

Testimony for SB0634: Health Insurance – Home Test Kits for Sexually Transmitted Diseases – Required Coverage

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The Problem:

- One million new cases of Sexually Transmitted Infections (STIs) per day in the U.S.
- Cases reported to the CDC are at an all-time high: 1.8 million cases of chlamydia (19% increase since 2015) and 616,392 cases of gonorrhea (56% increase). Syphilis and congenital syphilis have increased dramatically.
- STIs are associated with severe sequelae such as HIV acquisition, pelvic inflammatory disease, infertility, low birthweight, and adverse birth outcomes.
- Cases and Rates in Maryland: (2019 Latest available) Chlamydia: 37,779 cases, 624.9/100,000 population; Gonorrhea: 11,598 cases, 191.8/100,000; Syphilis: 868 cases, 14.4/100,000.
- Adolescents and young adults bear most of the burden of STIs.

Diagnostic Advances:

- In the last 15 years molecular methods have allowed more accurate tests, as well as more obtainable sample types to be used, such as vaginal swabs, urine, penile meatal swabs, and dried blood spots.
- Companies have obtained FDA clearance for self-collected urogenital swabs for these STI tests.
- Some companies (e.g., 247 Lab Kit, Everywell, Let's Get Checked, My Lab Box, Nurx, Planned Parenthood, Verisana, iDNA, Alpha Medical, binx Health, Virtuwel) are offering internet-recruited individuals the ability to collect samples at home for mail in to testing sites for performance of molecular tests for chlamydia and gonorrhea. These are expensive and not covered by insurance.
- Universities (e.g., Johns Hopkins University's program, IWANTTHEKIT (IWTK) also offer public health screening for home collected urogenital samples for free.
- The OraQuick® (Orasure) home test for HIV antibodies is the only test in the US thus far that can be purchased at a pharmacy over-the-counter (OTC) or for mail out to individuals for performance by the individual at home. It is expensive.

Terminology and Other Considerations:

- It is necessary to distinguish between **home-collection** of specimens at home for mailing (e.g., chlamydia and gonorrhea) and **home-tested** samples that are self-performed (e.g., HIV).
- Surveys have shown that women prefer self-collected vaginal swabs and men are willing to self-collect penile-meatal swabs at home or in a clinic. Many prefer collection at-home for convenience, and issues of privacy and stigma.
- New point-of-care (POC) tests have been developed recently that can be obtained by doctors' offices and clinics, tested by a health care worker, and provide results in 30 min at the clinical encounter. This makes it possible to treat patients before they leave the clinic. Thus far, there are two such POC tests. Adoption and insurance coverage will help the STI epidemic. In the future, it might be possible for them to be performed by individuals at home.

Solutions:

- Many online companies, who offer testing for specimens collected at home and mailed to a testing site, charge high prices (e.g., \$50-300), but these tests are not covered by insurance. **Making these tests billable to insurance by law would be game changing.**
- IWANTTHEKIT (IWTK) is good public health practice and is free but not billable by insurance. Funding is an issue for the future.
- We opened IWTK in 2004, which provides **free and confidential home-collection, mail-in STI testing** to residents of Maryland. Our program has tested over 20,000 genital, rectal, and oropharyngeal specimens from >10,000 female, male, and non-binary gender-identifying users for individuals 14 years and older. It has been funded by NIH grants, occasionally by the State of MD, and recently (2019) by the Baltimore City Health Department. Baltimore residents can also order a free home test-yourself HIV test. Sustainability is a future issue. **Making these tests covered by insurance is important.**
- IWTK users obtain test results on the HIPAA-secure IWTK website; positive results are also sent to the clinic pre-selected by the user for follow-up treatment. Treatment success is high.
- The **monthly average** of IWTK testing kits requested **during COVID-19** (221.3) compared to pre-COVID-19 (29.7) **increased 645%. In January, 2022, we performed 1,016 tests from 714 kits.**
- Home collection and testing provide a reliable, convenient, and private method to access STI/HIV diagnostics, obviating the need for in-person clinic visits where the risk of COVID-19 exposure may be high.

Conclusions:

- **Passing SB 0634 will enable more persons with insurance to get tested for STIs.**

