FDA Updates Blood Donor Screening Guidelines to Help Prevent Hepatitis B Transmission

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The U.S. Food and Drug Administration (FDA) has changed its guidance on how best to reduce the risk of hepatitis B virus (HBV) transmission via donated cells and organs, the Regulatory Affairs Professional Society reports. Under the new rules, nucleic acid tests will now be used to screen potential donors for the liver virus.

According to health authorities, nucleic acid tests (or NATs) offer significant improvements in how early hepatitis B can be detected in the body when compared with previous testing standards, such as hepatitis B surface antigen (HBsAG) tests and hepatitis B core antigen (anti-HBC) tests. How much earlier? Around 40 days, according to the latest studies on NAT.

The thinking behind the FDA's update is that it takes some time for a newly infected person to produce enough hepatitis B antibodies to show up on the traditional screening test, creating a so-called window period for potential transmission. Nucleic acid testing, which scans HBV DNA genetic material reduces this in-between time. Plus, experts say the new technology has a much higher likelihood of detecting newer mutations of the virus.

The FDA also said the recommendation to add NATs to existing donor-screening protocols is still necessary in the United States, as the liver virus is "transmitted by blood transfusions more frequently than hepatitis C virus (HCV) or HIV" and has been documented to spread via tissue transplantation in the past.

New guidelines for human cells, tissues and tissue-based products will require facilities to start using all three tests (NAT, HBsAG and anti-HBC) to screen for hepatitis B within the next six months and to accept only donors who test negative for HBV on the three tests.

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