# Sexually Transmitted Infections:

A Review of the 2022 Vaccine and Diagnostic Research and Development Pipeline and Investments



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# **Sexually Transmitted Infections:**

## A Review of the 2022 Vaccine and Diagnostic Research and Development Pipeline and Investments

Rates of sexually transmitted infections (STIs) continue to rise globally with too little public health intervention and investment. STIs are widespread and can have severe health consequences, including infertility, severe pregnancy and newborn complications, cancer, and increased risk of HIV acquisition. While many STIs are curable, they often go undiagnosed and untreated because they tend to cause few or no initial symptoms. Available diagnostics are often too costly to use for routine screening in many low to middle-income countries (LMICs), and few vaccines exist to address the most common STIs. Far too little funding goes to research and development of new vaccines, diagnostics, and other prevention and treatment tools. Advocacy and action are needed to increase funding and accelerate the development and delivery of solutions that meet the needs of end users.

To highlight ongoing work in the STI vaccine and diagnostic research and development (R&D) field and identify gaps, AVAC is publishing its first STI resource tracking report. This report examines disbursements by the U.S. National Institutes of Health and the Bill & Melinda Gates Foundation for vaccine and diagnostic R&D among seven pathogens: chlamydia, genital herpes, gonorrhea, hepatitis B, human papillomavirus (HPV), syphilis, and trichomoniasis. With the NIH and the Gates Foundation being the largest investors across a vast range of global health R&D areas, this report sets a solid foundation for collecting global STI vaccine and diagnostics investments in future reports.

## STI and Sexual Health Resource Tracking Reports

This report examines STI vaccine and diagnostic R&D funding from the NIH and the Gates Foundation, as well as tracking recent advances in the STI vaccine and diagnostic pipelines generally. Several other reports examine similar topics, helping to provide additional insights into and context for STI and sexual health funding efforts. AVAC publishes several resource tracking reports including *HIV Prevention Research & Development Investments* and the *Global Investment in HIV Cure Research and Development report*.

Policy Cures Research tracks annual investments into R&D for new products and technologies to address priority global health pathogens, through their G-FINDER project. In addition, they recently published a report specifically on sexual and reproductive health products and technologies, with a focus on products or technologies that are applicable to low- and middle-income country settings for topics including STIS, HPV, cervical cancer, and contraception. These products and technologies include basic research, drug, vaccines, biologics, microbicides, and diagnostics. The G-FINDER analysis excludes investments for products or technologies that are intended for high-income countries, and syphilis diagnostics because affordable, easy-to-use, point-of-care diagnostics exist and are appropriate for use in LMICs.

<u>TogetHER for Health</u> publishes an annual analysis of funding for cervical cancer prevention in lowincome and lower middle-income countries including HPV immunizations and cervical cancer screening. Therefore, the <u>TogetHER for Health</u> report provides financial information on screening, treatment, and vaccination programs compared to this report which focuses on vaccine and diagnostic R&D.

Overall, these reports provide a comprehensive understanding of the STI R&D and programming investments for multiple pathogens. Each report is unique in its focus and goal, and our hope is that this report can add to the current understanding of what investments are being made specifically for STI vaccines and diagnostics and identify opportunities and disparities in funding.

# Global Investment in STI Vaccine and Diagnostic Research and Development

Decades of neglect and stigma have allowed sexually transmitted infection rates to skyrocket globally. According to the World Health Organization, <u>more than a million</u> new STI cases now occur every day. Each of these infections can cause individual discomfort, embarrassment, and shame; many will result in serious or even devastating long-term consequences:

- HPV infections can lead to six types of cancer, including anal, cervical, oropharyngeal, penile, vaginal, and culver cancer, and genital warts;
- Hepatitis B infections are among the top drivers of liver cancer;
- Chlamydia and gonorrhea infections can lead to pelvic inflammatory disease and infertility among women;
- When passed to a fetus during pregnancy, STIs, such as syphilis, can result in miscarriage, stillbirth, or severe congenital health problems; and
- Some STIs, including herpes, gonorrhea, and syphilis can increase a person's risk of acquiring HIV.

Despite the potential severity of STIs, limited funding, and lack of awareness on the impact of these infections has delayed progress in developing new prevention, detection, and treatment tools. Increased financial investments are needed now to develop new vaccines and diagnostics that can help to better prevent, detect, and treat STIs.

