Response to TGA Consultation:

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

22 November 2019

To whom it may concern:

Re: TGA review of certain self-testing IVDs in Australia

Thank you for the opportunity to comment on the current review of the regulation of certain self-testing in vitro diagnostic medical devices (IVDs) in Australia for the Therapeutic Goods Administration of the Australian Department of Health. This submission is made by Dr Lisa Dive, Associate Professor Ainsley Newson, and Dr Diego Silva. It is made in our capacity as individual academics who work at Sydney Health Ethics in the Sydney School of Public Health, University of Sydney.

Sydney Health Ethics (https://sydney.edu.au/medicine-health/our-research/research-centres/sydney-health-ethics.html) is a large and research active bioethics centre at the University of Sydney. We undertake research, teaching and engagement around a variety of ethical and social issues in health, medicine and the life sciences. Our research draws on methods from the humanities and social sciences, including philosophical reasoning, qualitative research, creative arts and deliberative public engagement. We have been established for over 20 years and have obtained a large number of research grants from a range of Australian and international funders

Our submission consists of general comments relevant to the current review, and we have made both general comments and responses to the consultation questions about self-tests for infectious diseases, and genetic self-tests (direct to consumer).

General comments

In addition to responding to specific questions identified in the review below, we have some overarching comments related to the model of regulation and the framing of the proposed changes.

The proposed changes are described as responding – at least in part – to consumer demand ("a growing desire by consumers to have more say in their healthcare decisions" p. 6 consultation document), but justification is required to support this as a reason for changing regulation. There are several unstated and unsubstantiated assumptions underlying this motivation for changing the regulation of self-testing IVDs, which we would challenge.

Assumption 1: Consumer demand should drive access to testing

Understanding and responding to consumer preferences are important, since (a) individuals know what is most important to them and what they value, and (b) responding to consumer preferences can assist individuals to become active participants in their own health care, protection, and promotion (often referred to as 'empowerment'). **However, we caution against presuming that consumers' desire to access IVDs will necessarily improve their health.** The corollary of 'empowerment' is 'responsibility', since persons in positions of power are presumed to be in a better position to control their fates than those who are not. The rhetoric of 'empowerment', while laudable in its aims, has the potential to increase blame and stigma. Decades of behavioural science and public health science research strongly suggest that many of the most important factors that improve health are not within the purview of individuals' responsibility. For example, there is ample evidence to conclude that health is socially and economically determined, as recently noted by – among others – the Institute of Health and Welfare.[1] True consumer empowerment for health would be for individuals to drive their health care with the support and partnership of doctors, nurses, and allied health professionals – the evidence in favour for such shared decision-making is substantial.[2] The recent trend to place the responsibility for individuals' health upon individuals alone feeds into the false narrative that they are able to unilaterally shape their health, which is false, and can lead to stigma and blame.

Assumption 2: Easier access to health-related information is better for individuals

There is little evidence to suggest that easier and greater access to health-related information alone will be in the best interests of individuals. In fact, after more than half a century of research, **we know that simply increasing individuals' knowledge of health-related information does not always lead to health-promoting behaviour**.[3] [4] Changing one's health behaviour and seeking treatment for illnesses requires the support of family, friends, or healthcare workers – preferably all three. Obtaining potentially life-altering health information through IVDs risks isolating people and generating self-stigma (as, for example, in the case of sexual transmitted infections - STIs).

[1] Australian Institute of Health and Welfare (2018). *Australia's Health 2018*. Australia's health series no. 16. AUS 221. Canberra: AIHW.

[2] See, for example, the Australian Commission on Safety and Quality in Health Care's position on shared decision making: https://www.safetyandquality.gov.au/our-work/partnering-consumers/shared-decision-making

[3] World Health Organisation (1986). *Ottawa charter for health promotion*. Retrieved from World Health Organization website: http://www.who.int/healthpromotion/conferences/previous/ottawa/en/

[4] See also Victorian Government's position on the Ottawa Charter: https://www.betterhealth.vic.gov.au/health/ServicesAndSupport/ottawa-charter-for-health-promotion

Consultation questions

Self-tests for infectious diseases

General remarks

One of the main reasons posited by the TGA to provide IVDs for infectious diseases is that **self-testing for infectious diseases might reduce the demand on healthcare services; however, no evidence is provided to support this assumption**. It is unclear, for example, how self-testing for influenza could reduce the demands on hospital emergency departments and general practitioners during seasonal peaks. A search we have performed in the pubmed.com database has found no evidence to uphold this or similar claims.

