Secretary of Health for the state of Maryland. Dr. Benjamin is a graduate of the Illinois Institute of Technology and the University Of Illinois College Of Medicine. He is board-certified in internal medicine, a Master of the American College of Physicians, a fellow of the National Academy of Public Administration, a fellow emeritus of the American College of Emergency Physicians, and a member of the National Academy of Medicine. He serves on several nonprofit boards such as Research!America, the Truth Foundation, and the Reagan-Udall Foundation. He is also a member of the National Infrastructure Advisory Council, a council that advises the President on how best to assure the security of the nation's critical infrastructure.

**Dr. Gregg A. Pane\***— Dr. Pane is currently the Senior Director, Healthcare Affairs, Association of American Medical Colleges. Formerly, the Medical Director, National Medical Policy and Operations, AETNA, Incorporated; Director, Department of Medical Assistance Services, Commonwealth of Virginia; Director, Division of Medical Assistance Services, Director, National Healthcare Preparedness Programs, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services; Director and State Health Officer, District of Columbia Department of Health; System Vice President, Clinical Quality and Safety Medical Director, Public Policy Initiatives, Henry Ford Health System; Chief Policy and Planning Officer, Veterans Health Administration; Vice President, Quality Management and Chief Medical Officer, Unisys Health Information Management; Medical Director, Louisiana Medicaid Program; Associate Adjunct Professor and Assistant Chief and Residency Program Director, Division of Emergency Medicine, University of California at Irvine.

**Dr. Kenneth W. Kizer\***—Dr. Kenneth W. Kizer is a distinguished professor and Director of the Institute for Population Health Improvement at the University of California, Davis. His previous positions include founding President and CEO, National Quality Forum; Chairman, Chief Executive Officer and President, Medsphere Systems Corporation; Under Secretary for Health, U.S. Department of Veterans Affairs; Director, California Department of Health Services; Director, California Emergency Medical Services Authority; and Chairman, The California Wellness Foundation. Among his multiple current roles at IPHI, he serves as the Chief Medical Officer for the California Department of Managed Healthcare, Director of the California Cancer Reporting and

Epidemiologic Surveillance Program, and Chief Quality Improvement Consultant for the Medi-Cal Quality Improvement Program. He is a member of the National Academy of Medicine and a fellow or distinguished fellow of twelve professional societies.

Dr. Shoshanna Sofaer\*— Dr. Sofaer is Managing Researcher at the American Institutes for Research and Senior Scholar at the Graduate School of Public Health and Health Policy at the City University of New York and is an independent consultant. From 1998 to 2014 Dr. Sofaer was the Robert P. Luciano Professor of Healthcare Policy at the Baruch College School of Public Affairs. She previously held academic positions at George Washington University Medical Center and the UCLA School of Public Health. She completed her M.P.H. and Dr.P.H. degrees at the UC Berkeley, School of Public Health. Her career spans the fields of healthcare delivery and public health. She is a nationally recognized policy expert in such diverse areas as Medicare, health insurance access and reform, disparities in maternal and infant outcomes, quality measurement, public reporting and patient and family engagement. Dr. Sofaer studied issues in the delivery of care for infectious diseases included HIV/AIDS and TB. She has expertise in a variety of qualitative and quantitative research methods, and in the translation and dissemination of findings, topics on which she has trained many other researchers. Dr. Sofaer has published over sixty-five peer-reviewed articles and designed and led over thirty research and evaluation studies in her fields of expertise. She is a member of the Board of Directors of Academy Health, the professional society of health services and policy researchers and Public Health Solutions, the largest non-profit public health organization in New York City.

Mr. William H. Gimson\*—Mr. Gimson is a senior executive with experience leading large organizations through transformative changes. Currently a health management consultant, he most recently served as the Chief Operating Officer of St. Boniface Hospital in Haiti during challenging times that included a cholera outbreak, a Zika epidemic and the Hurricane Matthew response. Mr. Gimson is the Former Executive Director, Cancer Prevention and Research Institute of Texas. Previously, Mr. Gimson had a long career with the Centers for Disease Control and Prevention in positions including Chief Operating Officer, Associate Director for Budget and Finance, and Associate Director Chronic Disease Division, among others. Mr. Gimson served on a Provincial Reconstruction Team (PRT) in Iraq in 2008 as the civilian leader of the PRT health section. Awards include HHS' Secretary's Award for Distinguished Service, Presidential Meritorious Rank Award and Distinguished Rank Award, and the Roger W. Jones Award for Executive Leadership, American University, Washington, D.C. Mr. Gimson has an MBA from Duke University and BA from the University of Wisconsin-Milwaukee.