Vaccines could make a huge contribution to lowering rates of STIs and the associated consequences. A recent bright spot in STI innovation has been the rollout of vaccines to prevent hepatitis B and HPV and scientists believe it is possible to develop preventive and/or therapeutic vaccines for other STIs, including chlamydia, genital herpes, gonorrhea, and syphilis. However, funding to advance R&D for these vaccines has been insufficient and most research remains mired in the early stages.

Furthermore, because STIs often cause few or no initial symptoms, people often remain unaware of their infections and do not seek timely treatment. Faster, simpler diagnostics are essential to identify and treat STIs before they can cause serious damage. Today, most STI testing requires taking blood, urine or anatomical samples that must be processed in a laboratory. Rapid, inexpensive point-of-care tests could identify more infections, especially in low-income settings, and deliver faster results so that patients could obtain treatment without a follow-up visit.

In 2019, the National Institute of Allergy and Infectious Diseases (NIAID) launched a network of <u>STI Cooperative Research Centers</u> to develop vaccines against chlamydia, gonorrhea, and syphilis in the United States. In 2023, the Centers for Disease Control and Prevention (CDC) formed the <u>Sexually</u> <u>Transmitted Infections Impact Research Consortium</u>. Members of the consortium are expected to conduct clinical trials and implementation research, including efforts to develop, test, and implement new STI diagnostic tools.

Building on these important efforts to develop and deliver the transformative new tools needed to reverse increases in STIs will require substantial commitment, investment, and collaboration from the public, private, and philanthropic sectors.

This report on STI vaccine and diagnostic R&D is intended to help decision-makers and advocates identify current funding investments, opportunities, and gaps. Tracking investments over time can also demonstrate the effects of public policies and initiatives (such as <u>WHO's STI Vaccine Roadmap</u>) on funding decisions and help guide the prioritization of research projects.

## **Table of Contents**

| Overall STI Vaccine and Diagnostic Research and Development Funding | 5  |
|---|----|
| NIH Funding by Institutions and Centers                             | 7  |
| Funding Distributions among Institutions                            | 8  |
| STI Vaccine Research and Development                                | 10 |
| STI Diagnostic Research and Development                             | 12 |
| Industry Activities   | 14 |
| Recommendations   | 14 |
| Methodology and Request for Data                                    | 16 |

## Overall STI Vaccine and Diagnostic Research and Development Funding

Philanthropic and public funding for STI vaccine and diagnostic R&D totaled nearly US\$103 million in 2022. The majority of this funding stemmed from the NIH, which invested nearly US\$78 million, approximately 76% of reported funding disbursements. This is similar to the G-FINDER Sexual and Reproductive Health Research and Development report, which reported that 78% of total STI funding from the public and philanthropic sectors was disbursed by the NIH. Figure 1. STI Vaccine and Diagnostic R&D Funding by Sector Public: 76% \$77,875,231 Total: US\$102,902,991 Philanthropic : 24% \$25,027,760

Figure 2. STI Vaccine and Diagnostic R&D Funding by Topic



Additionally, 90% of funding was dedicated towards vaccine, 7% towards diagnostic, and 3% towards projects that examined both vaccine and diagnostic R&D. The disparity between vaccine and diagnostic funding can be partly attributed to the lack of funding information available from industry and private companies, where the bulk of diagnostic development take place. By pathogen, the majority of funding (51%) was dedicated towards HPV R&D with gonorrhea and syphilis representing the other top three pathogens funded.



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|  | Pathogen       | Amount        | Percent |
|--|----------------|---------------|---------|
|  | НРV            | \$52,294,266  | 51%     |
|  | Gonorrhea      | \$18,254,811  | 18%     |
| Show and a start with the start with | Syphilis       | \$9,189,620   | 9%      |
|  | Multi-pathogen | \$8,539,381   | 8%      |
|  | Chlamydia      | \$8,281,969   | 8%      |
|  | Genital Herpes | \$3,505,300   | 3%      |
|  | Hepatitis B    | \$2,837,644   | 3%      |
|  | Total          | \$102,902,991 | 100%    |

### NIH Funding by Institutes and Centers

The NIH is made up of 27 institutes and centers (ICs), and six of them dedicated funding towards STI vaccine and diagnostic funding totaling US\$78 million in 2022. These six ICs included the National Cancer Institute (NCI), National Institute of Allergy and Infectious Diseases (NIAID), National Institute of Biomedical Imaging and Bioengineering (NIBIB), Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institute of Dental and Craniofacial Research (NIDCR), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Additionally, The NIH Office of the Director dedicated funding towards STI vaccines and diagnostics as well.

