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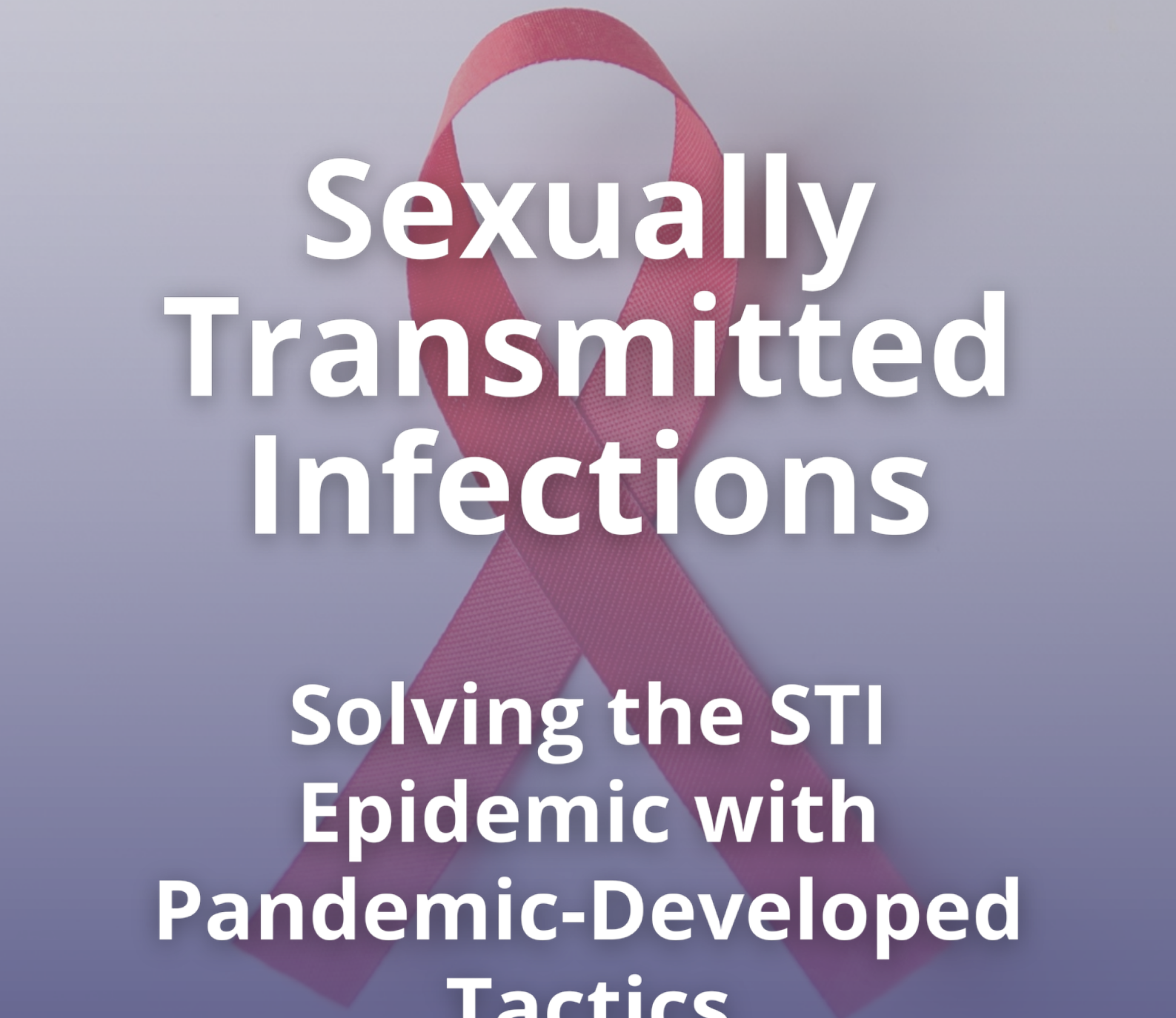
FUTURE DIAGNOSTICS



Sexually Transmitted Infections

Solving the STI Epidemic with Pandemic-Developed Tactics

About Senzo: Senzo Health is a diagnostics technology company developing future testing solutions for healthcare and industry, based in London, Cambridge and the USA.

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STIs

The shocking stats:

Recent trends indicate a significant rise in Sexually Transmitted Infections (STIs).

In the United States, the economic impact of STIs is staggering. Approximately 20% of the population have an STI - that is 1 in every 5 adults - totalling 68 million. There are around 25 million new infections each year, costing over $16 billion in direct lifetime medical expenses. Chlamydia, trichomoniasis, genital herpes simplex virus (HSV), and human papillomavirus (HPV) account for 98% of infections, with nearly half of new cases arising in youth aged 15-24.
https://www.cdc.gov/nchhstp/newsroom/fact-sheets/STI/STI-Incidence-Prevalence-Cost-Factsheet.html

Globally there are around 374 million new infections each year caused by a curable STI (chlamydia, gonorrhoea, syphilis and trichomoniasis). Over 500 million people are estimated to have HSV. Around 1 million pregnant women are infected with syphilis annually causing over 350,000 adverse birth outcomes, and HPV infections are linked to more than 311,000 cervical cancer deaths annually. More than 1 million sexually transmitted infections (STIs) are acquired every day worldwide, the majority of which are asymptomatic.

