



America's Blood Centers[®]
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1717 K Street NW, Suite 900, Washington, DC 20006
Tel: 202-393-5725 | Fax: 202-899-2621

www.AmericasBlood.org

ABC Supports FDA's Updated Guidance on vCJD

America's Blood Centers (ABC) strongly supports the updated **guidance** released by the Food and Drug Administration (FDA) today regarding variant Creutzfeldt-Jakob disease (vCJD). This move will allow more people to safely donate and strengthen our nation's blood supply at a critical time.

Commonly referred to as Mad Cow Disease, vCJD is a rare disease of the central nervous system. Despite initial concerns of potential transmission, science continues to show that the transmission risk of vCJD by blood components remains only theoretical.

Based on updated evidence, the FDA's new guidance removes the deferral recommendations associated with geographic risk of vCJD for time spent in the United Kingdom (U.K.) from 1980-1996; time spent in France and Ireland from 1980-2001; and receipt of a blood transfusion in the U.K., France, or Ireland from 1980-present.

Permanent deferrals remain in place for donors who volunteer that they are suspected of having vCJD, CJD or any other transmissible spongiform encephalopathies; have a blood relative diagnosed with familial prion disease; or who received cadaveric pituitary human growth hormone, or a human cadaveric (allogeneic) dura mater transplant.

Our member blood centers are looking forward to welcoming back previously deferred donors. However, these changes cannot be made overnight – they must be implemented in a controlled environment in accordance with good manufacturing practices.

It will take time for blood collection establishments to update their computer systems and donor history questionnaires to incorporate these changes, as required by the FDA. Individuals are strongly encouraged to contact their local blood center to confirm the implementation timeline, their eligibility, and to **schedule appointments** to donate.

While the blood supply is currently stable, there is an ongoing need for blood donation, especially during the summer months.

In April of 2020, FDA eliminated the deferral of U.S. military personnel, Department of Defense civilians, and their families who spent time at U.S. military installations in Europe outside of the UK during the period of 1980-1996, a change ABC has been long working with FDA to implement. This change allowed more people to donate blood without risking the safety of our nation's blood supply. ABC appreciates our continued partnership with FDA and continues to

advocate for FDA to apply evidence-based decision making to ensuring the safety of the blood supply.

Moving forward, ABC will continue to encourage the FDA and the Centers for Disease Control and Prevention to keep surveilling vCJD globally and applying a risk-based approach that includes periodic evaluation and adjustment in deferral criteria accordingly.

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