Review of the regulation of certain self-testing IVDs – NSW Health Division of Population Health Considerations & Recommendation

Background

The TGA is consulting on whether the requirements of the *Therapeutic Goods (Excluded Purposes) Specification 2010* (the Excluded Purposes Specification) remain relevant or should be amended.

The Excluded Purposes Specification applies to home-use IVDs for serious diseases and commenced on 1 July 2010, in conjunction with the IVD regulatory framework. Examples of self-testing devices that are not permitted include genetic testing, tests for notifiable infectious diseases, and tests for cancer or myocardial infarction.

Examples of self-testing that is allowed under the Excluded Purposes Specification include pregnancy testing, blood glucose testing to monitor diabetes, and HIV testing (exempted in July 2014). Self-tests that are permitted are regulated by the TGA to ensure sensitivity, specificity, stability, ease of use, clear advice on test interpretation, limitations and seeking medical advice.

Self-testing IVDs that are used as part of a public health screening program sponsored by a state, territory or Commonwealth government are also exempted.

The Extended Purposes Specification includes situations where the sample is collected and tested at home by a lay person, and where the sample is collected by a lay person and sent for testing by another person and results returned without the direct supervision of a health professional.

Questions raised by TGA

The TGA are seeking feedback on whether these prohibitions on self-testing are still relevant for notifiable infectious diseases, particularly noting the successful exemption of HIV self-testing. The TGA gives examples of hepatitis C, STIs and influenza where self-testing may provide individual and population benefit, including earlier initiation of treatment, and improving access to testing for hard-to-reach or remote populations.

TGA are also interested in views on restricting genetic self-testing and self-testing for other serious diseases. While these tests may be of relevance to other sections of NSW Health, this paper is limited to considering restrictions on notifiable infectious diseases.

Assumptions for infectious disease self-testing

- TGA will effectively regulate for sensitivity, specificity, stability in environmental conditions, ease of use, clarity of instructions
- TGA will effectively regulate that consumer information covers false positive, false negative, and directs appropriate medical care for positive or uncertain results
- Only relatively common conditions, or conditions that are a high risk for certain sub-populations are likely to attract manufacture/registration of self-test kits:
    - hepatitis C for IVDU
    - chlamydia, gonorrhoea for MSM and others at high risk for STIs
    - influenza during epidemic periods
    - respiratory and enteric pathogens for parents of young children
    - dengue and other vector borne diseases for travellers

Potential benefits of infectious disease self-testing

- Reduces delay of getting medical appointment for testing
- Reduces turn-around time for results
- Increases likelihood of detection for those at ongoing risk
- Increases timeliness of appropriate treatment
- Encourages appropriate isolation/precautions
- Increases self-efficacy for populations which may be more likely to self-test than see a doctor: IVDU, LGBTQI, CALD, young adults, regional & remote residents, residents in areas with GP shortages, shift workers
- Consistent with goals of hepatitis C strategy to reduce the number of people with undiagnosed infection, particularly amongst hard-to-reach populations
- May provide an avenue to register dried blood spot testing for HIV and hepatitis C

Potential risks of infectious disease self-testing

- Diagnosis is not appropriately confirmed (confirmation may not be indicated for all conditions e.g. influenza, gonorrhea or chlamydia with relevant exposure & symptoms)
- Where confirmatory testing is not undertaken then condition may not be notified
- Despite comprehensive consumer information, patients may be falsely reassured by a negative self-test, and appropriate testing and treatment delayed

Possible mitigations

- Adverse events (including late and missed diagnoses) arising from self-testing can be notified to TGA, and if warranted, the exemption for a self-test could be revoked
- Quantities of self-tests distributed could be monitored to provide an indication of the impact on notification rates
- Self-testing could be added to notifiable disease questionnaires

Limitations

- This paper is from the perspective of Population Health; other sections of NSW Health may have different perspectives.
- This paper is limited to considerations of self-testing for notifiable infectious diseases; other sections of NSW Health will have perspectives on other types of self-testing devices.

Recommendation

That Population Health Division advise TGA that NSW Health supports allowing a wider range of IVDs for self-testing of notifiable infectious diseases to be registered, and that a self-test for hepatitis C is a priority to support elimination efforts.