



XVth REGIONAL CONGRESS OF THE ISBT, ATHENS

SHOULD HBV NAT BE IMPLEMENTED IN FRENCH BLOOD DONORS ?

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Background

Since NAT implementation for HIV-1 and HCV RNA in France, the residual risk (RR) of transfusion-transmitted infections (TTI) has dramatically decreased. The RR estimates, for a three-year period from 2001 to 2003 showed a significant decrease from 1/1,700,000 and 1/1,560,000 before NAT implementation to 1/3,150,000 and 1/10,000,000 after NAT implementation for HIV and HCV respectively. As for HBV, the serological screening is only based on both HBsAg and anti-HBc assays. For the same period, the RR estimate for HBV is 1/640,000, five times higher than HIV one and 16 times higher than HCV one.

Aims

As the overall RR of TTI is mainly related to HBV, and given the availability of HBV NAT assays, a study was conducted to determine whether HBV NAT has the ability to further reduce the HBV RR and then should be implemented in blood donor screening in France.

Methods

We have estimated the WP reduction by NAT in comparison with one of the most sensitive HBsAg screening assays, on 10 commercial seroconversion panels (Bioclinical Partners, Franklin, MA, USA). The NAT test was the Procleix Ultrio assay® (Genprobe / Chiron, San Diego, USA). The HBs Ag test was the Prism HBsAg (Abbott, France). The comparison was performed on both neat samples and diluted samples 1/8, 1/16, and 1/24, in order to simulate minipools of different sizes. Then, we have calculated the yield of

HBV-infected donations detected by NAT relative to Prism HBsAg assay.

Results

On the basis of a window period (WP) of 56 days, Ultrio Assay is projected to close the WP by an average of 15 days on undiluted samples, 5 days in minipools of 8 samples, 4 days in minipools of 16 samples and only 2 days in minipools of 24 samples.

The projected yield calculated on the basis of 2.4 million donations collected per year in France, would be 0.65 unit per Year for minipool-NAT and 2 to 3 units per year for individual donation NAT.

Conclusion

Introduction of minipool-NAT will offer only a little added benefit to transfusion safety relative to current serological screening strategies based on both HBsAg and anti-HBc assays. HBV minipool-NAT is then unsuitable for HBV screening in French blood donors. Single-sample NAT or minipool-NAT with smaller pool sizes and/or modified procedures (genome enrichment or test improvement) would be more relevant. Automation when technologically and practically feasible is a prerequisite for single-donation NAT.

Therefore, decision has been made not to implement HBV NAT in the French transfusion network until fully automated systems will be available. However, as the prevalence of HBV infections is higher in the overseas territories than in continental France, and as NAT is performed on individual donations in these sites, HBV-NAT has been implemented since December 2004 in these territories.