NIAID and NCI were the top funding ICs, representing 56% and 36% of total NIH STI vaccine and diagnostic R&D respectively Figure 4. STI Vaccine and Diagnostic R&D Funding by NIH IC

Total: \$77,875,231



Six NIH institutes, centers and offices directed over \$70 million to STI vaccine R&D, while four institutes and centers directed over \$5 million to STI diagnostic R&D.

| Figure 5  | STI Vaccine and | Diagnostic R&F | ) Funding by NIH IC | and Topic  |
|-----------|-----------------|----------------|---------------------|------------|
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| Торіс      | IC    | Funding Amount | Percent |
|------------|-------|----------------|---------|
| Vaccine    | NIAID | \$40,783,649   | 52.4%   |
| Vaccine    | NCI   | \$26,785,889   | 34.4%   |
| Vaccine    | NIDDK | \$954,675      | 1.2%    |
| Vaccine    | OD    | \$550,000      | 0.7%    |
| Vaccine    | NICHD | \$409,167      | 0.5%    |
| Vaccine    | NIDCR | \$366,795      | 0.5%    |
| Diagnostic | NIBIB | \$2,768,013    | 3.6%    |
| Diagnostic | NCI   | \$1,519,152    | 2.0%    |
| Diagnostic | NIDCR | \$728,113      | 0.9%    |
| Total      |       | \$77,875,231   | 100%    |

# **Funding Distribution among Institutions**

The US\$103 million spent on STI vaccine and diagnostic R&D, was distributed to 124 projects among 59 organizations and institutions in 14 countries. Organizations and institutions from the US (82%), Costa Rica (8%), Netherlands (2%), United Kingdom (2%), and Switzerland (2%) were primarily funded. Institutions in South Africa and Zambia were the only African countries where local organizations were funded to conduct STI vaccine and diagnostic research. In total, US\$814,279 was provided directly to these two countries, representing less than 1% of total funding spent.



Figure 6. Funding Distribution by Country of Institution

Because the number of investors in STI vaccine and diagnostic R&D is limited, it is important to identify which institutions and organizations are conducting this work. Among the 59 organizations funded to conduct STI R&D, 78% (n=46) were located in the US. The 20 top funded organizations accounted for US\$63,895,315, or 62% of total funding, and represented academic and research institutions, hospitals, and pharmaceutical and biotechnology companies.

#### Figure 7. Top 20 Funded Institutions and Organizations

| 1  | Fundacion Inciensa<br>Costa Rica   \$8,411,393  | •  | Saint Louis University<br>United States   \$2,792,310  |
|----|---|----|--|
| 2  | The General Hospital Corporation d/b/a<br>Massachusetts General Hospital<br>United States   \$6,631,309 | 12 | Intravacc<br>Netherlands   \$2,007,498   |
| 3  | Johns Hopkins University<br>United States   \$5.349.481   | 13 | United States   \$1,899,165  |
| 4  | University of Connecticut School of Medicine<br>United States   \$4,996,690                             | 14 | World Health Organization - International<br>Agency for Research on Cancer<br>Switzerland/France   \$1,712,555 |
| 5  | Henry M. Jackson Foundation for the<br>Advancement of Military Medicine<br>United States   \$4,243,394  | 15 | SteriPack (USA) Limited<br>United States   \$1,645,600   |
| 6  | Lawrence Livermore National Security<br>United States   \$3,964,587                                     | 16 | Therapyx<br>United States   \$1,300,000  |
| 7  | University of North Carolina at Chapel Hill<br>United States   \$3,845,879                              | 17 | Wellcome Sanger Institute<br>United Kingdom   \$1,184,366  |
| 8  | University of Alabama at Birmingham<br>United States   \$3,714,780                                      | 18 | <b>Shanghai Zerun Biotechnology Co., Ltd.</b><br>China   \$1,005,923   |
| 9  | University of Washington<br>United States   \$3,636,054   | 19 | BlueWillow Biologics<br>United States   \$987,515  |
| 10 | Georgia State University<br>United States   \$3,612,141   | 20 | Carogen Corporation<br>United States   \$954,675   |
|    |   |    |  |

The 20 top funded organizations accounted for US\$63,895,315, or 62% of total funding.