Many of these infections go undetected because of the lack of symptoms, but STIs have serious health consequences from stigma to infertility to cancer to pregnancy complications. These infections can elevate the risk of HIV and fuel antimicrobial resistance, further reducing the efficacy of treatment.
https://www.who.int/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis)

However, this current situation is not inevitable; the STI epidemic can be solved.

Stopping the spread:

STIs, unlike airborne pathogens, do not transmit through casual contact. **Owing to the specific transmission vector of these infections, targeted behavioral change is the simplest way to arrest the spread.** Abstinence from sexual activity is the most sure-fire method to avoid contagion. Monogamy between uninfected individuals also guarantees no transmission and the use of contraception can significantly reduce the spread. Additionally, vaccinations, such as those available for HPV, provide a proactive means to prevent certain types of infections before they occur.

However, the cornerstone of prevention is knowledge. **Knowing your status and that of a partner is fundamental to reducing infections.** Regular testing allows individuals to make informed decisions and take appropriate measures to protect themselves and their partner(s) if an infection is detected. Furthermore, many STIs are not only treatable but often curable. Better knowledge guides the correct behaviour and can often enable an infection-free future.
https://www.cdc.gov/std/prevention/default.htm

Given the frequently asymptomatic nature of these infections, large-scale testing is central to effective detection, control, and treatment.

The testing challenge:

To first halt and subsequently reverse today's increasing STI rates, expansive and regular testing, particularly among higher-risk demographics, is essential. **This requires a testing solution at a society-wide level.**

https://www.cdc.gov/STI/prevention/screeningreccs.htm

- All 13 to 64-year-olds should be tested for HIV.
- Sexually active women under 25 and those over 25 with risk factors should be tested for gonorrhoea and chlamydia every year.
- All pregnant women should be tested for syphilis, HIV, hepatitis B, and hepatitis C with higher-risk women also tested for chlamydia and gonorrhoea.
- All sexually active gay and bisexual men should be tested annually for syphilis, chlamydia, gonorrhoea, HIV, and hepatitis C if living with HIV.
- Anyone who shares injection drug equipment should get tested for HIV at least once a year.

There are clear similarities to the surveillance undertaken during the COVID-19 pandemic. **Unfortunately, unlike during the pandemic, there are firstly multiple pathogens to test for, and secondly, no high-accuracy at-home self-tests to enable testing at a whole-population scale.**

STI Dx Problem:

Currently, in the absence of high-accuracy at-home self-testing options, an individual needs to visit a clinic to confirm their STI status.

The most common STIs are Human Papillomavirus (HPV), tested via regular Pap smear tests, Chlamydia and Gonorrhoea, diagnosed through molecular tests, Syphilis, diagnosed through serology tests, and Herpes Simplex Virus (HSV), again diagnosed via serological testing. In summary, current STI testing requires clinical diagnosis and time-consuming and expensive central laboratory testing.

Additionally, the stigma associated with STIs presents a significant barrier to achieving the necessary surveillance via clinical, central lab testing alone.

Current rapid self-tests for STIs often rely on target detection that, while fast, can lack the necessary sensitivity. These tests may fail to detect lower concentrations of the pathogen or antibodies in the early stages of infection, leading to a higher likelihood of false negatives, reducing the early detection and timely treatment of STIs, which is crucial in preventing further transmission.

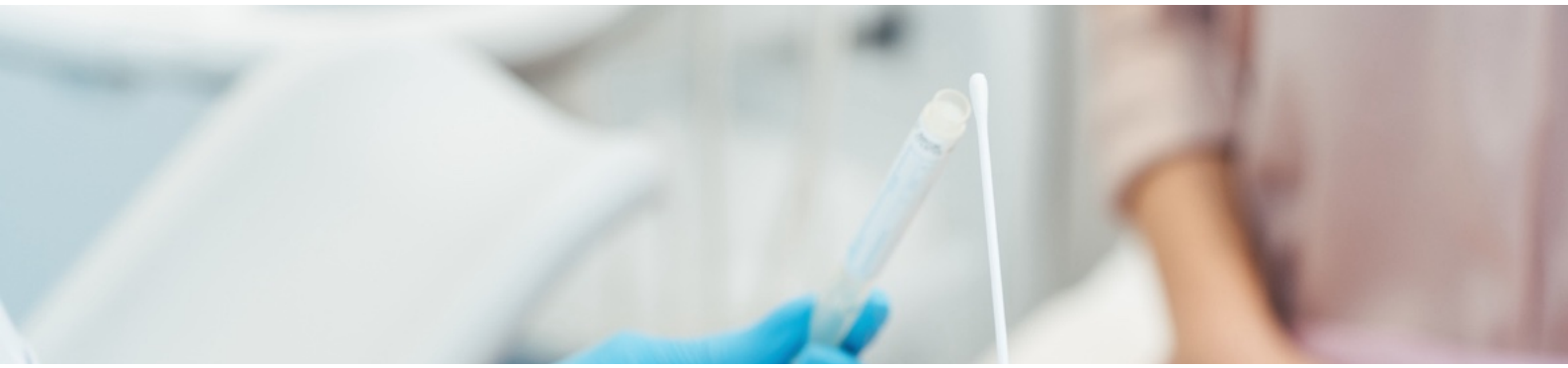
A 2021 meta-analysis on the accuracy of rapid self-tests - similar to COVID-19 lateral flow devices - for chlamydia found that these tests had a sensitivity of just 56%, far below what would be needed to identify infection and guide treatment decisions.
https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00241-8/fulltext

