Risk of HIV transmission to blood recipients when pre-transfusion screening of family/replacement donors is performed using Alere Determine™ in Malawian district hospitals.

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Abstract

Background

The Malawi Blood Transfusion Service (MBTS) is mandated to distribute blood and blood products to hospitals. This blood is collected from Voluntary Non-Remunerated Blood Donors (VNRBDs). Before distribution, blood is screened for Transfusion Transmissible Infections (TTIs) mainly using more sensitive Immunoassays as well as Nucleic Acid AmplificationTests (NAATs). Recurrent shortages of blood from the MBTS have resulted in district hospitals resort to collecting blood from family/replacement blood donors (FRBDs). In most of these hospitals, Alere Determine™ HIV 1/2 antibody test kits are used for pre-transfusion screening of HIV in blood donors. These rapid diagnostic tests have a longer window period and are less sensitive compared to the NAATs and immunoassays used at MBTS.In this case the use of rapid diagnostic tests therefore, poses a residual risk of transmitting HIV to blood recipients when the blood donors are in window period of HIV infection.

Aim

To determine the risk of downstream HIV transmission to blood recipients associated with the use of Alere Determine™ HIV 1/2 antigen/antibody tests in the pre-transfusion screening of FRBDs.

Methods

A cross-sectional study was conducted at Karonga and Thyolo district hospitals as well as Mulanje Mission Hospital. Venous blood specimens that tested HIV non-reactive with Alere Determine™ HIV-1/2 antibody tests were used to prepare Dried Blood Spot (DBS) specimens. The prepared DBS samples were tested again for HIV using the Abbott HIV-1 Qualitative Polymerase Chain Reaction (PCR) assay which uses the Nucleic acid amplification testing principle.

Results

Out of the 94 DBS specimens that were tested using the Abbott HIV-1 Qualitative PCR assay, 92 tested negative and 2 tested positive for HIV-1.This therefore means that 2.13% of the specimens tested positive for HIV-1, despite testing non-reactive during the initial

screening of donors with Alere Determine™ rapid diagnostic tests in respective district hospitals.

Conclusion

The results of this study indicate a 2.13% risk of downstream HIV transmission to blood recipients when Alere Determine™ rapid diagnostic tests are used for pre-transfusion screening of FRBDs. For an infection as deadly as HIV, such a risk is quite significant and cannot be undermined. These results give a good reflection of the residual risk to all blood recipients, however if a similar study can be done with a larger sample size it would give a more reflective extent of the risk posed by using Alere Determine™.