Burnett Foundation Aotearoa

To: The Honourable Matt Doocey, MP From: Burnett Foundation Aotearoa

Date: 1 May 2024

Title: Briefing: Funded Home Self-Tests for Sexually Transmitted Infections (STI)

Summary

New Zealand is currently experiencing significant STI outbreaks, and rates of transmission continue to grow each year. Gay, Bisexual, and other men who have sex with men (GBM) are disproportionately affected by the current outbreaks, however, we are also seeing high rates of sexually transmitted infections (STI) among Māori and Pacific women, and each year there are new cases of congenital syphilis. Unfortunately, the process for accessing STI testing in-person remains cumbersome, and is often costly. Burnett Foundation Aotearoa subsidises home testing for STIs for our key populations at-risk; however, innovation and funding is needed at a much larger scale in order to adequately address the growing STI epidemics.

Background

Currently there are a few options for HIV and STI testing. Burnett Foundation Aotearoa and some other community organisations offer free in-person rapid finger-prick HIV/syphilis testing. We also take swabs for a full STI screening that are processed at a sexual health clinic. Free testing through sexual health clinics is available but there is very limited access, particularly outside cities in rural or regional areas. Furthermore, access to sexual health clinics is also only funded for NZ citizens, residents, or people on a two-year work visa. While GPs are also able to do testing, the cost of consultation appointments and wait times are still barriers.

Burnett Foundation Aotearoa also offers free HIV self-test kits through our website, Grindr, vending machines at community venues, and specific collection sites. Self-testing kits for STIs are a growing method to reach more populations and are also added as an extra for those self-testing for HIV. Burnett Foundation Aotearoa is seeing a strong shift towards self-testing for HIV. In 2023, Burnett Foundation Aotearoa provided more than 6000 HIV tests and more than 2/3 were home self-tests for HIV, while less than 1/3 of clients accessed in-person testing in a clinic [1]. Data from the Sex and Prevention of Transmission Study also showed that approximately a quarter of respondents who last tested HIV negative likely received this result using Burnett Foundation Aotearoa's devices. 9.3% received their negative result via Burnett Foundation Aotearoa Clinics and 16.1% via a self-test kit, most likely obtained through Burnett Foundation's website.

Burnett Foundation Aotearoa offers home self-testing for HIV, and we partner with <u>Sexual Health 101</u> to provide self-sampling for STIs, which can be delivered in discreet packaging, or picked up from discreet locations. These are subsidised to the cost of \$20 for our targeted populations. Self-testing for HIV requires a gum swab being taken to collect fluid from the mouth, and results are available in 20 minutes.

STI testing for chlamydia, gonorrhoea, and syphilis occurs through providing swabs for people to do self-swabbing and urine collection, visiting the laboratory for blood tests, and requires the user to send test results back to a laboratory and wait for the result. This enables a full STI screening and connects people into care. Sexual Health 101 also independently offers these as a take-home kit which costs \$85. These tests are designed for precautionary testing rather than for people with common STI symptoms, which requires a full blood test.

Burnett Foundation Aotearoa make great effort to ensure that our tests have acceptable safety, quality, and performance, and that they are accurate. Efficacy is measured through sensitivity (i.e., the percentage of results that will be positive when HIV/STIs are present) and specificity (i.e., the percentage of results that will be negative when HIV/STIs are not present). Our Oraquick self-tests for HIV have 92% test sensitivity, and 99.98% specificity [2]. This means that one false negative result would be expected out of every 12 test results in people with HIV, and one false positive result would be expected out of every 5,000 test results in people without HIV. Our rapid in-person tests for HIV and syphilis have sensitivity of 99.3%-100%, and specificity ranging from 99-99.8% [3].

Burnett Foundation Aotearoa do not provide rapid point-of-care or self-tests for gonorrhoea, and chlamydia, as they are not clinically reliable or effective. There are over-the-counter antigen-based point of care STI tests for chlamydia, gonorrhoea, and herpes available from <u>some pharmacies</u>, and the <u>Ettie Rout kits</u>; however, these tests are not fit for purpose due to their low sensitivity, meaning the tests miss a lot of infections (approximately 37-63% of those with chlamydia [4], and 30-88% of those with gonorrhoea [5]). These tests give false reassurance to the user, meaning they do not connect into care and treatment, and contribute to ongoing transmission.

Problem

NZ is currently experiencing significant syphilis, chlamydia, and gonorrhoea outbreaks, and rates of transmission continue to grow each year. According to provisional data from ESR, there were 713 cases of infectious syphilis in 2023. This is the highest number since 2019 when we had 725 cases, and compares to only 506 diagnosed and notified cases in 2022. The increase has been most marked in GBM. Missed opportunities for testing in antenatal care also led to 3 cases of congenital syphilis in 2023, and one neonatal death. Sadly, there has been a vacuum of leadership over previous governments to address these outbreaks.

