Questions and Answers on Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products

Questions about New Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD)

Why do we recommend new blood donor deferrals for possible exposure to BSE and vCJD?

FDA is taking this step as a prudent measure to assure the safety of the blood supply by further reducing the theoretical risk from vCJD. In 1999, we recommended the first donor deferral for people who may have been exposed to the vCJD agent, which is believed to be the same as the agent of bovine spongiform encephalopathy (BSE, or "mad cow" disease). We recommended deferral of donors who resided in the United Kingdom (U.K.) for 6 months or more between 1980 and 1996. At this time, we are recommending new blood donor deferrals for possible exposure to BSE and vCJD for the following reasons:

1. Since 1999, the rate of vCJD cases in the U.K. has been on the rise.
2. Significant exposures to potentially contaminated U.K. beef occurred in France and cases of vCJD have appeared in France.
3. Significant exposures to potentially contaminated U.K. beef occurred at U.S. military bases in Europe
4. In Europe, outside the U.K., the BSE epidemic has been increasing.
5. Particularly in the U.K., transfusion recipients may have been exposed to donors already infected with vCJD.

What are the new donor deferrals for possible exposure to vCJD?

1. Residence in the U.K. for 3 months or more, between 1980 and 1996.

Rationale: The U.K. has experienced the largest epidemic of BSE, and also has the largest number of cases of vCJD (over 100). However, in 1996, the U.K. instituted and enforced rules to prevent contaminated cattle from entering the human food chain (www.defra.gov.uk/animalh/bse/public-health/public-health-index.html). Due to these effective food chain protections, the risk of exposure to the BSE agent has been greatly reduced. For this reason, the donor deferral extends only through 1996.

2. Military personnel (current and former), and their dependents, who spent time in military bases in northern Europe 1980-1990, or southern Europe (1980-1996), for 6 months or more.

Rationale: British beef was eaten at military bases during these time periods. The maximum amount of U.K. beef eaten was about 35% of the total beef diet.

3. Donors who lived in France for 5 years or more, between 1980 and the present.

Rationale: The French imported at least 5% of their beef supply from the U.K. before 1996. There are also 5 cases of vCJD in France. This deferral will go into place before the European deferral (# 5., below).

4. Donors who received a transfusion in the U.K. between 1980 and the present.

Rationale: Although there are no known cases of transfusion of vCJD, it is too early to rule out this possibility. Since the U.K. has the highest number of vCJD cases, and is likely to also have the highest number of people incubating vCJD, we recommend deferral of people who have received blood products from U.K. donors.

5. Blood donors who lived in Europe for 5 years or more, between 1980 and the present.

Rationale: Most European countries now have reported BSE, although in fewer cattle than in the U.K. However, methods to prevent BSE from getting into human food are not completely in place in all European countries, so we recommend deferral up to the present time.

How effective are the new donor deferrals at reducing risk of vCJD from transfusion?

Combined with the effect of our previous recommendations, our new recommendations, added to the previous U.K. deferral, eliminate an estimated total 90% of overall risk (calculated by "risk-weighted" person-days of exposure to infected beef), and may decrease the number of donors an average of an additional 5% nationwide. The new deferrals reflect an attempt to minimize the theoretical risk of transmission of vCJD, while maintaining critical supplies of blood products.

Why can people who have lived in Europe for 5 years or more, give Source Plasma, but not blood?

Blood donors are deferred, but donors of "Source Plasma," who have lived in Europe (except France and the U.K. as above), may continue to donate. Unlike blood, Source Plasma undergoes manufacturing into highly processed products ("plasma derivatives"), several of which have been in short supply. Donors who have lived in Europe have a low likelihood of incubating vCJD, compared to people who lived in France or the U.K. Furthermore, published studies show that some of the steps used in plasma derivative manufacturing remove agents which are similar to the vCJD agent, thus adding a potential margin of safety. Thus we consider the risks and benefits of deferring Source Plasma donors, as opposed to blood donors, for residence in Europe to be different.

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Questions about the New Deferrals and the Blood Supply

How will the new deferrals affect the blood supply?

Based upon a 1999 survey, we estimate that about 5% of blood donors may be deferred. However, in some locations, such as in large coastal cities, where more people travel, up to 10% of donors may be deferred.

What measures are being taken to attenuate the impact of the new donor deferrals?

1. We have recommended two separate phases of donor deferrals, to spread out the potential impact on supplies over time. Phase I will start May 31, 2002, and includes deferral of people who lived in the U.K. (3 months or more, 1980-1996), in France (1980-present), or on military bases (as described above), or who had a transfusion in the U.K. Phase I will provide 82% of the additional risk reduction accomplished by the revised deferral policy and is estimated to eliminate approximately 59% of current potential vCJD risk.

   For blood donors who lived in Europe for 5 years or more, deferrals will start on October 31, 2002. Phase II will provide the balance (18%) of the additional risk reduction accomplished by the revised deferral policy, and is estimated to eliminate an additional 13% of current potential risk.
2. We have asked blood banks that choose to have broader deferrals than those we recommend, to implement pilot studies, to see whether the loss of donors can be tolerated without causing local blood shortages.
3. The Department of Health and Human Services has instituted a system for monitoring the blood supply, nationwide, in an effort to detect blood supply shortages.
4. We continue to encourage more blood donations, as well as cooperation among blood banks to assist each other in cases of local shortages.

If I am deferred, will I ever be able to donate again?

Because it is still uncertain whether blood can transmit vCJD, and because it is possible that donor screening tests may be developed to exclude anyone carrying the disease, it is possible that you will be able to donate again in the future. Along with our expert Transmissible Spongiform Encephalopathy Advisory Committee (TSEAC), we are continuing to monitor the BSE epidemic, human exposure to BSE, possible testing methods for blood, and scientific advances which will help us understand whether or not blood or blood components are able to transmit vCJD. New advances in science and epidemiology may enable you to donate again in the future.

What will happen when new countries, not now on the blood donor deferral list, are discovered to have BSE?

Since the publication of our draft guidance in August 2001, BSE was diagnosed in Japan, which is not on the blood donor deferral list. The source of this outbreak is believed to be contaminated material from BSE cattle, which was imported and fed to Japanese cows. The news media has reported that other countries may also have received potential BSE-contaminated material which they could have fed to their own cows. We may consider additional deferrals based upon possible exposure to BSE in Asia or elsewhere, but only after additional information about the potential level of BSE exposure and food chain controls in these other countries is acquired and, preferably, would anticipate doing so after the currently recommended deferrals have been implemented and their impact is assessed.

How is FDA monitoring the risk of vCJD transmission by blood?

We monitor the risk by keeping up to date with new published, and unpublished scientific work from academia and industry. Much of this material is made publicly available at meetings of the TSEAC. We maintain close contacts, and consult with experts in other agencies that are also involved in BSE and vCJD, such as the U.S. Department of Agriculture and the Centers for Disease Control and Prevention, as well as with international government agencies. FDA also maintains its own pool of scientific experts in these diseases who perform active research to address questions of transmission of spongiform encephalopathies, such as BSE and vCJD by blood.

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Further Information

Where can I obtain more information?

1. Previous TSEAC transcripts, containing discussion and information about many of the issues and decisions, above:

- TSEAC Transcripts, December 18, 1998
- TSEAC Transcripts June 1-2, 2000
- TSEAC Transcripts, January 18-19, 2001
- TSEAC Transcripts June 28, 2001

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