Review of the regulation of certain self-testing in vitro diagnostic medical devices (IVDs) in Australia

DHHS response

1. Should self-tests for other infectious diseases be allowed?

1.1 Considering the experience with HIV self-testing should self-tests for other infectious diseases be supplied and used in Australia subject to appropriate risk mitigations?

The Department of Health and Human Services (DHHS) broadly supports access to self-testing in vitro diagnostic medical devices (IVDs) for infectious diseases that provide reliable and acceptable results. Access to self-testing IVDs has the potential to positively impact the number of people who have an infection who know their disease status. Once a person becomes aware of their infection, they are more likely to seek treatment and thereby prevent ongoing transmission.

Self-testing is highly acceptable to consumers as testing is convenient and can be performed in privacy. In addition, IVDs allow test access in remote areas and can be a cheaper alternative for some patients who seek regular screening, for example, for sexually transmitted infections (STIs) and in those who would otherwise not screen. There is evidence that self-testing for STIs improves testing uptake and frequency in high risk groups such as university students (Habel et al, 2018, Sexually Transmitted Diseases).

There is the potential that ongoing prohibition of supply of self-testing IVDs may lead to consumers purchasing kits online which would not meet the Therapeutic Goods Administration's (TGA's) safety and performance requirements for self-testing IVDs. In addition, these kits would be unlikely to provide additional information and links to treatment services.

Given the experience with HIV self-testing in Australia and further evidence of success internationally with self-testing for other infectious diseases, DHHS feels that the benefits of self-testing outweigh the potential risks. The DHHS therefore supports supply of self-tests for other infectious diseases in Australia subject to appropriate risk mitigation.

1.2 Are there any tests for particular infectious diseases that should not be available as a self-test? Please provide reasons why not.

It is the opinion of the DHHS, that IVDs for self-testing should not be available in Australia if they have potential to promote inappropriate antibiotic use and therefore promote antimicrobial resistance. An example of a specific self-testing IVD is the QuickStripe™ *Streptococcus pneumoniae* urinary antigen test, which is used to aid the diagnosis of community acquired pneumonia secondary to *Streptococcus pneumoniae*. Up to 65% of young children are colonised with *Streptococcus pneumoniae*, which can result in a false positive urinary antigen test. This test may promote the inappropriate use of antibiotics in children. Other examples of self-testing IVDs that are at risk of promoting inappropriate antibiotic use include those for Group A Streptococcus and urinary tract infections.

It is the opinion of DHHS that self-testing IVD supply in Australia should be subject to individual test performance and a careful consideration of whether communication is clear to consumers / patients about the limitations of the test and other actions to consider. In general, IVDs should not be available for any infectious disease if the test performs poorly resulting in a high number of inaccurate results.

1.3 Do you have any additional suggestions on how potential risks to consumers could be mitigated if self-tests for other infectious diseases were allowed to be supplied in Australia?

In addition to the concerns about test accuracy already identified, there are other risks from a public health perspective. Self-testing IVD results will not contribute to surveillance data, which allow public health units to monitor and control infectious diseases. Furthermore, self-testing denies the consumer the opportunity for counselling about test results and linkage to care. There is also potential to miss the opportunity for further screening, for example, a complete STI screen.

To mitigate against these risks, it is crucial to provide the consumer with robust culturally appropriate information in clear and concise language. Information provided with self-testing IVDs should include an explanation of the limitations of self-testing, such as an extended window period for detection, recommendations to seek formal testing and treatment, information about partner notification (where relevant) and access to appropriate support services.

2. Should direct to consumer genetic tests be allowed?

2.1 Should Direct to Consumer Genetic Tests be permitted in Australia (following evaluation by the TGA) to provide consumers with an alternative to overseas testing which has not been evaluated by the TGA for its quality and performance?

Current regulations do not allow the local provision of direct to consumer (DTC) genetic testing in Australia. This exclusion should remain for all DTC genetic tests purchased off the shelf or over the internet.