When examining specific projects, out of the total projects funded, 106 (82%) were led by US-based organizations.

Little information is available on how organizations spend money received, including what percent is directed towards the stages of research and development projects focus on, what proportion supports research and researchers among communities most impacted by STIs including those living in limited-resource settings, and institutional indirect costs. Figure 8. STI Vaccine and Diagnostic R&D Funding among US and International Organizations



#### **Innovative Spotlight: DoxyPEP**

A growing body of evidence shows that taking a single oral dose of doxycycline within 72 hours after sex can substantially reduce risk for chlamydia, gonorrhea, and syphilis among men who have sex with men and among transgender women. This new strategy—doxycycline postexposure prophylaxis, or DoxyPEP—holds significant promise, and public health agencies are working to provide guidance on its use. But DoxyPEP research is not yet complete. DoxyPEP did not show efficacy in the one trial conducted to date, in Kenya, among women, who suffer some of the worst consequences of STIs. More trials are needed to learn if there are ways for women to use DoxyPEP successfully.

Research is also needed to explore the potential for DoxyPEP in low- and middle-income countries, and to understand how to increase DoxyPEP awareness and demand among key populations. It will also be important to monitor individual and population-level effects of this use of doxycycline. In particular, while studies to date have not indicated that DoxyPEP use contributes to antibiotic resistance, health authorities should watch closely for any changes in light of the global threat of antibiotic resistance.

Despite these ongoing challenges, DoxyPEP is an important new development and a powerful reminder that with the proper investments, further innovation in STI prevention is possible – and much needed.

# STI Vaccine Research and Development

Funding towards STI vaccine development includes projects focused on examining a specific vaccine candidate. Out of the pathogens included, US\$50 million was spent on HPV vaccine R&D, US\$18 million for gonorrhea vaccine R&D, US\$9 million for syphilis vaccine R&D, US\$8 million for chlamydia vaccine R&D, US\$3.5 million for genital herpes vaccine R&D, and US\$2.8 million for Hepatitis B vaccine R&D. A few projects described research focused on multiple pathogens, including one project researching both chlamydia and genital herpes vaccines, and another examining HPV and hepatitis B vaccines. These projects totaled approximately US\$1 million, accounting for about 1% of vaccine R&D funding. Overall, STI vaccine funding is incredibly limited and lags behind other infectious diseases including HIV, where US\$794.6 million was invested in HIV vaccine development in 2021.



#### Figure 9. STI Vaccine R&D Funding by Pathogen

The <u>2019 NIH awards</u> to support the development of vaccines to prevent STIs has been instrumental for funding efforts. These awards provided US\$41.6 million to support chlamydia, gonorrhea, and syphilis research over a five-year period with the goal of producing at least one vaccine candidate ready for testing in clinical trials. Overall, cooperative agreements like these made up 38% of NIH supported vaccine and diagnostic funding, and 30% of total funding, highlighting the impact of these awards. In 2023, <u>NIAID released a new request for application</u> to continue to the development of STI vaccines. Because these awards have been a primary source of funding for vaccine R&D, support from the NIH remains essential for advancing the STI R&D field.



The current STI vaccine pipeline includes:



Chlamydia: Statens Serum Institut and Imperial College London have completed small phase I safety and immunogenicity studies of a potential chlamydia

vaccine. Additionally, in 2023, Sanofi announced an expansion into chlamydia vaccine development.



**Genital herpes**: Several therapeutic herpes simplex virus (HSV) vaccine candidates have entered clinical trials in recent years, including a Phase II study led by Sanofi Pasteur, Immune Trial Design, PATH and NIAID that is expected to report results in mid-2024. Additionally, **BioNTech** began a Phase I trail for a prophylactic HSV-2 vaccine and Moderna and GSK are evaluating therapeutic vaccines. In 2023, the bio-tech firm. Rational Vaccines. was awarded US\$2.8 million dollars from the NIH to support their herpes work and develop therapeutic and prophylactic vaccines and

diagnostic tests. Modeling studies demonstrate that both preventive and therapeutic HSV vaccines could have significant public health and economic impact, including reduction of HIV infections and savings of hundreds of millions of dollars in healthcare costs.

