Joint position statement on behalf of NZ POCT AG, NZMN, NZSHS, NZ ASID and NR POCT Network- on the sale and use of rapid antigen-based sexually transmitted infection point of care tests for chlamydia, gonorrhoea, and herpes.

April 17th 2024

The New Zealand Point of Care Testing Advisory Group (NZ POCT AG), the New Zealand Microbiology Network (NZMN), the New Zealand Sexual Health Society (NZSHS), the Northern Region Point of Care Testing Network (NR POCT Network), and the New Zealand branch of the Australasian Society for Infectious Diseases (NZ ASID) advise that currently available over-the-counter antigen-based point of care STI tests for chlamydia, gonorrhoea, and herpes are not fit for purpose, and that in the interest of public safety, these tests should not be promoted, marketed, sold, or used in New Zealand. This advice is aligned with the Health and Disability Services Consumer's Code of Rights 1996 and the NZ Best Practice Guidelines for Point of Care Testing. We also strongly recommend that a regulatory framework and national clinical governance structure for POCT must be established. In addition, any tests offered in home STI test kits should align with national STI testing best practice guidance.

Backgound

There is currently no regulation of point of care tests (POCT) in New Zealand.[1] This has created a void that enables the marketing and selling of POCT devices and kits to a public who trust quality claims made by suppliers and manufacturers. The latter, with the best of intentions, have commercial interests and make claims of good quality based on limited information gathered under controlled conditions, without transparency, and not on relevant patient populations.

While over-the-counter point of care tests for chlamydia and gonorrhoea suitable for home use would revolutionise access to STI testing for many hard-to-reach populations, currently available antigen-based point of care tests for chlamydia and gonorrhoea are not clinically reliable. The reason for this is primarily due to their low sensitivity, meaning the tests miss a substantial proportion of people with these infections, approximately 37-63% of those with chlamydia infections,[2] and 30-88% of those with gonorrhoea,[3] leading to false reassurance and the continuing possibility of transmission to others. These tests rely on antigen detection which cannot detect low amounts of organism.

There are currently no World Health Organization-approved rapid antigen-based STI tests for chlamydia or gonorrhoea globally.[4] Similarly, serological testing for herpes virus is not recommended due to poor sensitivity and specificity.[5] The use of these tests therefore presents a risk for personal health and for the health of others and they are not safe for use.

Point of care testing for STIs is a rapidly changing field, and new tests may be developed in the future which have increased reliability. A safe POCT device is sensitive and specific, and consistently provides accurate results, that support screening or monitoring of a condition relevant to the consumer's clinical background. It is important that POCT devices or kits are robustly verified within a quality framework designed and supported by laboratory medicine and medical laboratory testing experts before allowing the sale and use of these devices by the public.[6-8]

Over-the-counter rapid antigen-based STI test kits are marketed for the detection of chlamydia, gonorrhoea, and herpes. Many of these products have no internationally recognised certification that they meet any requirements for diagnostic use and the manufacturer's claims of sensitivity and

specificity are not supported by any robust or analysable data. Consequently, the unregulated use of these tests presents a risk for personal health and for the health of others and they should not be made available for public use in New Zealand unless verified and approved by a local accredited laboratory.

The NZ POCT AG, the NZMN, the NZSHS, NR POCT Network, and NZ ASID strongly advise that all relevant parties considering the use of POCT for STIs consult with their local accredited laboratory or the NZ POCT AG before promoting, selling, or encouraging the use of any POCT device or kit. In addition, that **all** currently available POC STI tests for chlamydia, gonorrhoea, and herpes be removed from the New Zealand market. These steps are consistent with the Code of Health and Disability Services Consumers' Rights 1996, particularly Right 4: Right to services of an appropriate standard, and Right 6: Right to be fully informed.[9]

We also strongly recommend that a regulatory framework and national clinical governance structure for POCT must be established. In addition, any tests offered in home STI test kits should align with national STI testing best practice guidance.[10]

References

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