Australian Red Cross
BLOOD SERVICE

28 January 2015

Ms Michelle McNiven
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Email: [redacted]

Dear Ms McNiven,

RE: Consultation: Proposed performance requirements for tests to detect the presence of human immunodeficiency virus (HIV)

The Australian Red Cross Blood Service (the Blood Service) appreciates the opportunity to provide feedback on the above consultation. The Blood Service screens over 1.3 million donations per annum for transfusion transmissible infections including HIV. Distinct from diagnostic testing, blood screening is conducted in a low prevalence population which poses particular challenges.

Overall we endorse the guiding principles and format of the proposed performance requirements however we raise the following issues for consideration:

Unaddressed risks specific to the blood supply

While the proposed performance requirements clearly define the appropriate use of HIV self-tests and point-of-care tests (PoCTs), which excludes their use for the purpose of blood screening, there is the potential that some users may:

1. Use HIV PoCTs to determine their HIV infection status prior to donation, and where the result is negative, fail to disclose risks which they self-assess as irrelevant
2. Seek to donate blood as a method of 'confirming' an HIV PoCT result

In the context of point 1 above, the specific concern principally relates to community challenges regarding the current Blood Service policy for donors engaging in HIV risk behaviour and failing to disclose this during the pre-donation health and eligibility assessment. The Blood Service relies on the donor's honest and frank disclosure (termed 'compliance') to all screening questions on the pre-donation donor questionnaire to ensure appropriate 'self-deferral' of donors engaging in risk behaviours – including high risk sexual contact.

While the HIV testing window period has been minimised by the combination of HIV p24/HIV 1-2 Ab testing and HIV-1 RNA testing of all donations, there remains a window period of about 6 days. Therefore it is critical that donors engaging in very recent HIV risk behaviour

appropriately self-defer. We are aware that a small number of donors donate in contravention of a number of HIV risk behaviour policies (i.e. are 'non-compliant') and some do so because they 'self-assess' their HIV risk as negligible.[1] There is the possibility that negative PoCT results may be used by such individuals to justify donation in contravention of the policy. This is clearly inappropriate and poses a risk to the safety of the blood supply.

In respect of point 2, the Blood Service notes the possibility that users of HIV PoCTs may seek to use blood donation as a method of 'confirmation' of their HIV status rather than access appropriate laboratory diagnostic testing as required under section 2.2 of the proposed performance requirements. This concern is based on Blood Service research that identifies that some donors already inappropriately donate for the principal purpose of accessing testing for transfusion transmissible infections including HIV.[1] This is termed 'test-seeking' and is a recognised phenomenon internationally. Again this behaviour poses a risk to the blood supply and the Blood Service seeks to minimise its occurrence.

In recognition of the above concerns, we propose that as a condition of sale of HIV self-tests the sponsor be required to clearly address these concerns in the product insert and highlight them to users of the tests in any accompanying instruction material.

Technical issues

HIV testing performed at point of care, or in a self-testing environment, is generally less sensitive than laboratory-based testing. We understand that the decision to register a test that is less sensitive takes into consideration the benefits, such as improved accessibility to the test leading to increased testing rates; as well as the undesirable effects, such as false negative results. We also acknowledge that tests that use oral fluid as the specimen may improve acceptance and accessibility for some patients compared with those tests that use blood as the specimen.

We note however that there is variability in the antibody sensitivity of the available registered tests, and also that the sensitivity requirement is lower for assays using oral fluid as the specimen.

We recommend that the TGA set minimum performance criteria for each specimen type. We strongly support statements regarding the limitations of the test, covering both the 'effective' sensitivity and specificity of the test as well as clear warnings on the risk of false negative results. This avoids the potential for the performance criteria for an acceptable assay being dictated by the intrinsic limitation of the particular assay.

Risk mitigation strategies

We recommend more explicit guidance on quality control in terms of enrolment in an appropriate quality assurance program and description of ongoing post marketing surveillance as risk mitigation strategies.

We recommend more explicit “linkage to care” as part of the risk mitigation strategies. For example, the details of relevant sexual health clinics in different states can be provided as part of the product inserts, and that the suppliers/sponsors should be providing market data to Commonwealth and State governments to facilitate epidemiology research and rate monitoring.

Yours sincerely,

JENNIFER WILLIAMS
Chief Executive

References

1 Lucky TT, Seed CR, Waller D*, et al.*: Understanding noncompliance with selective donor deferral criteria for high-risk behaviors in Australian blood donors. *Transfusion*. 2014;**54**: p. 1739-1749.