#### **HPV Vaccines**

Vaccines to prevent several strains of HPV first became available in 2006, thanks to decades of public and private investment in R&D. In the decade that followed, a Swedish study indicates that incidence of cervical cancer among girls vaccinated before age 17 fell by nearly 90%. However, HPV vaccine rollout remains slow in low- and lower-middle-income countries. where 9 in 10 cervical cancer deaths occur. In 2020, the World Health Assembly adopted the Global Strategy to Accelerate the Elimination of Cervical Cancer as a Public Health Problem. but HPV vaccination, as well as cervical cancer screening and treatment, will need to be dramatically expanded for the world to meet the strategy's targets.



**Gonorrhea**: Observational studies show that some vaccines against meningitis B, which is caused by a pathogen closely related to the bacteria causing gonorrhea, may reduce new gonorrhea infections. Clinical trials are underway to study the effectiveness of these vaccines against gonorrhea, while several other, different types of gonorrhea vaccine candidates are in

preclinical development. In 2023, <u>GSK received the US Food and Drug Administration (FDA) Fast</u>

Track designation for their investigational gonorrhea vaccine. Fast Track designation can facilitate the development and expedite review of potentially important new drugs and vaccines to treat and prevent serious medical conditions with unmet medical needs.



**Syphilis**: Researchers are currently pursuing a two-pronged approach that would reduce syphilis transmission and prevent the dissemination of syphilis bacteria through the bloodstream, to stop it from causing congenital infections and neurological damage. This research remains in the preclinical phase.



Trichomoniasis: The current state of trichomoniasis vaccine development research is in the discovery and exploratory stage and none of the projects examined, mentioned research on a specific trichomoniasis vaccine candidate. Comparatively, vaccine candidates for other pathogens have entered into preclinical and clinical studies, which is the funding this report focuses on.

Additionally, while vaccines that prevent HPV and hepatitis B exist, research is still needed to develop therapeutic vaccines and those that offer protection against different strains. Overall, vaccine development is an ongoing process for each pathogen with different candidates reaching different stages of the development pipeline. In recent years, public health agencies have taken significant steps to jumpstart innovation in STI vaccine development. The World Health Organization, in collaboration with the U.S. National Institutes of Health and global technical partners, published a comprehensive roadmap for the development of new STI vaccines. This roadmap, first released in 2014 and updated in 2016, describes an end-to-end approach that is intended to guide investment, accelerate development of new vaccines and ensure faster, more targeted rollout of vaccines to those who could benefit the most.

# **STI Diagnostic Research and Development**

Funding and development for STI diagnostics is often concentrated in private, for-profit companies, which provide limited information about funding disbursements. However, public and philanthropic organizations reported some diagnostic R&D funding. Out of total STI funding reported, 7% is dedicated towards diagnostic research, which is substantially lower than vaccine research. As with vaccine R&D, the NIH spending accounted for the vast majority of diagnostic R&D investments (73%, compared to 76% for STI vaccine R&D).

Of diagnostic funding available, 66% was dedicated to multi-pathogen research, 33% towards HPV, and 1% towards hepatitis B. Multi-pathogen diagnostic projects included research on syphilis, gonorrhea, genital herpes, and chlamydia.



Figure 10. STI Diagnostic R&D Funding by Pathogen

# **Industry Activities**

Diagnostic R&D funding was primarily dedicated towards institutions based in the US and one institution in Zambia received funding to conduct diagnostic research. Additional support for research projects outside of the US is needed to better meet the needs of those in other countries.

Below are additional details about the STI diagnostic R&D pipeline:

The <u>Genital Inflammation Test (GIFT</u>) is a point-of-care test that detects biomarkers of genital inflammation caused by STIs and bacterial vaginosis (BV), using a quick, non-invasive, affordable, and user-friendly device. Because STIs/BV are associated with higher rates of HIV, one of the aims of this test is to improve detection of inflammation to better prevent HIV. GIFT is a lateral flow test similar to a pregnancy test. These types of tests are generally quick, non-invasive, affordable, and user friendly. The project has been funded by the South African Medical Research, South Technology Innovation Agency, and EDCTP. While these organizations did not report funding amounts for this report, this project serves as an example of what can be accomplished in the diagnostic R&D space with diverse funding initiatives.

Self-collection receives FDA marketing approval. In 2023, the FDA approved marketing of a chlamydia and gonorrhea test with at-home sample collection for LetsGetChecked's Simple 2 Test. The Simple 2 Test includes the Simple 2 Home Collection Kits that were validated for use with the cleared Hologic Aptima 2 Combo Assay. This was the first diagnostic test for chlamydia and gonorrhea with at-home sample collection to be granted marketing authorization. Additionally, this was the first FDA-authorized test with at-home sample collection for an STI other than HIV, offering great promise for additional tests. The Simple 2 Test is available over the counter and intended for use in adults aged 18 years and older.