#### \*Academy Fellow

#### **Academy Study Team**

Brenna Isman, Director of Academy Studies— Ms. Isman oversees the Academy's studies and provides strategic leadership, project oversight, and subject matter expertise to all of the project study teams. In coordination with the Academy Panels of Fellows, she guides the teams in developing work plans, research methodology, and comprehensive analysis and recommendations. Ms. Isman has led Academy projects assisting a national regulatory and oversight board in development and implementation of its strategic plan, as well as a statutorily required assessment of the National Aeronautics and Space Administration's use of its Advisory Council and a study of regulatory affordability for the Environmental Protection Agency. Her expertise includes directing organizational studies of the U.S. State Department's Office of Inspector General and strategic plan development for the Postal Regulatory Commission and the Social Security Administration, as well as organizational change consulting support for the U.S. Coast Guard. Ms. Isman also led the Academy's work on the Collaborative Forum, which investigated best practices for states' management of federally funded programs. She holds an MBA from American University and a Bachelor of Science in Human Resource Management from the University of Delaware.

Cynthia Heckmann\*, Project Director—Ms. Heckmann is a fellow of the National Academy of Public Administration. A retired senior executive, Ms. Heckmann previously served as Project Director on the Academy's review of the study and administrative processes of the National Academies of Science, Engineering and Medicine, the Secret Service's organizational change efforts, the National Science Foundation's use of cooperative agreements in support of large-scale research facilities, the Department of Justice's Civil Rights Division, and the Center for Disease Control and Prevention's human resource process review. Her extensive career at the Government Accountability Office includes serving as the Chief Human Capital Officer (CHCO) and Deputy Chief Information Officer. Ms. Heckmann also has executive branch experience, as well as state government experience. Ms. Heckmann served as a strategic advisor on research studies for the Partnership for Public Service and is currently a CHCO SAGE—Strategic Advisor for Government Executives—for the Partnership. She holds a Master of Public Administration from Northeastern University and a Bachelor of Arts from Simmons College. She also attended the Senior Executive Fellows Program at Harvard University's John F. Kennedy School of Government and Yale University's School of Organization and Management.

#### \*Academy Fellow

**Laurie Ekstrand, Ph.D,** *Senior Advisor*— Laurie Ekstrand is a retired senior executive. At the Government Accountability Office (GAO), she led work as the Director, Healthcare, and earlier as Director, Homeland Security and Justice. Ms. Ekstrand started her GAO career as a statistician, and later became Chief Social Scientist for the General Government Division before selection for the Senior Executive Service. In addition to her GAO work, she developed course work and taught monitoring and evaluation at the World Bank, American University, and the University of Maryland. Post-retirement, Ms. Ekstrand led projects at the Academy and has worked as an evaluation consultant for the National Oceanic and Atmospheric Administration, the Department of Housing and Urban Development, the National Institute of Corrections, GAO, and several non-profit organizations. She earned her doctorate in political science and statistics at Florida State University.

Richard Pezzella, Research Associate— Mr. Pezzella joined the Academy in June 2018 after completing a series of internships around Washington, D.C. Previously, during the summer of 2016, he worked in Washington, as a grassroots organizer with Mayday America, a campaign finance reform group. After college graduation, in May 2017, Mr. Pezzella returned to Washington to intern in the office of Congressman Eliot L. Engel, and for the government relations and communications firm, Signal Group. His areas of interest and expertise include infrastructure, public health, international relations, technology, and space policy. Mr. Pezzella graduated in May 2017 from SUNY New Paltz with a Bachelor of Arts in Anthropology and International Relations and comes originally from Brooklyn, New York.

