



Blood Centers
of the Pacific

Update

Newsletter for Hospitals
April, 2000

nvCJD: How this new FDA policy will affect donors and hospitals.

1. What is CJD?

- Creutzfeldt-Jakob Disease (CJD) is a rare and very slow-developing disease that is invariably fatal. It occurs in about one in a million people worldwide. Although the vast majority of cases (85 percent) are sporadic (with no identifiable cause), about 10 to 15 percent occur in families as a result of a gene mutation.
- In addition, in a small number of instances (less than 5 percent), CJD has been transmitted by the transplantation of corneas and dura mater (a brain-associated membrane), by injections of human pituitary-derived growth hormone, and by the reuse of electroencephalogram electrodes previously used on CJD patients.

2. What is the relationship of CJD and nvCJD to "mad cow disease"?

- CJD and Bovine Spongiform Encephalopathy (BSE or "mad cow disease") belong to the same family of diseases generally called Transmissible Spongiform Encephalopathies (TSEs). These diseases have been known for many years, and they affect humans and many animal species (sheep, goats, mink, etc). CJD was first reported in the 1920s.
- Until recently, there had been no evidence of transmission of mad cow disease to humans. However, in 1996, the first cases of a new variant form of CJD affecting humans (nvCJD) were reported from England. The clinical features and epidemiology of nvCJD are different from classic CJD and researchers believe they are related to mad cow disease. Whether or not the patients contracted their disease by eating beef from diseased cattle is not known.
- Differences include age group affected and time of disease progression (CJD affects older people in a slowly progressive disease; nvCJD affects a younger population and progresses rapidly)--both are fatal.

3. What precautionary measures is BCP currently taking against CJD?

- Although the possibility of transmission of CJD by blood transfusion is only theoretical, BCP has taken prudent precautions by deferring donors at risk of CJD.

Individuals at risk are:

- Recipients of human pituitary growth hormone;
- Recipients of transplants of dura mater (a brain tissue); and
- Donors with more than one family member with a diagnosis of CJD.

4. What new precautionary measures against nvCJD will BCP be taking after April 15th, 2000?

- Although the possibility of transmission of nvCJD by blood transfusion is only theoretical, BCP will follow FDA guidelines by asking donors specific questions about travel to the United Kingdom and length of stay.



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The questions are:

- Have you visited or lived in the United Kingdom (UK) from 1980 through 1996? (England, Scotland, Wales, Northern Ireland, Isle of Man or the Channel Island)
- If so, did you spend a total of six (6) months or more in the UK from 1980 through 1996?
- Donors who say "yes" to both questions are permanently deferred at this time.

5. Is CJD/nvCJD a risk for transfusion recipients?

- To date, no cases of CJD/nvCJD transmission by blood, blood products or plasma derivatives have been reported. Furthermore, there is no evidence of increased risk of CJD/nvCJD in patients who receive multiple transfusions, such as people with hemophilia or thalassemia. Neither CJD/nvCJD is transmitted by casual contact or sexual contact.

6. Why is the current situation with respect to CJD different from the early days of AIDS?

- AIDS was an epidemic, with cases doubling every six (6) months. In contrast, the rate of CJD cases has been remarkably constant since the disease was first identified 75 years ago - about one case per million population, worldwide.
- An early clue to the fact that AIDS could be a problem for the blood supply was the identification of cases among hemophilia patients. Active surveillance by the Centers for Disease Control has NOT found increased incidence of CJD among hemophilia patients. In fact, no cases have been identified so far. A few cases are expected just because of the 1:1,000,000 incidence of sporadic CJD.

7. Is BCP notifying hospitals about blood products donated by donors who are known to be at risk for CJD or nvCJD?

- When BCP learns that a current or previous donor has been diagnosed with CJD or has a risk of CJD or nvCJD, BCP disqualifies that donor and identifies any prior donations by the individual. BCP then notifies the hospitals that received the blood components, if the component has not expired. If the component is still available, it will be destroyed.
- The hospital can choose whether or not to notify the recipient. Recipient notification has been controversial and is not required by the FDA. Some believe that notification will unnecessarily frighten people about a disease which is ultimately fatal and has no cure since transfusion transmission is yet unproven. Others believe that people have a right to know any information that could potentially affect their health.
- If the donor's plasma has been shipped to a pharmaceutical company for manufacturing into plasma products, the blood center also notifies the pharmaceutical company.
- Americas Blood Centers and BCP are working closely with the federal agencies to monitor the CJD situation and will implement new safeguards and precautions as they are recommended.

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