Although there are potential benefits in allowing DTC genetic testing (e.g. increased access to testing, consumer autonomy and individual empowerment/responsibility of own health), only a small number of DTC tests meet the validity and health utility standards required to responsibly make these tests available to the public (NHMRC, 2014).

Genetic testing and the interpretation of genetic data is complex and context dependent. DTC genetic tests may produce false positive or false negative results, which can lead to physical or psychological harm. Furthermore, the results of genetic tests may be of 'unknown significance', in which case expert interpretation of the results is required with the genetic test considered within the context of the patient's clinical presentation and family history. In addition, as the evidence base is evolving rapidly, the interpretation of a genetic test may change over time, in which case genetic counselling is important in the reporting of negative results. There is risk in patients receiving and acting upon the results of DTC genetic tests in isolation and without interpretation from an appropriately trained professional.

Patient wellbeing and safety should be strongly considered in the TGA's assessment of DTC genetic testing. Health providers and funders should also consider their fiduciary responsibility of providing potentially unnecessary follow-up health care services for false positive or false negative DTC tests.

Genetics experts, clinical geneticists or genetic counsellors should be available to help consumers determine whether a genetic test should be performed and provide interpretation of results. Authorising DTC genetic tests may lead to more consumers accessing these tests, thereby requiring advice from their General Practitioner or other genetics-trained health clinician. Our current primary care and genetics workforce is already struggling with growing demand to provide services, which may lead to greater accessibility issues for the public seeking advice pertaining to DTC test results and other genetic services more broadly.

There are privacy concerns around who has access to consumers' results, how genetic information should be handled regarding third party access and secondary uses, and the potential impact on life, disability or long term care insurance. We do not yet have national agreement on these issues. Furthermore, without regulation, the secure storage of data obtained from DTC genetic testing cannot be assured.

2.2 Are there any particular genetic tests that should not be available as a self-test? Please provide reasons why not

Current regulations do not allow the local provision of direct-to-consumer (DTC) genetic testing to be provided in Australia. This exclusion should remain for all DTC genetic tests purchased off the shelf or over the internet. This advice is in line with the NHMRC's statement on Direct-to-Consumer Genetic Testing (2014) for individuals to exercise caution due to mixed quality and reliability of tests. As only a small number of tests have demonstrated their clinical value, the majority of DTC genetic tests are still considered research activities.

2.3 Do you have any suggestions on how potential risks to consumers could be mitigated if genetic self-tests were allowed to be supplied in Australia?

It is not recommended that genetic self-tests be supplied in Australia. However, if DTC genetic testing was allowed to be provided in Australia, known risks could be mitigated by:

- Only allowing DTC tests that have been assessed against relevant criteria, such as safety, laboratory validity and clinical utility
- Consumers engaging with qualified medical professionals and the analysis completed via a nationally accredited laboratory (i.e. NATA-endorsed)
- Referral to an appropriate health service, pre-supply of DTC, to determine clinical appropriateness of testing
- Providing additional training, substantive and formal, for health clinicians such as general practitioners, genetic counsellors, genetic clinicians and bioinformaticians.
- Building the health literacy of the general public, including relevant patient cohorts, via education and marketing campaigns
- Clinical genetic consultations supported via a Medicare rebate for both credentialed physicians and genetic counsellors, to reduce financial risk of state-funded genetics services, allowing for greater equity and access to these services

A national consensus on privacy concerns regarding third party access, secondary uses and impacts for insurance.

3. Should self-tests for other serious diseases or conditions be allowed?

3.1 Should self-tests for serious diseases be able to be supplied in Australia following evaluation by the TGA to determine their safety and performance?

Response

3.2 Are there any particular tests for serious diseases that should not be available as a self-test? Please provide reasons why not.

Response

3.3 Do you have any suggestions on how potential risks to consumers could be mitigated if self-tests for serious diseases were allowed to be supplied in Australia?

Response