## **Appendix B: Participating Individuals and Organizations**

## **United States Department of Health and Human Services**

- ADM Brett P. Giroir, M.D., Assistant Secretary for Health, United States Department of Health and Human Services
- Dr. Tammy R. Beckham, DVM, PhD, Acting Director, National Vaccine Program Office and Office of HIV/AIDS and Infectious Disease Policy, United States Department of Health and Human Services

#### **National Institutes of Health**

• **Dr. Carolyn Deal**, Branch Chief, Sexually Transmitted Diseases Branch, National Institute of Allergy and Infectious Diseases, National Institutes for Health

#### **United States Centers for Disease Control and Prevention**

## **Division of STD Prevention**

- **Dr. Gail Bolan**, Director, Division of STD Prevention
- **Dr. Raul Romaguera**, Deputy Director, Division of STD Prevention
- Janice Norwood, Deputy Director, Program and Management Operations
- **Jo Valentine**, Associate Director, Office of Health Equity

Health Services Research and Evaluation Branch

- **Dr. Tom Gift**, Branch Chief, Health Services Research and Evaluation Branch
- Dr. Harrell Chesson, Health Economist, Health Services Research and Evaluation Branch
- Jennifer Ludovic, Policy Team Lead, Health Services Research and Evaluation Branch

Program Development and Quality Improvement Branch

- Dr. Jennifer Fuld, Branch Chief, Program Development and Quality Improvement Branch
- Dr. Marion Carter, Program Evaluation Team Leader, Program Development and Quality
   Improvement Branch

Social and Behavioral Research and Evaluation Branch

- **Dr. Matthew Hogben**, Branch Chief, Social and Behavioral Research and Evaluation Branch
- Surveillance and Data Management Branch
  - **Dr. Hillard Weinstock**, Branch Chief, Surveillance and Data Management Branch
  - **Dr. Lizzi Torrone**, Surveillance and Special Studies Team Leader, Surveillance and Data Management Branch
  - Dr. Ninad Mishra, Public Health and Informatics Team Leader, Surveillance and Data Management Branch

#### **National Coalition of STD Directors**

- **David Harvey**, Executive Director
- **Stephanie Arnold Pang**, Director, Policy and Government Relations
- Amanda Dennison, Director, Programs and Partnerships

## **Other Organizations of Interest**

- **Dr. Adam Visconti**, Director, DC Health and Wellness Clinic
- Dr. Judith Wasserheit, Chair and Professor, Department of Global Health, University of Washington
- John Auerbach, President and CEO, Trust for America's Health
- Naomi Seiler, Associate Professor, George Washington University

## **Appendix C: Selected Bibliography**

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# **Appendix D: Disease Matrix**

All data below derived from CDC Fact Sheets and NNDSS Case Definitions.

| Chlamydia                               |   |
|---|---|
| NNDSS Clinical Description              | Infection with Chlamydia trachomatis may result in urethritis, epididymitis, cervicitis, acute salpingitis, or other syndromes when sexually transmitted; however, the infection is often asymptomatic in women. Perinatal infections may result in inclusion conjunctivitis and pneumonia in newborns.   |
| Causative Bacteria                      | Chlamydia trachomatis   |
| NNDSS Laboratory Criteria for Diagnosis | Isolation of C. trachomatis by culture, OR  Demonstration of C. trachomatis in a clinical specimen by detection of antigen or nucleic acid  |
| Symptoms                                | In men: testicular pain, tenderness, and swelling. In women: vaginal bleeding or discharge. In both sexes: urinary discharge and painful urination.   |
| Potential Complications                 | In both sexes: infertility, and multi-systemic infection, which can be life threatening. In women: Pelvic Inflammatory Disease may manifest, which can cause miscarriage, infertility, and extreme pain. Pregnant women may suffer ectopic pregnancy, which can be fatal to both the child and mother. Babies born with chlamydia or exposed at birth may develop conjunctivitis or pneumonia, which can result in death. |

