



Blood Donor Deferral for Variant Creutzfeldt-Jacob Disease (vCJD)

- Variant Creutzfeldt-Jacob disease (vCJD), the human form of Bovine Spongiform Encephalopathy (BSE or “Mad Cow Disease”) is a fatal, progressive neurological condition first identified in the United Kingdom (UK) in 1996. As of August 2018, there have been 231 people affected by vCJD worldwideⁱ, with about 76% of cases occurring in the UK and 12% in France.
- Most cases of vCJD were acquired by consumption of bovine (cow) meat products contaminated with the BSE prion during a BSE epidemic in the UK from 1980-1996. However, three cases of apparent vCJD transmission by receipt of blood products from infected, asymptomatic donors were reported in the UK. Therefore, vCJD was recognized as a relevant transfusion-transmitted infection by the FDA in 21 CFR 630.3(h).
- Owing to the lack of a licensed screening test to detect vCJD in blood donations, a geographically based blood donor deferral, dependent on time spent in areas at risk for vCJD transmission was initially instituted in 1999. The policy was later modified to include a specific deferral of US military personnel, DoD civilians, and their families who were stationed in Europe due to importation of UK beef onto US military bases.
- Despite the perceived risk, no cases of vCJD have been reported in US military personnel, DoD civilians, or their families in the 21 year period since the deferrals were implemented. The US military ceased importing UK beef onto military bases in 1996.
- In a 2017 *Transfusion* article, modeling by the FDA recognized that the UK, Ireland, and France had the greatest risk of vCJD. We believe inclusion of US military in Europe outside of the UK in the modeling would have shown that these donors are not a significant source of risk for vCJD transmission. ⁱⁱ The CDC has reported four confirmed cases of vCJD in the United States; none were US military personnel, DoD civilians, or their families and none were due to blood transfusion transmission.
- Modifications to cattle feed and testing of cattle for BSE appear to have resulted in diminishing reports of vCJD. The 2019 Annual Epidemiologic Report on Communicable Diseases in Europe reported 2 cases in 2016: one from Italy and one from the UK. The World Health Organization for Animal Health has listed the US as having negligible risk for BSE.
- In light of the long period of time which has passed since control of the BSE epidemic in the UK (1980-1996), the rarity of transfusion transmission of vCJD, the fact that no cases have been reported in US military personnel, DoD civilians, and their families, **America's Blood Centers (ABC) believes that the FDA should take immediate action to remove the deferral for, and allow re-entry of, US military personnel, DoD civilians and their families who spent time at US military installations in Europe outside of the UK during the period of 1980-1996, thus allowing this cohort to make a valuable contribution to America's blood supply.**
- Additionally, ABC believes the FDA and CDC should continue to surveil for vCJD and BSE globally and continue to apply a risk-based approach to vCJD, with periodic evaluation and adjustment in deferral criteria accordingly.

ⁱ Center for Disease Control and Prevention, variant Creutzfeldt-Jakob Disease (vCJD),
<https://www.cdc.gov/prions/vcj/index.html>

ⁱⁱ Yang et al. Geographical exposure risk of variant Creutzfeldt-Jakob disease in US blood donors: a risk-ranking model to evaluate alternative donor-deferral policies *Transfusion* 2017;57;924-932.