Another justification for allowing self-tests for infectious diseases is that it could be a way to increase testing in hard-to-reach populations. Again, no clear evidence is provided to support this assumption. Such evidence is needed prior to this claim being used to inform policy or regulation. Moreover, **it is not clear that self-testing for STI is advisable from a public health justice perspective**. First, although the TGA consultation paper mentions that "…self-tests for viruses such as Hepatitis C may help increase testing rates and improve outcomes particularly in hard-to-reach populations", and the cite *The Fifth National Hepatitis C Strategy*,[5] it is unclear where in that report this claim is actually made. Second, and more importantly, positing IVDs as a tool for helping hard-to-reach populations in infectious diseases testing for STI bypasses the vital ethical – and conceptually prior – question, namely: why are certain populations 'hard-to-reach' and what can be done about this?

Finally, proposing self-testing for any infectious disease regardless of mode of transmission (e.g., airborne, droplet, fluids, etc) potentially devalues the role and importance of public health in the control and prevention of infectious diseases. Infectious diseases affect individuals *and* the public; public health cares for individuals by directing them to clinical resources, and protects the public through measures such as surveillance, contact tracing, and health promotion. Allowing for self-testing without providing the social support mechanisms for individuals (as noted above) also risks the public's health by ignoring the public dimensions of infectious diseases.[6]

Responses to questions

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?

- Based on our understanding of the research, in Australia the success of HIV self-testing is dependent upon several factors, not least of which is providing the self-testing free of charge and providing multiple kits for testing at a particular moment in time due to the lesser sensitivity of the self-test.[7]

[5] Department of Health: *Fifth National Hepatitis C Strategy 2018-2022*, Australian Government: Canberra. Available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1//$File/Hep-C-Fifth-Nat-Strategy-2018-22.pdf

[6] Rumbold, B., Wenham, C. & Wilson, J. Self-tests for influenza: an empirical ethics investigation. *BMC Med Ethics* 18, 33 (2017) doi:10.1186/s12910-017-0192-y.

[7] Jamil, M.S. et al. (2017), 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* 4(6): e241-e250.

- Critically, the authors of the Australian study cited above note that the study can only conclude that self-testing results in greater overall testing among men-who-have-sex-with-men, but is silent on other populations and it cannot determine whether self-testing changes sexual risk behaviour.
- Another important factor to consider – as found in a study from Glasgow, UK – suggests that the success of self-testing for HIV is dependent upon a gay or bisexual man's level of education. More specifically, the higher the level of education, the greater the awareness of self-testing. According to the authors, it is unclear what effect self-testing for HIV would have on men who are of lower socioeconomic status or who lack digital literacy.[8]
- Despite the reasons to be cautiously optimistic of self-testing for HIV, **given the heterogeneity of infectious diseases, it seems illogical to assume that any success of self-testing in HIV would seamlessly translate to other infectious diseases**, particularly those beyond STIs. **Much more research needs to occur before rolling out IVDs in the case of infectious diseases**. Policy on self-testing for infectious diseases should be done on the basis of discrete diseases and **must be based on sound evidence**.

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

- No comment to add here.

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?

- Approaches to clinical medicine and public health must account for the intrinsic complexity of medicine and healthcare. Any implementation of self-testing for infectious diseases must consider and account for how it would affect the complex and holistic nature of clinical medicine and public health. If the TGA were to move forward with self-tests for infectious diseases, it must do so with a series of pilot projects that test the viability of self-testing without disrupting the public health's goal of controlling infectious diseases.

Genetic self-tests (direct to consumer)

General remarks

Increased access to genetic testing in itself should not be assumed to be in the best interests of individuals. As noted on p. 9 of the consultation document, interpretation of genetic information can be challenging and could be unnecessarily alarming.[9] The potential advantages of direct-to-consumer (DTC) genetic testing (GT) listed include "individual empowerment allowing consumers to make independent medical decisions". However, it is unclear how consumers will be able to make decisions based on results of a genetic test without consulting a healthcare professional. Indeed, we would be concerned that individuals could use such information to make incorrect inferences about

[8] Flowers, P. et al. (2017), Preparedness for use of the rapid result HIV self-test by gay men and other men who have sex with men (MSM): a mixed methods exploratory study among MSM and those involved in HIV prevention and care. *HIV Med* 18: 245-255. doi:10.1111/hiv.12420

[9] Newson, A.J., et al. 2016. "Known unknowns: building an ethics of uncertainty into genomic medicine." *BMC Medical Genomics* 9(1): 57.

health risks to themselves or their family members. Evidence exists to suggest this is already occurring in populations where DTC genetic tests are more widely available.[10]

We also query the assumption that providing people with genetic risk information will change their health-related behaviours. At the very least, this evidence is still emerging and will be dependant upon factors such as health literacy, and the cost and ease of the necessary intervention[11]. A 2017 systematic review found no evidence that genetic information positively impacts health behaviours.[12] While many of the studies included in this review had limitations, it would be erroneous to assume that procuring genetic information will result in health behaviour change.