| Gonorrhea                               |   |  |
|---|---|--|
|   | A sexually transmitted infection commonly manifested      |  |
| NNDSS Clinical Description              | by urethritis, cervicitis, proctitis, salpingitis, or     |  |
|   | pharyngitis. Infection may be asymptomatic.               |  |
| Causative Bacteria                      | Neisseria gonorrhoeae                                     |  |
|   | Observation of gram-negative intracellular diplococci in  |  |
|   | a urethral smear obtained from a male or an               |  |
|   | endocervical smear obtained from a female, OR             |  |
| NNDSS Laboratory Critoria for Diagnosis | Isolation of typical gram-negative, oxidase-positive      |  |
| NNDSS Laboratory Criteria for Diagnosis | diplococci by culture (presumptive Neisseria              |  |
|   | gonorrhoeae) from a clinical specimen, OR                 |  |
|   | Demonstration of N. gonorrhoeae in a clinical specimen    |  |
|   | by detection of antigen or nucleic acid                   |  |
|   | In both sexes: painful or difficult urination or urethral |  |
|   | discharge. Oropharyngeal infections may present with a    |  |
| Symptoms                                | sore throat. Rectal infections can involve discharge,     |  |
| Symptoms                                | itch, or painful bowel movements.                         |  |
|   | In men: testicular pain.                                  |  |
|   | In women: vaginal bleeding.                               |  |
|   | In both sexes: infertility, and multi-system infection    |  |
|   | (Disseminated Gonococcal Infection), which can be         |  |
| Potential Complications                 | fatal.  |  |
|   | In women: Pelvic Inflammatory Disease, ectopic            |  |
|   | pregnancy, and miscarriage.                               |  |

| Syphilis                   |  |
|----------------------------|--|
|                            |  |
| NNDSS Clinical Description | Primary: A stage of infection with Treponema pallidum characterized by one or more ulcerative lesions (e.g. chancre), which might differ considerably in clinical appearance.  Secondary: A stage of infection caused by T. pallidum characterized by localized or diffuse mucocutaneous lesions (e.g., rash – such as non-pruritic macular, maculopapular, papular, or pustular lesions), often with generalized lymphadenopathy. Other signs can include mucous patches, condyloma lata, and alopecia. The primary ulcerative lesion may still be present.  Early Primary/Non-Secondary: A stage of infection caused by T. pallidum in which initial infection has occurred within the previous 12 months, but there are no signs or symptoms of primary or secondary syphilis.  Unknown Duration/Late: A stage of infection caused by T. pallidum in which initial infection has occurred >12 months previously or in which there is insufficient evidence to conclude that infection was acquired during the previous 12 months.  Congenital: A condition caused by infection in utero with Treponema pallidum. A wide spectrum of severity exists, from inapparent infection to severe cases that are clinically apparent at birth. An infant or child (aged less than 2 years) may have signs such as hepatosplenomegaly, rash, condyloma lata, snuffles, jaundice (nonviral hepatitis), pseudoparalysis, anemia, or edema (nephrotic syndrome and/or malnutrition). An older child may have stigmata (e.g., interstitial keratitis, nerve deafness, anterior bowing of shins, frontal bossing, mulberry molars, Hutchinson teeth, saddle nose, rhagades, or Clutton joints).  Syphilitic Stillbirth: A fetal death that occurs after a 20-week gestation or in which the fetus weighs greater than 500 g and the mother had untreated or inadequately treated syphilis at delivery. |
| Causative Bacteria         | Treponema pallidum   |
| NNDSS Subtypes             | Syphilis, primary  |

