



Hepatitis B Surface Antigen Testing Does Not Increase Safety of the Blood Supply and Should Be Eliminated

Background

Hepatitis B is a liver infection that can result in acute or chronic disease. Symptoms include pain, jaundice, and vomiting potentially leading to cirrhosis and liver cancer. It is caused by the hepatitis B virus (HBV) and can be spread through bodily fluids, including blood.

In 1970, to protect the blood supply and avoid transfusion transmission, the United States (US) began testing donated blood for hepatitis B surface antigen (HBsAg), which is produced during active HBV infection. Testing for antibody to hepatitis B core antigen (anti-HBc) was voluntarily implemented in 1987, with licensed anti-HBc testing mandated in 1991. FDA Guidance requiring nucleic acid testing (HBV NAT) was finalized in October 2012.

Testing to reduce or eliminate the transfusion transmission of HBV is important and must be continued. While the HBsAg test was the best available screening tool when introduced, current testing technology has rendered this test duplicative. Thus, the continuing inclusion of the HBsAg test does not further increase safety over the two remaining blood donor tests and should be eliminated.

Improved blood safety following implementation of HBV-NAT testing in the U.S.

HBV-NAT can detect infection up to 11 days sooner than when only HBsAg and anti-HBc had been used for this purpose.¹ Accordingly, the residual risk of HBV transfusion-transmission has dropped from approximately 1 in 200,000 units prior to the use of HBV-NAT testing to around 1 in 3 million units at this time.²

In 2013, Stramer et al.'s analysis of HBV testing data from almost 13 million US-based donations demonstrated no confirmed HBV-infectious units containing HBsAg that would have been "missed" by routine testing for HBV-NAT and anti-HBc alone.³ Dodd et al.'s extension of this analysis, performed on an additional 22.4 million donations and published in 2018, revealed that the elimination of HBsAg screening would have a negligible deleterious impact – i.e., an increased risk of new HBV transfusion-transmissions of less than 1 per 4 million donations.⁴ More recently, a study from the Netherlands further supports the view that HBsAg testing no longer enhances blood safety.⁵

Cost of HBsAg testing in the U.S.

A study of the incremental cost-utility of NAT after implementation of serology screening has prompted the need for reevaluation of the current test strategy.⁶ At an estimated cost of \$1.00 to \$1.50 per HBsAg test, this represents a cost of approximately \$15 to \$22.5 million annually.⁷

Recommendations:

The testing requirement adds unnecessary financial burdens without commensurate benefit and therefore **HBsAg should no longer be a required donor screening test.**

References

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