Aide-Mémoire

Risks and benefits of point-of-care testing for public health management of infectious diseases

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To:	Hon Dr Shane Reti, Minister of Health		
Copy to:	Hon Casey Costello, Associate Minister of Health Hon David Seymour, Associate Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

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Purpose

1. This aide memoire responds to your request for an in-depth outline of the risks and benefits of point-of-care testing for the public health management of infectious diseases. This follows a recent entry in the weekly report (week commencing 6 May 2024) in which concerns were raised with regards to the position statement on the sale and use of point of care tests (POCTs), specifically for sexually transmitted infections (STIs).

Background

2. The position statement was published by a consortium of clinical organisations including: 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).

3. The position statement outlines the public health risks associated with low-performance POCTs currently being sold privately online and through pharmacies without clinical oversight. The position statement also calls for several measures to address these risks, namely:

   a. distributors of POCTs consulting with local accredited laboratories before any marketing or sales occurs

   b. removing all POCTs for chlamydia, gonorrhoea, and herpes currently in the New Zealand market, due to poor or unverified performance and clinical risks

   c. establishing a regulatory framework and national clinical governance structure for POCTs.

4. POCTs are a type of medical device known as *in vitro* diagnostic (IVD) medical devices and can be used for a wide variety of clinical applications, in a wide variety of settings. This can range from benchtop machines used in specialised hospital settings (e.g. a blood gas analyser in an Intensive Care Unit) to very simple at-home devices based on filter paper and special antibodies (e.g. pregnancy tests or COVID-19 rapid antigen tests). This aide-mémoire focuses on the use of simple POCTs for the diagnosis and response to infectious disease.

5. POCTs can be "self-test" (i.e. where a person tests themselves and acts on the result without immediate input from a health professional or peer worker), or "clinician-assisted", where the test is undertaken with a trained worker present – this may improve test performance, as well as improve the interpretation of results and subsequent actions taken.

6. There are currently low-performance devices used as POCTs for STIs available commercially in New Zealand, both online and through major retailers such as s 9(2)(b)(ii) s 9(2)(b)(ii) . These kits are generally rapid antigen-based tests, similar to those used for SARS-CoV-2 detection or pregnancy tests. There is no public information available about the actual volumes of these kits being imported and sold in New Zealand.

7. These kits advertise having high levels of "clinical accuracy" – this is not a meaningful clinical term, and independent research calls these claims into question.[1] The position statement authors cite one study that found such tests may have a false negative rate between 37% - 88%. A false negative rate higher than 50% would be worse performance than flipping a coin.

8. The core concern raised by the POCT position statement is that when tests with poor sensitivity (the ability to detect an infection if one is present) are used, there is a high risk of false negative results. Given many STIs are asymptomatic even while the person is infectious, a false negative result may lead to a person and their sexual partners being falsely reassured that they do not have an infection and may affect their sexual behaviours in a way that increases the risk of transmission. Examples may be forgoing the use of condoms, or not seeking post-exposure prophylaxis after a sexual encounter.

9. The position statement calls for the establishment of a regulatory framework for POCTs, and a national clinical governance structure for POCT to oversee implementation of effective clinical pathways for their use.

Point of Care Tests for Infectious Diseases

Some POCTs work very well when strong clinical governance is in place…

10. While there are concerns about poorly performing POCT devices, some do have very high sensitivity and are currently being used in publicly funded settings.

11. Body Positive is a non-governmental organisation (NGO) based in Auckland that runs point-of-care testing programmes at a drop-in clinic at their offices, as well as at sex-on-site venues. They use the INSTI combined HIV and syphilis test and have strong processes to refer anyone with a positive result for confirmatory testing and treatment at infectious disease or sexual health services. This is a peer-led model where non-clinical staff lead interactions with clients – this improves access and cultural safety for men who have sex with men (MSM), and is enabled by the use of fingerprick POCTs rather than tests requiring a blood sample from a vein in the first instance.