| Syphilis                                 |   |  |
|--|---|--|
|  | Syphilis, secondary   |  |
|  | Syphilis, early non-primary non-secondary                   |  |
|  | Syphilis, unknown duration or late                          |  |
|  | Syphilis, Congenital  |  |
|  | Syphilitic Stillbirth                                       |  |
|  | Neurological/nervous system manifestations                  |  |
|  | (neurosyphilis), including blindness (ocular syphilis),     |  |
|  | dementia, and paralysis                                     |  |
| Potential Complications                  | Infertility   |  |
|  | Miscarriage or stillbirth                                   |  |
|  | Organ failure   |  |
|  | Death   |  |
| Sympton                                  | ns by Stage   |  |
|  | A single sore, known as a "chancre", appears at the site    |  |
|  | of infection. As that site can be within an orifice or      |  |
|  | located in an area otherwise hard to see, and often is      |  |
| Primary                                  | painless, the infected individual may not notice it. The    |  |
|  | chancre will heal around a maximum of six weeks after       |  |
|  | appearance, regardless of treatment.                        |  |
|  | Skin rashes or lesions/sores will appear at sensitive       |  |
|  | membranes, most often the mouth, vagina, or anus. In        |  |
| Secondary                                | certain, more severe cases, a flu symptoms, hair loss,      |  |
| ·  | and headaches may coincide with the rash. With or           |  |
|  | without treatment, the symptoms will end.                   |  |
|  | In the latent stage, the patient will present with no       |  |
| Latent (early non-primary non-secondary) | symptoms. This state can last for years.                    |  |
|  | Often occurring 10-30 years after first infection, tertiary |  |
|  | syphilis affects the nervous system (including the brain),  |  |
|  | eyes, heart, blood vessels, liver, and even bones and       |  |
| Tertiary                                 | joints. Depending on the organs affected, this can leave    |  |
|  | permanent damage and, in some instances, result in          |  |
|  | death.  |  |
|  | A condition present in infants infected with syphilis       |  |
|  | perinatally or at time of birth. Congenital syphilis can    |  |
| Congenital                               | result in miscarriage or stillbirth, or premature birth, if |  |
|  | infection and symptom expression occurs during              |  |
|  | milection and symptom expression occurs during              |  |

| Syphilis |  |
|----------|--|
|          | pregnancy. Some babies born with CS may not display          |
|          | any symptoms at birth, but instead develop symptoms          |
|          | resembling tertiary or neurosyphilis later on in life.       |
|          | These effects can occur anywhere from a few weeks to         |
|          | even years after birth. Deformities and damage caused        |
|          | by CS can be irreversible and result in lifelong disability. |

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## **Appendix E: PCHD Grant Announcement**

# PS19-1901 Strengthening Sexually Transmitted Disease Prevention and Control for Health Departments (STD PCHD)

CDC's Division of STD Prevention aims to supports 59 state, local, and territorial health departments to conduct STD surveillance, prevention, and control through the new PS19-1901 STD PCHD cooperative agreement. This NOFO is the successor to PS14-1402 STD AAPPS, which ends December 31, 2018.

### Purpose and focus

- To prevent and control three major STDs: chlamydia (CT), gonorrhea (GC), and syphilis
- To contribute towards the following national aims:

| I | Elimination of congenital syphilis           | Prevention of STD-related reproductive health problems |
|---|--|--|
| I | Prevention of antibiotic resistant gonorrhea | Effective response to STD-related outbreaks            |
| I | Reduction of primary and secondary syphilis  | Reduction of STD-related health disparities            |

Priority populations include adolescents and young adults, men who have sex with men, and pregnant women

#### Strategies

- Represent a core program of STD prevention and control for health department STD programs
- Build on important work done under the previous funding cycle (PS14-1402 STD AAPPS), and includes some new strategies, such as enhanced surveillance and more work to assure recommended gonorrhea and syphilis treatment
- Organized into five Strategy Areas, with surveillance as the top priority, followed by disease investigation and the promotion of CDC-recommended clinical prevention services (see next page)
- Affirm the need for recipients to tailor and prioritize their work to their own context
- Promote collaboration with CDC-funded HIV programs, National Network of STD Prevention Training Centers, and National Coalition of STD Directors, various other federally-funded and non-governmental partners at national, state, and local level

#### Administration

- Estimated 2019 funding is \$95,000,000, with awards ranging from \$300,000 to over \$7,000,000, calculated from
  a funding formula based on population and STD morbidity
- Eligible recipients include the 50 states, District of Columbia, Puerto Rico, US Virgin Islands, Los Angeles (CA), San Francisco (CA), Baltimore (MD), Philadelphia (PA), New York City (NYC), Chicago (IL)
- Period of performance runs 5 years, from January 1, 2019-December 31, 2023
- DSTDP's Program Development and Quality Improvement Branch (PDQIB) administers the cooperative agreement, in collaboration with numerous other Branches in the Division
- Program Official and contact for technical questions is Dr. Jennifer Fuld, Chief, PDQIB (JFuld@cdc.gov)