In 1993 the Rockefeller Foundation posted a prize of $1 million for the development of an inexpensive, simple, rapid self-test to detect genital chlamydial or gonococcal infection. The prize was never claimed and was withdrawn in 1998.

The WHO developed the ASSURED test criteria to promote the development of accurate tests that work everywhere, for everybody:

"The World Health Organization Sexually Transmitted Diseases Diagnostics Initiative (SDI) has developed the ASSURED criteria as a benchmark to decide if tests address disease control needs: Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free and Deliverable to end-users."
https://sti.bmj.com/content/82/suppl_5/v1.short

A 2011 survey of STI clinicians found that the most requested innovation would be a 90%+ accurate, fast, and affordable STI test for C. trachomatis:



Clinicians want fast, accurate, and affordable tests. "STI professionals preferred C. trachomatis as the top priority for a new POCT with sensitivity over 90%, low cost, and a very short completion time."
https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0019263

Today, where rapid diagnostic tests do exist, they lack the necessary sensitivity, sometimes being even counterproductive, adding complexity and cost to the diagnostic process:

"Testing for hepatitis C in the United States requires an antibody test, and if that is positive, a lab-based nucleic acid test to confirm infection. This process is cumbersome, results in some people never getting a confirmed diagnosis, and delays treatment."
https://www.cdc.gov/nchhstp/newsroom/2023/viral-hepatitis-cure-cascade.html

As a 2020 paper on Point-of-Care Testing for Sexually Transmitted Infections put it:

"Although there are inexpensive, rapid, and accurate POC tests available for syphilis, there are few such tests available for the diagnosis of chlamydia, gonorrhoea, or trichomonas, and currently none with the ability to detect antimicrobial resistance in N gonorrhoeae. Research evaluating implementation strategies for the currently available tests and the development of additional POC tests that are rapid, accurate, and affordable are urgently needed to address the rising number of STIs worldwide."
https://meridian.allenpress.com/aplm/article/144/11/1344/442555/Point-of-Care-Testing-for-Sexually-Transmitted

STI Dx Solution:

As governments work to address the current STI epidemic via education, contraception, vaccination, and treatment, **a foundational technology remains missing:** the development and widespread deployment of accurate, rapid, self-test diagnostics for the most prevalent STIs.

The necessity of such technology is underscored by the staggering statistics of STIs both in the U.S. and globally and the significant economic and health burdens they impose.

Accurate and inexpensive point-of-care (POC) tests are urgently needed to control sexually transmitted infection epidemics so that patients can receive immediate diagnoses, stop the spread, access treatments, and in many cases cures.
https://www.tandfonline.com/doi/abs/10.1586/14787210.2014.880651

The path to solving the STI crisis lies not only in the current prevention and treatment strategies but crucially in developing new diagnostic capabilities.

The task is clear: to create a range of diagnostic tools that meet the ASSURED criteria – affordable, sensitive, specific, user-friendly, rapid and robust, equipment-free, and deliverable to end-users for the world's most prevalent STIs.

The focus, effort, and investment in developing such diagnostics will be pivotal in turning the tide against this global health emergency.

About Senzo

Senzo is an In Vitro Diagnostics (IVD) company developing innovative, accurate, and accessible testing products.

Senzo was founded with the vision of utilising novel technologies, with a focus on enhanced sensitivity, to create mobile, point-of-care and self-testing products and devices with the ability to accurately, quickly, and cost-effectively conduct testing where and when healthcare professionals and patients need it most.

Senzo is creating game-changing products and systems which bring testing to the patient, eliminating the need for the current slow, expensive central-lab testing paradigms. With insights generated at the point of care, patients can make better decisions faster, and healthcare professionals can identify life-threatening diseases at an earlier stage, improving treatment outcomes and saving lives.

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