[1] **Guy RJ, Causer LM, Klausner JD, Unemo M, Toskin I, Azzini AM, Peeling RW. Performance and operational characteristics of point-of-care tests for the diagnosis of urogenital gonococcal infections. Sex Transm Infect. 2017 Dec;93(S4):S16-S21. doi: 10.1136/sextrans2017-053192. PMID: 29223959.**

12. The Burnett Foundation (formerly the New Zealand Aids Foundation, located in Auckland, Wellington, and Christchurch) offer free in-person HIV and syphilis POCTs, as well as distributing free HIV self-test POCTs online and through vending machines and other specific collection sites. In-person POCTs have a sensitivity of over 99%, while the self-test POCTs are 92% (false negatives occur in about 1 of every 12 HIV-positive people). The Burnett Foundation also offer full STI tests at their sites (using swabs processed in a lab rather than POCTs) and partner with a service called 'Sexual Health 101' which distributes swabs for STIs that are completed by people at home and then dropped off at community labs. They do not use chlamydia, gonorrhoea, or herpes POCTs due to the high false negative rates of these tests.

13. POCTs for Hepatitis C and HIV are also available at some New Zealand Needle Exchange Programme sites, supported by Body Positive and local primary care services.

14. Western Australia and the National Aboriginal Community Controlled Health Organisation are currently running a major syphilis POCT programme, with a focus on improving rural access to testing, with immediate treatment for positive results. The programme uses a syphilis POCT approved by the Therapeutic Goods Administration, and tests are paired with blood samples to ensure gold-standard comparative testing is also occurring.

15. These programmes are developed in close consultation with clinical and laboratory experts, with defined referral pathways for positive tests and rigorous assessments of the model of care. Some degree of clinical control comes from these being publicly funded services, with strong processes around procurement and contracting by Health New Zealand as the funder.

…but a lack of regulation creates problems in some areas

16. POCTs are also currently or potentially used for a range of other infectious diseases with public health implications outside of sexually transmitted and blood-borne infections.

17. The most well-known example is rapid antigen tests (RATs) for SARS-CoV-2. RATs have significantly poorer test performance than polymerase chain reaction (PCR) tests, but are much more readily available, can be repeated frequently, are less invasive and expensive, and are a good indicator of infectivity in people with known infection.

18. In April 2021, the Director-General of Health issued an order that "prohibited a person from importing, manufacturing, supplying, selling, packing, or using a point-of-care test for SARS-CoV-2 or COVID-19 unless approved by the Director-General of Health." This was in response to concerns about the quality of RATs available commercially internationally, and that this testing method was not appropriate in the context of New Zealand's COVID-19 approach at that point in time. This order was required due to the absence of a proactive regulatory framework through which POCTs devices could have been assessed and approved.

19. Because there was no pre-existing regulatory requirement for medical devices to be approved, a bespoke process involving both Health New Zealand (Health NZ) and the Ministry of Health (the Ministry) was established to give exemptions for specific POCTs for SARS-CoV-2. Over 700 applications were received, but only 25 were assessed as

meeting safety, quality, and performance requirements and eventually approved for use in New Zealand.

20. The COVID-19 Public Health Response Act 2020, under which the POCT order was made, is due to self-repeal in November 2024. Once the act self-repeals there will no longer be a legal basis for regulating COVID-19 POCT supply. As long as RAT kits continue to be supplied at no cost by Health NZ, this will have no practical impact. However, once free RATs are no longer supplied by the government there could be an emerging market for low sensitivity RATs, for example to meet industry Health and Safety requirements.

21. Consideration has been given to the use of rapid antigen tests for *group A streptococcus*. This would be particularly useful for the diagnosis of strep throat in primary care and other community settings, which would then be able to guide antibiotic treatment. This is particularly important for the prevention of acute rheumatic fever. At present, despite the very high incidence of streptococcal infections in New Zealand, there are no POCTs for this condition that have sufficient evidence of real-world performance to be safely incorporated into clinical care models. Further development of this technology is a high priority for the prevention of rheumatic fever. The Ministry has previously supplied a Briefing (H2023022903 refers) covering these issues to the former Associate Minister of Health, Hon Barbara Edmonds.

22. s 9(2)(h) [redacted]

Making Sure Point of Care Tests Are Safe and Clinically Appropriate

New Zealand is vulnerable to poor-quality tests due to a lack of a regulatory framework

23. At present, there is no regulatory framework for POCTs devices that ensures they are safe, effective, and used in appropriate ways. Any person or company may import, market and sell medical devices, including POCTs devices, in New Zealand, regardless of the actual performance of the product. Most medical devices are required to be notified within 30 days of being placed on the market to the Web-Assisted Notification of Devices (WAND) database, operated by Medsafe. However, POCTs are exempt from this requirement. In any event, a medical device can be notified to the WAND database without it having had any prior evaluation by a New Zealand or overseas regulator.