The Simple 2 Test can be purchased without a prescription.

# WHO Diagnostic

Spotlight: In 2023, the WHO released several new reports and manuals to provide information on diagnostics currently available and help guide diagnostic development. The guidance includes detailed target product profiles (TPPs) for point-of-care diagnostic tests for syphilis, chlamydia, gonorrhea, and trichomoniasis. These TPPs offer developers a blueprint for creating products that warrant inclusion on WHO's essential medicines lists. The STI diagnostic landscape report reviews commercially available technologies (tests, platforms, and systems for use in resourcelimited setting) for syphilis, chlamydia, gonorrhea, trichomoniasis, Mycoplasma Genitalium, herpes, and HPV. Finally, the laboratory and point-of-care diagnostic testing for STIs, including HIV manual provides a basic understanding of the principles of testing.

Users will complete a health questionnaire for a health care provider to evaluate. They will then collect their own specimen including a vaginal swab or urine sample, using the provided kit, which they then mail back to the designated laboratory for testing. Results are delivered online within 2-5 days and a healthcare provider will follow-up with the user in cases of a positive or invalid test results.

Overall, STI tests with at-home specimen collection or self-collection help to broaden access to testing and offer patients the ability to collect specimen where they feel safe and can easily access. However, barriers and challenges with these tests still exist. The Simple 2 Test is currently being sold for US\$99, which could make this test prohibitively expensive for many people. Additionally, as STI awareness is still suboptimal and there are few resources available to ensure that the tests users are ordering are the tests needed, which could lead to over- and under-testing of different STIs including syphilis, Mycoplasma Genitalium, and trichomoniasis. Finally, while the Simple 2 Test is the only one currently with FDA marketing approval, other STI tests exist with at-home collection, further creating a market that can be difficult for user to navigate when trying to identify the STI tests that they need. Many biopharmaceutical companies, laboratories, and diagnostic developers do not provide information on financial disbursements. However, they continue to support STI diagnostic R&D. In 2022, private companies reported supporting projects focused on studies to determine STI prevalence and antibiotic resistance marker prevalence in across various populations and at local, regional and national levels; studies evaluating a research use only molecular test for syphilis in highrisk populations; STI prevalence/associations in the context of HIV prevention programs for young MSM/transgender men/transmasculine nonbinary individuals.

Additionally, an HPV test developed by Abbott received FDA approval in 2023. This is one of few tests approved for primary screening for cervical cancer. Historically, Pap tests were used to screen for cervical cancer. However, guidelines have started to shift and some now recommend testing for cancer-causing types of HPV, which is referred to as primary screening. The Alinity m high risk (HR) HPV assay is approved as a test for HPV detection and for use in routine cervical cancer screening.

Despite advancements in STI diagnostics, logistical and infrastructure barriers prevent many LMICs and limited resource settings from being able to implement these new tools. Cost, the need for trained health professionals to operate tests, and limited laboratory capacity are some barriers that make it difficult to implement new STI diagnostics. Affordable, user-friendly, effective, and rapid point-of-care tests are desperately needed to fill gaps in the STI testing field.

#### Pipeline Spotlight – New gonorrhea antibiotics

In the absence of vaccines and effective diagnostics, treatment remains the best current defense against most STIs. Four of the most common infections—chlamydia, gonorrhea, syphilis, and trichomoniasis—are currently curable. But new treatments are needed, most urgently in the case of gonorrhea, which has acquired resistance to all but one class of antibiotics. Recently a phase 3 study of oral zoliflodacin was shown to be effective in treating gonorrhea. Under a partnership between Global Antibiotic Research & Development Partnership (GARDP) and Innoviva, goal is for this treatment to undergo the licensure process in about 160 low- and middle-income countries. Pending regulatory approval, zoliflodacin will also be available in high-income markets including North and Latin America, the Asia-Pacific, and Europe.