NOFO release date: April 30, 2018 Anticipated award date: November 1, 2018
Application deadline: July 31, 2018 Project start date: January 1, 2019

| STD PCHD Strategy Areas |  |   |                                     |  |
|-------------------------|--|---|-------------------------------------|--|
| Surveillance            | Disease<br>Investigation &<br>Intervention | Promotion of CDC-<br>Recommended<br>Screening,<br>Diagnosis, &<br>Treatment | Promotion of<br>Prevention & Policy | Data Use for<br>Program<br>Improvement |

#### Cross cutting

- Partnerships
- STD-related HIV Prevention

#### Strategy Area I: Conduct Surveillance

- 1. Conduct Chlamydia (CT) surveillance
- 2. Conduct Gonorrhea (GC) surveillance
- 3. Conduct syphilis surveillance
- 4. Conduct congenital syphilis (CS) surveillance
- Conduct surveillance of adverse outcomes of STDs

## Strategy Area II: Conduct Disease Investigation and Intervention

- 6. Respond to STD-related outbreaks
- Conduct health department disease investigation for pregnant women and other reproductive-age women with syphilis
- Promote Expedited Partner Therapy (EPT)
   (where permissible) to partners of chlamydia and/or gonorrhea cases
- Conduct health department syphilis disease investigation and intervention for men with syphilis

## Strategy Area III: Promote CDC-Recommended Screening, Diagnosis, and Treatment

- 10. Promote quality STD specialty care services
- 11. Promote CDC-recommended treatment
  - a. Gonorrhea
  - b. Syphilis
- Promote CDC-recommended screening for, and treatment of, STDs among priority populations
  - c. Pregnant women
  - d. Adolescents and young adults
  - e. MSM

# Strategy Area IV: Promote STD Prevention and Policy

- 13. Promote STD prevention to the public
- Promote STD prevention and reporting to provider community
- Monitor STD-related policies and policy development

## Strategy Area V: Analyze and Use Data for Program Improvement

- Conduct epidemiologic analysis, translation and dissemination
- Conduct data-driven planning, analysis, monitoring and evaluation for program improvement

## **Appendix F: PCHD Grant Formula and Funding Tables**

#### **Anticipated Award Levels for Year 1 of PS19-1901 STD PCHD**

Anticipated award levels to support core STD prevention and control strategies and activities required in PS19-1901, Strengthening STD Prevention and Control for Health Departments (STD PCHD) were determined based on a funding formula. Awards to eligible project areas were calculated taking into account the project area's population and morbidity (chlamydia, gonorrhea, syphilis) from 2012-2016. These data were used to calculate each project area's share of the total amount available to support STD PCHD (an estimated \$95,000,000). CDC then adjusted the allocation to ensure an established floor of \$300,000 to each project area, and to cap the amount of reduction from 2018 funding at 5 percent. These amounts are estimates based on current resources and are subject to the availability of funds.

Funding allocation may change over the period of performance. New award levels will be implemented in the first year of award funding, and awards will be re-calculated each year of the period of performance, using 2012-2016 morbidity, a floor of \$300,000, and a maximum year-to-year reduction of 5%, assuming that CDC/DSTDP's available funding remains level over the period of performance. Awards for future years of this cooperative agreement are subject to availability.

### **Funding Formula and Related Rules**

- 50 percent based on the population (age fifteen to forty-four) of each eligible project area
- 50 percent based upon disease burden (2012-2016) for primary and secondary syphilis, gonorrhea, and chlamydia. Disease burden is further broken out by:
  - 80 percent based on the number of reported cases of STDs (primary and secondary syphilis, gonorrhea, and chlamydia) from 2012-2016
  - 20 percent based on rates of reported STDs (primary and secondary syphilis, gonorrhea, and chlamydia) from 2012-2016
- All project areas are allocated a minimum of \$300,000
- Any decreased in funding from 2018 and 2019 for eligible project areas are capped at 5 percent