24. Consumer protection laws on product claims do apply, however it is unlikely that individual consumers would complain to the Commerce Commission on the basis of poor test performance, as this can only be validated by laboratory testing.

25. In an analogous case, it is noted that general consumer law was not considered sufficiently robust to ensure sunscreen products sold in New Zealand meet appropriate standards. In that case, the Sunscreen (Product Safety Standard) Act 2022 was passed to

codify a specific product safety standard. In addition, what may be acceptable under consumer protection laws may still fall short of what is acceptable in comparable jurisdictions with robust medical device regulations, and still result in unacceptable risks to public health.

26. You have previously received advice about the implications of repealing the Therapeutic Products Act (H2023033595 refers) that includes provisions for regulating devices such as POCTs. The briefing included advice regarding POCTs for SARS-CoV-2 and other emerging disease threats. In particular, concerns were raised about:

    a. the absence of safety, quality or performance assessments prior to import or supply of medical devices

    b. a very limited ability for Medsafe to assess a sponsor's claim on the performance of medical devices

    c. the absence of mandated standards for the provision of new devices and limited ability to respond to safety or performance issues

    d. the absence of requirements for sponsors to have safety monitoring systems, and limited legislative tool for recalls.

27. The Medicines Act 1981 (the Act) does confer a limited power to respond to unsafe medical devices, albeit with very small penalties. POCTs devices as IVDs are considered as medical devices under the Act, however the concerns raised above about these particular tests are unlikely to meet the threshold for restricting sale i.e., that "the use of that device may be injurious to the health of the person using it." In addition, this power to investigate any medical device that are believed to be unsafe sits with the Director-General, but there is limited specific expertise and workforce dedicated to monitoring medical device safety in the Ministry.

28. The United Kingdom, United States of America, European Union, Canada and Australia all have requirements for accreditation or approval of POCTs devices before they are marketed to the public, with established agencies for regulation and enforcement. New Zealand is a conspicuous outlier in the international POCT regulation landscape.

29. The absence of a robust regulatory regime for medical devices, including IVDs, also creates financial risks for health services and risks wasting valuable public funds – as these services and procurers may purchase defective or poor-performing devices.

Clinical governance is present, but not embedded

30. Clinicians have taken it upon themselves to form semi-formal structures for the governance of POCT use. A National POCT Advisory Group has been formed by Health NZ clinicians and laboratory staff to provide a forum for advice on the use of POCTs in clinical services and community service models. There are a number of regional POCT networks as well.

31. However, these groups can only advise on POCTs, and do not have a formal approving or clinical governance roles. Any service may incorporate POCTs into their model of care without mandated oversight from a network. The use of POCTs in private services such as general practice and pharmacies sits outside of their remit.

32. A regulatory approach would ideally incorporate or enable a clinical governance element, where the use of products approved by a regulator are then overseen by a clinical governance structure with the remit of ensuring appropriate clinical use, and interacting with the regulator where risks are identified.

Next Steps and policy decisions to be considered

33. In our view, the public health risks arising from the marketing and sale of low-quality POCTs devices warrants a proactive regulatory approach. This would include instituting a regulatory mechanism that defines a regulator and empowers that regulator to assess the safety, quality, and performance of POCTs and approve or reject the import, marketing and sale of tests based on this assessment.

34. Other benefits of this approach include:

    a. bringing New Zealand in line with comparator countries

    b. preventing the need for any bespoke legislation or approvals pathway in the event of a significant health emergency

    c. allowing Health NZ to both act as a sponsor for POCT products, and to import and supply tests in the event of a health emergency where no commercial supplier comes forward (eg, under a licence or authorisation issued by a medical device regulator).

35. On 1 May 2024, the Cabinet Social Outcomes Committee (SOU-24-MIN-0032) requested Hon Casey Costello, Associate Minister of Health, in consultation with Hon David Seymour, Associate Minister of Health (Pharmac), to report back to the committee by November 2024 on proposals for the future direction of the regulation of medical devices.

36. Health officials will work to provide advice to Ministers on how best to address the issues around POCT for this report back.

Ross Bell

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Date: 6 June 2024