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Clinical performance requirements and risk mitigation strategies for IVD self-tests for serious infectious diseases

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Australian Federation of AIDS Organisations

The Australian Federation of AIDS Organisations (AFAO) is the national federation for the HIV community response in Australia. AFAO works to end HIV transmission and reduce its impact on communities in Australia, Asia and the Pacific. AFAO's members are the AIDS Councils in each state and territory; the National Association of People with HIV Australia (NAPWHA); the Australian Injecting & Illicit Drug Users League (AIVL); the Anwernekenhe National HIV Alliance (ANA); and Scarlet Alliance, Australian Sex Workers Association. AFAO's affiliate member organisations – spanning community, research, public health and clinical workforce – share AFAO's values and support the work we do.

Background

The Australian Federation of AIDS Organisations (AFAO) welcomes the opportunity to provide feedback to the consultation on the Clinical performance requirements and risk mitigation strategies for IVD self-tests for serious infectious diseases. AFAO's interest in the regulatory framework for self tests for serious medical conditions is derived from its role as Australia's national peak community controlled HIV organisation.

AFAO comments are informed by the organisation's expertise in HIV and, more specifically, our experience in supporting self testing as an alternative means to testing in clinical settings. The comments are further informed by the organisation's experience in advocating for the approval of Australia's first self test device and supporting the implementation of this device across Australia.

AFAO notes the TGA's requirement that successful devices need "to balance the need for high quality tests with clinical characteristics that are fit for purpose." We agree, in principle, with this approach. However, our experience with HIV self testing in Australia illustrates the need for a flexible approach that accommodates the profile of specific medical conditions. In practice, the regulatory framework of Australia's healthcare system is configured to deliver health and diagnostic services through healthcare and clinical settings and outside healthcare settings, as is the case with a self test device.

Recommendation

AFAO believes Australia's regulatory system for approving medical devices should approve IVD self tests where safety and quality requirements are met and there is evidence to demonstrate consumer demand for the device.

Key points

- An application for registration on the ARTG of a self test device should not be delayed by the absence of local assessments demonstrating safety and quality. In this situation, the TGA should make use of assessment reports and evidence from Comparable Overseas Regulators (COR), if there is an alignment of standards between those of the TGA and the overseas regulator.

- Pharmacies need transition support to build their capacity to become points of sale for approved self testing devices by ensuring pharmacy staff have the expertise to advise on safe use of devices and interpretation of results.

- The TGA's advertising code needs to be flexible enough to accommodate health promotion campaigns led by non-government organisations, who are trusted by the communities they serve to deliver and interpret point of care diagnostic tests and have no commercial interest in the device being promoted.

- The TGA needs to strike a balance between conducting essential post market monitoring and assessments of approved devices and creating an environment that encourages innovation and the entry of new and advanced technology into the Australian market

Self testing and HIV

There is only one approved HIV self test in Australia. This section briefly provides the policy context of self testing in Australia and the rationale behind the approval of the current self test. Additionally, this section gives the reader an insight into AFAO's experience, as a community controlled HIV organisation, with self test devices in Australia.

The eighth *National HIV Strategy 2018 – 2022*[1] includes the following action: "Expand the use and accessibility of a range of HIV and STI testing technologies and options and tailor testing approaches to the needs of priority populations and sub-populations particularly where there is a need to improve early diagnosis."

[1] https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1/$File/HIV-Eight-Nat-Strategy-2018-22.pdf, page 27

The need for HIV self tests in Australia was informed by evidence identifying a gap in HIV testing frequency among priority populations. The primary issues underpinning sub-optimal HIV testing frequency in clinical settings in Australia relate to the need to attend a health service to access a test, time taken for test results to be available, poor access to health-care providers, feelings of stigma associated with testing, and the risk of discrimination.[2]

An Australian study found HIV self-testing would increase testing frequency among those not testing frequently enough and would initiate testing among non-testers who are at risk of HIV acquisition.[3] Self-testing was shown to support autonomy, and provide added confidentiality, privacy and convenience for people who may not otherwise engage in HIV testing. The devices are highly acceptable and easy to use with little to no support from trained staff required.[4]

Despite our excitement at the approval the first self test in Australia, the uptake of HIV self testing has been underwhelming for two reasons. First, the unintended reach of the Therapeutic Goods Administration's advertising code to prevent health promotion activities by Civil Society Organisations with no commercial interest in the device's use. Secondly, restrictions on the point of sale of the approved device to online purchases and sales through a very limited number of health agencies has restricted the options for a consumer to purchase an HIV self test. For self tests to meaningfully improve public health outcomes they need be available at scale. AFAO's hope is that our feedback to this inquiry supports improvements in Australia's health system to make future approvals of self tests more expedient and access more equitable and practical.

The public health threat associated with COVID-19 has magnified the utility of self testing, particularly while there is no vaccine available. As an infectious disease, a sensitive and high quality self test device could be implemented at scale to support people to return to work, travel overseas and visit elderly parents or family and friends at increased risk of poor health outcomes from a COVID-19 infection. While such a test may not exist, the regulatory framework needs to be amended to accommodate the timely approval of such a test when one becomes available,

Summary

AFAO makes the following comments based on the organisation's experiences of working with the manufacturer of Australia's only HIV self test, Atomo Diagnostics, and the regulator, the Therapeutic Goods Administration, to support the registration of Australia's first HIV self test device on the Australian Register of Therapeutic Goods (ARTG) in November 2018.

1. **Self tests for medical conditions with low or only localised prevalence**

For medical conditions with low to no prevalence among the general population, such as blood borne viruses, there is often an absence of local evidence to demonstrate safety and quality, and demand among priority populations. The absence of local evidence can delay the process of registration on the ARTG, while sufficient local evidence is obtained. This situation exposes a system that is geared towards the approval of self test devices for medical conditions where prevalence is generalised among the population, rather than localised.