Funding Table: PS19-1901, STD PCHD, Estimated Funding Amount – Eligible Project Areas

| Project Area Name                                    | Funding Amount |
|--|----------------|
| Alabama  | \$1,733,855    |
| Alaska   | \$359,688      |
| Arizona  | \$1,801,559    |
| Arkansas   | \$1,073,706    |
| Los Angeles, CA                                      | \$3,219,056    |
| San Francisco, CA                                    | \$1,125,294    |
| California, (excl. Los Angeles and San<br>Francisco) | \$7,078,931    |
| Colorado   | \$1,295,830    |
| Connecticut  | \$830,137      |
| Delaware   | \$393,193      |
| District of Columbia                                 | \$909,974      |
| Florida  | \$5,134,801    |
| Georgia  | \$3,399,360    |
| Hawaii   | \$431,710      |
| Idaho  | \$357,773      |
| Chicago, IL  | \$1,899,190    |
| Illinois, (excl. Chicago)                            | \$2,297,045    |
| Indiana  | \$1,688,905    |
| Iowa   | \$715,402      |
| Kansas   | \$725,826      |
| Kentucky   | \$1,111,407    |
| Louisiana  | \$2,021,618    |

| Project Area Name                 | Funding Amount |
|-----------------------------------|----------------|
| Maine                             | \$300,000      |
| Baltimore, MD                     | \$1,066,274    |
| Maryland, (excl. Baltimore)       | \$1,326,768    |
| Massachusetts                     | \$1,567,664    |
| Michigan                          | \$2,544,720    |
| Minnesota                         | \$1,243,036    |
| Mississippi                       | \$1,295,885    |
| Missouri                          | \$1,699,642    |
| Montana                           | \$300,000      |
| Nebraska                          | \$491,187      |
| Nevada                            | \$896,412      |
| New Hampshire                     | \$300,000      |
| New Jersey                        | \$2,330,297    |
| New Mexico                        | \$681,125      |
| New York City, NY*                | \$4,662,949    |
| New York, (excl. New York City)   | \$2,399,058    |
| North Carolina                    | \$2,964,791    |
| North Dakota                      | \$300,000      |
| Ohio                              | \$3,116,458    |
| Oklahoma                          | \$1,128.030    |
| Oregon                            | \$973,878      |
| Philadelphia, Pennsylvania        | \$1,843,711    |
| Pennsylvania (excl. Philadelphia) | \$2,206,892    |

| Project Area Name | Funding Amount |
|-------------------|----------------|
| Rhode Island      | \$351,107      |
| South Carolina    | \$1,529,483    |
| South Dakota      | \$330,964      |
| Tennessee         | \$1,905,200    |
| Texas             | \$7,271,037    |
| Utah              | \$638,562      |
| Vermont           | \$300,000      |
| Virginia          | \$2,087,388    |
| Washington        | \$1,860,059    |
| West Virginia     | \$530,257      |
| Wisconsin         | \$1,317,457    |
| Wyoming           | \$300,000      |
| Puerto Rico*      | \$1,035,448    |
| Virgin Islands    | \$300,000      |
| Total             | \$95,000,000   |

<sup>\*</sup>These amounts are inclusive of Direct Assistance funds. For example, if this Funding Table shows an amount of \$1,000,000, but you receive \$200,000 of Direct Assistance, then you should write your application so that the budget is \$800,000.

## **Appendix G: GISP Sites**

#### **GISP Jurisdictions**

- Albuquerque, NM
- Atlanta, GA\*
- Austin, TX\*
- Baltimore, MD\*
- Birmingham, AL\*
- Boston, MA
- Buffalo, NY
- Chicago, IL
- Cleveland, OH
- Columbus, OH
- Dallas, TX
- Greensboro, NC
- Honolulu, Hawaii
- Indianapolis, IN
- Kansas City, KS/Kansas City, MO
- Las Vegas, NV
- Los Angeles, CA
- Minneapolis, MN
- New Orleans, LA
- New York, NY
- Orange County, CA\*\*
- Philadelphia, PA
- Phoenix, AZ
- Pontiac, MI

- Portland, OR
- San Diego, CA
- San Francisco, CA
- Seattle, WA\*
- Tripler Army Medical Center, Hawaii\*\*

<sup>\*</sup>Sentinel Site and Regional Laboratory

<sup>\*\*</sup>County or other non-city jurisdiction

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1600 K Street, N.W.

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Washington, D.C. 20006

Phone: (202) 347-3190 Fax: (202) 223-0823

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