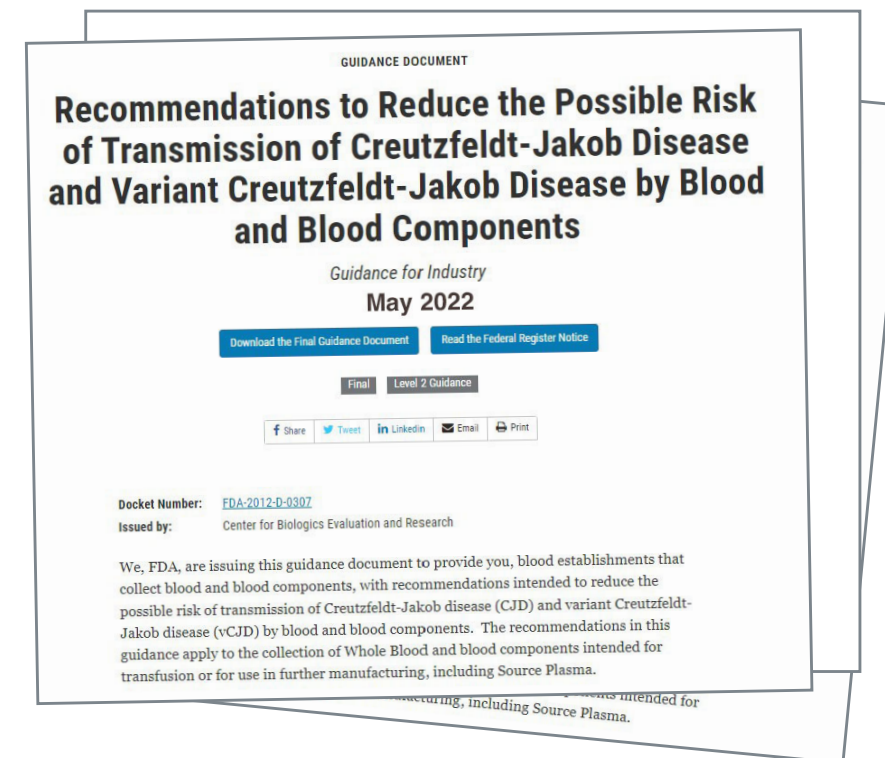


Will Donors Return After Deferral: One Center's Experience with Reinstatement After New FDA Guidance on Creutzfeldt-Jakob Disease

Rachel Beddard, MD, Shirley Aranel, Beatrice Fisher, Monica Gomez-Garcia, Lupe Mendoza, Alexandra Tovar and Samantha Gomez Ngamsuntikul, MD

Background/Case Studies:

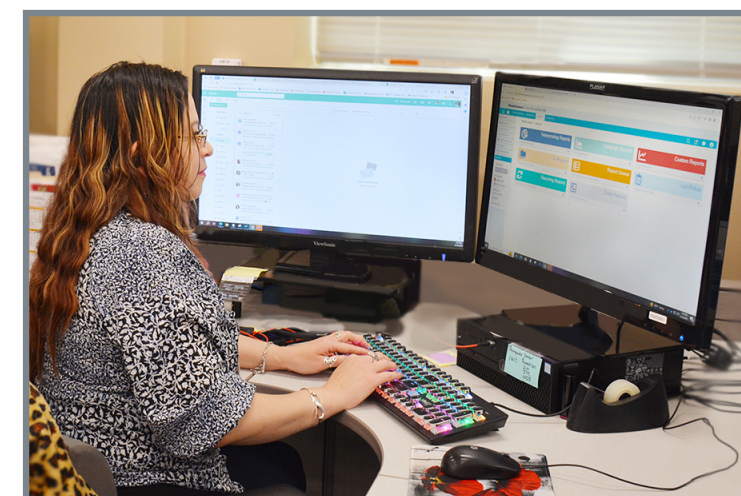
FDA provided its initial guidance related to Creutzfeldt-Jakob Disease (CJD) in 1999, focusing on donors diagnosed with CJD or with residence in the UK. This initial guidance has been changed multiple times through the decades to address the risks associated with other geographies in Europe (including military bases), receiving a blood transfusion within certain geographies in Europe, receiving human pituitary derived growth hormone, receiving bovine insulin, and having blood relatives with CJD. In May 2022, the FDA released their most recent CJD guidance "Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components". This most recent guidance removed donor deferral for geographic risk of CJD providing a large potential pool for requalified blood donors.



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Study Design/Methods:

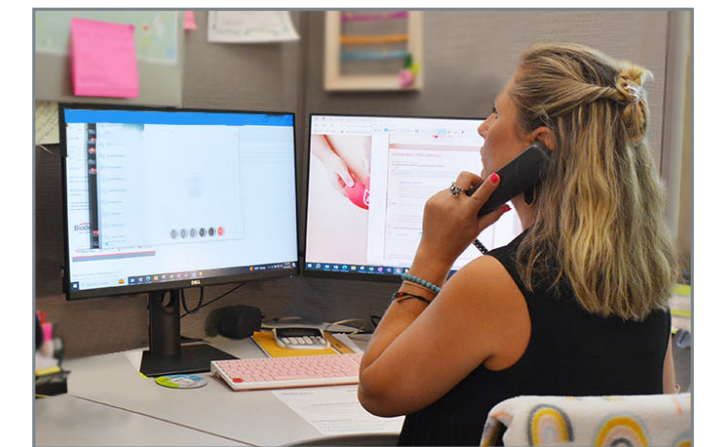
Our center ran a report through our blood establishment computer system (BECS) to capture all donors deferred for geographic BSE risk. Donors deferred within the last three years were prioritized for personal reinstatement efforts. Quality assurance (QA) reviewed each donor's records to determine if any other deferrals applied. If eligible for reinstatement, QA removed the deferral electronically and then donor recruitment (DR) staff attempted to call each donor to inform them of the changes in donor criteria and invite them to donate.



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Results/Findings:

Our center had a total of 13,221 donors deferred for geographic risk of CJD between January 1, 2001, and December 31, 2022 with 399 deferred in the last three calendar years. QA staff determined that 366 of the 399 were eligible for reinstatement. To date, DR staff has attempted contact for 331 of the 366 donors eligible for reinstatement. Of these 331 donors, 68 could not be contacted (wrong phone number, no phone number, no answer), voice mails were left for 179, and 84 were reached personally. Of the 84 donors that were spoken to personally, 31 have indicated intent to return to donation, 13 have set an appointment and 6 have already donated.



QA removed the deferral electronically and then donor recruitment (DR) staff attempted to call each donor to inform them of the changes in donor criteria and invite them to donate.

Conclusion:

Following release of the FDA guidance on recommendations to reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components, our center has been successful in recapturing these deferred donors through personal interaction. Out of 331 reinstatement eligible donors that have been contacted so far, 5.7% have donated or set appointments and another 9.4% have indicated intent to return to donation.