A significant limitation to how Excluded Purposes Specification provisions will be able to operate in the area of DTC genetic testing is that third party reinterpretation services now effectively allow any DTC test to provide health-related information, including predictive information. Such services take the raw data files that many DTC providers give to customers and re-interrogate them. These services are actively marketed to consumers post-testing, for a nominal fee. As such, excluding particular purposes may not be an appropriate regulatory framework. It may now be necessary to undertake a wholesale reconsideration of the use of EPS at all – at present regulation in Australia appears to look to the intention or purpose of the test. However, as third party reinterpretation illustrates, the all-encompassing way that this information is obtained (through next generation sequencing, generating a large volume of data) means that a test with one intention can easily be repurposed.

We recognise that Australian consumers are actively procuring tests offered by overseas providers. Nevertheless:

- Mitigating harms to consumers from procuring DTC tests overseas does not necessarily entail allowing the same tests onshore. It may, instead, involve restricting access to testing from overseas providers; or better consumer protection and education within Australia.
- If the TGA is to offer approval of onshore tests, these tests must be subject to rigorous quality assessment, including a consideration of the impact of third party reinterpretation services.

[10] Schleit, J., et al. (2019). "First, do no harm: direct-to-consumer genetic testing." *Genetics in Medicine* 21, 510–511.

[11] For example, a pilot study of the role of polygenic risk scores to inform risk of melanoma has shown a small change in sun protection behaviours: Smit, AK, et al. (2017) "A pilot randomized controlled trial of the feasibility, acceptability, and impact of giving information on personalized genomic risk of melanoma to the public" *Cancer Epidemiology, Biomarkers & Prevention*, 26(2): 212-221. However, this is complex genetic information that needs to be interpreted alongside other information, such as a person's geographic location. As such, it would not be suitable for a DTC test.

[12] Hollands G.J., et al. (2016) "The impact of communicating genetic risks of disease on risk-reducing health behaviour: systematic review with meta-analysis." *BMJ*, 352 doi: https://doi.org/10.1136/bmj.i1102.

Responses to questions

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?

As our comments above imply, it is difficult to provide a single answer to this question. However, we are concerned that in permitting DTC genetic tests, the TGA could be seen to be tacitly endorsing health tests that consumers could access even when they have no need to do so. The DTC market is one which operates on a rhetoric of consumer empowerment. Consumers are urged to take control of their health care by obtaining testing, and acting on the results to optimise their health. The reality, however, is that the information that DTC tests provide remains a relatively minor component of managing human health. We also know that genetic information is subject to change in meaning over time, as new research results emerge. Further, the genetic databases that many commercial DTC companies use to provide consumers with results are very poorly representative of ethnic diversity.

For the most part, DTC tests are not necessary to individual healthcare – especially for healthy individuals. Of course, genetic tests can and do provide important information, but it is for those who need it. Removing knowledgeable health professionals from the process to determine whether to have a test means that many more people could be having genetic tests that they don't need, and which could cause them harm.

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

- We contend that access to any information that could have serious and long-term implications for an individual's health, and the health of their family, should be mediated by an appropriately trained health professional.

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?

The joint submission from the Australian Genomics Health Alliance and Genioz study[13] provides a comprehensive assessment of potential risks to consumers and how these might be mitigated. We endorse that summary and the suggestions it contains.

In particular, we consider the risk of overdiagnosis and subsequent follow-up (including possible over-treatment) in the (publicly funded) healthcare system to be of ethical importance. This is because of the harm to individuals that will occur and because of the implications for allocation of scarce healthcare resources.

We would urge the TGA to look to the recent changes in the EU regarding medical devices. The regime in Europe looks to risk classification as the mode of regulation – see Regulation (EU) 2017/746. This approach classifies tests on their risk basis, mandates support and includes provision

[13] Note that Ainsley Newson is named on both the Australian Genomics/Genioz submission and this present submission. She is also Co-Chair of the Education, Ethics and Social Issues Committee of the Human Genetics Society of Australasia, which has also made a submission.

for monitoring effectiveness post-implementation. Any provisions should also be as accessible as possible to consumers, include access to unbiased information and offer enforcement provisions with real 'teeth'.

Self-tests for serious diseases

General remarks

We do not have responses to the consultation questions at this time, given that the review document does not specify in depth the types of tests or conditions that might fall under this category. We note that many arguments raised in previous sections are relevant to self-tests for serious diseases, in particular concerns about the potential harm arising from the possibility of people self-diagnosing a serious illness without contact with a healthcare professional. We also consider that equity should be a priority in the availability of follow-up testing and treatment that might be required after a self-test.

For further elaboration of some of the ethical considerations around liquid biopsies for early detection of cancer, we refer to this commentary by Associate Professor Ainsley Newson: https://www.australasianscience.com.au/article/issue-julyaugust-2018/unspoken-limits-liquid-biopsies.html

We thank you for the opportunity to respond on this issue and are happy to expand on any component of our submission and look forward to the next stage of consultation.

Yours faithfully,

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Dr Diego Silva