In this situation, AFAO supports the principle of the TGA making use of assessment reports and evidence from Comparable Overseas Regulators (COR), if there is an alignment of standards between those of the TGA and the overseas regulator.

AFAO believes that consideration should be given to the demographic profiles underpinning evidence in any COR's report as a point of comparison with the relevant Australian demographic. For example, if a COR report on HIV self testing is based on evidence of use among men who have sex with men in the overseas jurisdiction was available. This report would inform a TGA assessment of an HIV self test given the profile of Australia's HIV epidemic where the largest population affected by HIV is gay and bisexual men and other men who have sex with men, and for whom access to HIV self testing is of particular significance.

[2] Krause J, Subklew-Sehume F, Kenyon C, et al. Acceptability of HIV self-testing: a systematic literature review. BMC Public Health 2013;13:735-43.
[3] Jamil MS, Prestage G, Fairley CK, et al. Effect of availability of HIV self-testing on HIV testing frequency in gay and bisexual men at high risk of infection (FORTH): a waiting-list randomised controlled trial. Lancet HIV 2017;4:e241-e250
[4] Ibid.

Key point

- An application for registration on the ARTG of a self test device should not be delayed by the absence of local assessments demonstrating safety and quality and consumer demand. In this situation, the TGA should make use of assessment reports and evidence from Comparable Overseas Regulators (COR), if there is an alignment of standards between those of the TGA and the overseas regulator.

2. Optimising consumer access to self test devices

Medical conditions are often misunderstood and, unhelpfully, framed through inaccurate and outdated stereotypes, for example, the framing of HIV as life threating and receiving a positive diagnosis as overwhelming ... These framings weigh heavily on attitudes and understandings of the experiences of living with specific medical conditions. These misunderstandings can influence decision making around the scale of supports people recently diagnosed with medical conditions require. The consequence of these misunderstandings can inhibit ease of access to these technologies on the grounds that consumers require education in the safe use of the device, or medical care to correctly interpret test results.

The market conditions on the sale of HIV self tests prevented these devices from being sold directly to consumers through community pharmacies. This create the perverse situation where one of the main access points for purchasing HIV self tests in Australia is through public health clinics, an outcome self test devices was supposed to resolve.

To capitalise on the opportunity self testing presents to consumers, individuals need to be able to access approved devices through community pharmacies.

Key point

- Pharmacies need transition support to build their capacity to become points of sale for approved self testing devices by ensuring pharmacy staff have the expertise to advise on safe use of devices and interpretation of results.

3. The unintended reach of the TGA's advertising code to health promotion by Civil Society Organisations

The TGA's advertising code exists to ensure consumers are not misled about the quality and safety of medicines and medical devices. The policy rationale behind this regulatory framework is that consumers should make informed decisions about treatment initiation and the use of medical devices, in consultation with their treating physician and without undue influence from industry. AFAO is in full support of this rationale.

However, this rationale appears to have been developed without consideration of medical conditions that have a rich history of health consumer participation in policy setting, advocacy and the design and delivery of health promotion. One of the strongest facets of Australia's HIV response is the development of community informed health promotion campaigns delivered by HIV organisations with community-controlled governance structures. These campaigns have been very successful in promoting safe sex messages since the beginning of the HIV epidemic in the 1980s and were central to Australia achieving the fastest uptake of HIV Pre Exposure Prophylaxis (PrEP) in the world following the registration of Truvada as PrEP on the ARTG in May 2016.

Owing to changes to the Therapeutic Goods Administration's advertising code, the HIV sector's expertise in promoting new technology to communities has been significantly restricted. Further, messaging developed by community organisations for community has been censored by the TGA against, what AFAO considers, a narrow interpretation of the advertising code. The TGA's enforcement of the advertising code privileges safety and quality, to the detriment of timely access to devices from consumers who are able to make informed decisions to purchase devices based on evidence informed health promotion messaging. This is particularly important when the medical conditions in question affect defined population groups such as gay and bisexual men in the case of HIV.

Key point

- The TGA's advertising code needs to be flexible enough to accommodate health promotion campaigns led by non-government organisations, who are trusted by the communities they serve to deliver and interpret point of care diagnostic tests and have no commercial interest in the device being promoted.

4. The cost imposition of the TGA's post market monitoring and compliance

For conditions with low prevalence in the general community the market is small. This means sponsors and manufacturers are often investing in the Australian market with low profit margins. We know from our involvement with sponsors of point of care tests and anti-retroviral therapies that regulatory compliance is a significant cost for manufacturers.

It is entirely appropriate that the regulator conduct routine post market monitoring to ensure manufacturers are selling approved products that continue to meet quality and safety standards. The level of routine monitoring needs, however, to recognise that over regulation and the costs incurred with random and unexpected monitoring can act as a disincentive for manufacturers to enter the Australian market or seek re-registration on the ARTG for approved products.

Over regulation and monitoring costs can disincentivise innovation and enterprise and inhibit the availability of advanced medical technology in Australia. The market size for devices and therapies for non communicable illnesses with high prevalence in the general community (for example, dementia, cardio vascular diseases and diabetes) is likely to be large enough to absorb the ongoing costs of maintaining registration. For medical conditions with smaller markets, the risk of these costs being a barrier to new and advanced technology entering Australia or, in the case of an approved medicine or device, an incentive to voluntarily exit the market, is magnified.

Key point

- The TGA needs to strike a balance between conducting essential post market monitoring and assessments of approved devices and creating an environment that encourages innovation and the entry of new and advanced technology into the Australian market.