Unfortunately, there remain significant barriers to accessing STI testing which results in not enough people accessing regular testing. Common barriers to testing for STIs in clinics include not having access to sexual health clinics in regional or rural areas, services being offered at inconvenient times, fear of stigma and lack of confidentiality ^[6], perceived or actual costs, access to specialty care, not feeling at risk ^[7], or having had an earlier poor experience. Many in our community also report finding in-person testing to be invasive, as it sometimes requires giving a sexual history. This is especially true for temporary migrants, who must pay out-of-pocket for STI testing, and this cost can range from \$85-\$361 for the person every time.

Furthermore, there is currently no regulation of point of care tests or self-tests in NZ, or national clinical guidance structure for testing. While this has enabled organisations like Burnett Foundation Aotearoa to import HIV and syphilis testing devices, we make great effort to ensure that our tests are accurate. The void also enables the marketing and selling of testing devices for commercial interests, without any check over their efficacy or sensitivity, to a public who must trust the claims of quality made by the manufacturers and suppliers (as with the over-the-counter tests mentioned

above). A recent position statement on this issue was published by the New Zealand Sexual Health Society and other health sector colleagues advising that in the interest of public safety, these tests should not be promoted, marketed, sold, or used in NZ. The lack of regulation therefore means other tests currently available in the market are likely giving a false sense of security, and resulting in ongoing transmission.

A standardised approach to testing is further complicated by pathways to testing differing by region, due to the overly complex issue of laboratory contracts and funding.

It is important that STIs are picked up early in their infection, as if STIs like syphilis are left untreated, the infection stays in the body and can begin to damage the body's internal organs including the heart, brain, nervous system, and blood vessels [8]. Chlamydia can cause damage to reproductive systems, even when there are no symptoms [9]. In contrast, if people are in a pattern of regular testing, antibiotics to cure the infection can be given immediately.

Solution

At the moment, NZ is facing a perfect storm of growing STI outbreaks, a need for more STI testing, but limited access to clinics, and little regulation over the quality of tests. This has allowed commercially driven companies to take advantage of the public by offering poor quality tests, which is going to result in ongoing transmission if change does not occur. Home self-testing and self-swabbing for STIs is a more acceptable option than testing in clinics for many people, as it does not require speaking to a clinician to do the test, enables bodily autonomy, and allows people to take control of their health.

While there are not good quality self-test devices for STIs other than HIV, we would like to see self-sampling for STIs funded nationally, so that people can be freely provided swabs to swab themselves, which can then be sent off to labs for processing. At present, sexual health clinics are not encouraged or enabled to offer home STI self-sampling due to resource constraints, however there are also limitations due to the way regional labs are funded. We need a nationally commissioned home STI self-sampling service that cuts through issues with regional lab contracts and provides easy access to STI testing for high-risk groups, no matter where in NZ they are located.

National funding for self-sampling would dramatically enable increased access to and uptake of testing, driven by community need. However, these need to be accurate, effective, and good quality tests. These could be made available through Burnett Foundation Aotearoa, Sexual Health Clinics nationwide, GPs, and pharmacies.

Home self-tests for STIs like what Burnett Foundation and Sexual Health 101 offer need to be funded as a way to increase access to and uptake of testing, driven by community need.

Recommendation

A home STI self-swabbing service is commissioned and nationally funded, with a clinical guidance structure overseeing the quality of testing, in order to enable increased access to testing, and contain STI outbreaks.

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- 2. FDA. *Information regarding the OraQuick In-Home HIV Test*. 2020; Available from: https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/information-regarding-oraquick-home-hiv-test.
- 3. INSTI. *INSTI Multiplex HIV-1 / HIV-2 / Syphilis Antibody Test*. 2024; Available from: https://www.insti.com/multiplex-test/.
- 4. Kelly, H., et al., Systematic reviews of point-of-care tests for the diagnosis of urogenital Chlamydia trachomatis infections. Sex Transm Infect, 2017. **93**(S4): p. S22-s30.
- 5. Guy, R.J., et al., Performance and operational characteristics of point-of-care tests for the diagnosis of urogenital gonococcal infections. Sex Transm Infect, 2017. **93**(S4): p. S16-s21.
- 6. Siedner, M.J., et al., *Trends in CD4 count at presentation to care and treatment initiation in sub-Saharan Africa*, 2002-2013: a meta-analysis. Clin Infect Dis, 2015. **60**(7): p. 1120-7.
- 7. Wise, J.M., et al., Barriers to HIV Testing: Patient and Provider Perspectives in the Deep South. AIDS Behav, 2019. **23**(4): p. 1062-1072.
- 8. CDC. Syphilis CDC Basic Fact Sheet. 2022; Available from: https://www.cdc.gov/std/syphilis/stdfact-syphilis.htm.
- 9. CDC. *Chlamydia CDC Basic Fact Sheet*. 2022; Available from: https://www.cdc.gov/std/chlamydia/stdfact-chlamydia.htm.