# Recommendations

#### Increase STI R&D Funding

STI vaccine and diagnostic R&D funding lags behind other infectious diseases. In 2021, HIV prevention totaled US\$1.25 billion with \$794.6 million dedicated to preventive vaccines. This funding for HIV has helped lead to the development of pre- and post-exposure prophylaxis and effective treatments. Overall, this has helped to lower and prevent the spread of infections. Comparatively, STIs have received much less funding as rates continue to rise globally, jeopardizing the health of millions of people while costing healthcare systems billions of dollars. Additional investments are needed in STI R&D to develop prevention and treatment tools that are effective, affordable, and meet the needs of the communities impacted by these infections.

## Research Agendas Should be Person-Centered

A person-centered research agenda is needed to prioritize the health of people and communities. This approach includes the need for more public-private partnerships to help develop new STI vaccines, diagnostics, and treatments. Oftentimes, STI treatment and prevention tools, including antibiotics, remain under-researched and undeveloped due to low profit margins. This leaves many without access to the tools needed to better prevent and treat STIs and can lead to high levels of antibiotic resistance. Examples of public-private relationships include GARDP and Innoviva who found that an antibiotic, zoliflodacin, could be used to treat gonorrhea. By factoring public health constraints into the drug development process, developers are able to create products that can be implemented in LMICs. FIND provides another example of an organization that aims to connect countries, communities, funders, decision-makers, healthcare provides, and developers to promote diagnostic innovation with public health at the forefront.

Additionally, there is a need for more conscious efforts dedicated to developing tools that can be implemented in limited resource settings including LMICs. This includes point-of-care tests that are effective, affordable, and user-friendly, and vaccines that can be easily stored and administered.

## Engage Civil Society in Meaningful Partnerships

Civil society remains important for advocating for the tools they need to prevent and treat STIs and not just the tools developers and researchers are interested in developing or implementing them. Civil society has been imperative in moving the HIV and TB fields forward in developing new diagnostic, prevention and treatment options that are effective and able to be implemented in LMICs. Civil society has also helped to ensure access to cervical cancer prevention, including HPV vaccines. Therefore, civil society remains important for advancing the STI field and ensuring equitable access to current and new prevention and treatment tools including vaccines and diagnostics.

### Center People in Research Agendas

Many countries report a limited focus on STI prevention and testing and treatment guidelines that are out-of-date or do not meet patient needs and focus on syndromic management. Therefore, government involvement is needed to build national strategies that meet the current needs of communities and can help prevent infections. National strategies that include STI prevention needs and opportunities can also help in shaping advocacy campaigns and advising developers and funders on STI testing capacity to inform the development and implementation of new tests.

The <u>Global Health sector</u> strategies on, respectively, HIV, viral hepatitis, and sexually transmitted infections for the period 2022-2030 and the Sexually Transmitted Infections <u>National Strategic Plan</u> can help to inform national strategies. AVAC Partner Spotlight: Advocacy is needed to bring more awareness on the impact that STIs have on the health of people and communities and the need for vaccines and diagnostics to better prevent, detect, and treat infections. Seven AVAC partners in East and Southern Africa received funding to conduct projects on community needs to prevent, detect, and treat STIs. These advocacy projects helped build a stronger advocacy movement to improve funding and commitments in and around STI vaccines and diagnostics.

These projects showed that while STI rates in East and Southern Africa are high, few countries had STI strategic plans and testing strategies. Additionally, resource constraints, including financial, human, and infrastructural, posed significant challenges to advance STI prevention programs. Findings were presented during a 2023 two-part webinar series from November 7th and November 9th.

# Methodology and Request for Data

Data included in this report have been compiled from multiple sources, including documented budgets, program disbursements, and funding information self-reported from donors who submitted funding disbursements for fiscal year 2022. Some funding information might be missing due to lack of response from funders after information was requested. Additionally, some funders were not able to report specific funding amounts dedicated towards STI vaccine and diagnostics R&D and instead reported on activities they supported and conducted.

NIH funding was obtained from <u>NIH RePORTER</u> to obtain STI funding data from multiple centers and institutes. Private companies reported on STI R&D activities instead of specific funding. Funding data obtained has been aggregated. If you have questions, feedback, or information that you think should be included in future reports, please contact us at <u>sti@avac.org</u>.

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#### About AVAC

AVAC is an international non-profit organization that leverages its independent voice and global partnerships to accelerate ethical development and equitable delivery of effective HIV prevention options, as part of a comprehensive and integrated pathway to global health equity. Follow AVAC on Twitter <u>@HIVpxresearch</u>; find more at <u>www.avac.org</u>, <u>www.prepwatch.org</u> and <u>www.stiwatch.org</u>.