

Extending the Ban on British Donors regarding vCJD/BSE to all Western European Countries is not justified.

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Introduction

It has been proposed by one blood collecting organization in the United States to extend the “Ban on British Donors” regarding vCJD/BSE to all Western European countries. This extreme proposal will therefore include the Netherlands, as the Blood Bank of the Central Laboratory of the Blood Transfusion (CLB) in Amsterdam is a partner in the Euroblood Program of the NYBC and supports the NYBC Blood Program with 50,000 – 80,000 units of red cells per year. The CLB Blood Bank has been collecting for more than 10 years blood for the New York Blood Center (NYBC) under a sub-license of the FDA license of NYBC. The CLB Blood Bank has implemented all FDA requirements regarding blood centers and the quality of donor blood. This includes the questionnaire on the suitability of blood donors, notably, the question regarding the exclusion of donors who have resided in the UK between 1980 and 1996 for a cumulative period of six months or more, the so called “Ban on British Donors”.

The extreme proposal implies that all blood from donors in Western Europe is less safe compared to blood collected in the US. While the blood community in the world considered the risk on vCJD/BSE as a theoretical risk, the proposal suggests, without any new scientific evidence, that the measure to extend the “Ban on British Donors” to all Western European donors is necessary, because the risk of attracting vCJD/BSE in Western Europe by blood is real. This implies the following:

1. The proposal goes far beyond any epidemiological evidence regarding the theoretical risk of vCJD/BSE. This is contradictory to the current precautionary measures being taken in the US and Europe, which are based on documented and reproducible risk assessment studies and scientific data.
2. The proposal implies that the current precautionary blood safety measures in Europe, both on the level of the European Union and Council of Europe and at the level of individual countries, are insufficient.
3. For patients in the New York and New Jersey region who are in need for transfusions of red cells, the proposal to minimize the theoretical risk of vCJD/BSE will most likely enlarge the real risk of insufficient supply for these patients.
4. American citizens in Europe, both civilians and military personnel, who may be in need of a blood transfusion while they stay in Europe, will be in extra danger, because the blood safety in Europe is less than in the US. In such a situation the US Army may be legally responsible when military personnel in active service in Europe, receive a unit of European blood.

In this paper I will give a brief overview of the current situation in the Netherlands regarding the precautionary safety measures for vCJD/BSE.

Short History

For a number of years, the agriculture and the food industries in Europe have been confronted with a new disease, called Bovine Spongiform Encephalopathy (BSE).

This disease in cattle was originally diagnosed mainly in the United Kingdom, but later also in a number of other countries. The European Union and the Ministries of Agriculture of several European countries have issued very strict measures to prevent further spread of BSE. In 1996, a human disease was detected, which has similarities with BSE. This disease, variant Creutzfeldt-Jakob Disease, seems to have its cause in the eating of beef products, contaminated with BSE.

The origin of a new disease has brought the blood transfusion organizations and the health authorities in Europe to a high state of alertness, because the responsibility for safe blood and a safe blood program is one of the highest priorities. Despite intensive scientific research world-wide, the transmission of diseases related to BSE, so called Transmissible Spongiform Encephalopathies or TSE's, via products prepared from blood and blood plasma has not been found. However, the possibility of transmission cannot be excluded. As a result, in the Netherlands like in other European countries, several precautionary measures have been implemented to do everything to keep blood as safe as possible.

The facts

BSE

BSE is a disease in the neurons of the brain of cattle, which ultimately leads to the death of the animal. Prions seem to be responsible for the disease. Eating food that contains meat offal from cattle contaminated with prions responsible for BSE or scrapie, may be a risk factor for the disease.

The number of cattle with BSE differs considerably between countries. As of 27/02/2001 the situation in Europe was as follows: United Kingdom: 180,903; Ireland: 625; Portugal: 522; Switzerland: 370; France: 278; Germany: 46; Spain: 30; Belgium: 23; The Netherlands: 13; Italy: 6; Denmark: 4; Liechtenstein: 2; Luxembourg: 1. BSE has also been found in Canada: 1 and Falkland Islands: 1. There are no cases in other countries. So in Europe, the highest number of BSE cases is found in the UK, and the number of BSE cases outside UK is 1922 (1.04 %) (source: ourworld-top.cs.com/j1_braakman/BSE.htm).

In the Netherlands (13 cases: 0.007%), the following measures have been taken to prevent further spread of BSE:

1. Since 1989 it has been prohibited to feed cattle with animal offal.
2. Since 1990 it has been prohibited to import British bone meal
3. Since 1993 measures have been taken to prevent the mixture of bone meal for cattle and bone meal for other animals
4. Since 1997 risk material (brains, eyes, tonsils, spine and spleen) must be removed from slaughtered cattle, sheep and goats older than one year, and the risk material is quarantined and destroyed by burning
5. Since October 2000 the ileum has to be removed and burned as well
6. Since January 2001 brain matter from all slaughtered cattle older than 30 months has to be removed and tested for BSE.

Variant Creutzfeldt-Jakob Disease

Variant Creutzfeldt-Jakob Disease (vCJD) in human beings has many similarities with BSE based on the biological and biochemical properties of the prions. Up till now vCJD disease is diagnosed only in the United Kingdom, Ireland and France. On January 27, 2001, vCJD was diagnosed in the United Kingdom in 94 patients, in

France in 3 patients and in Ireland in one patient. The Irish patient with vCJD lived in the United Kingdom until the moment just before the disease revealed itself. The French vCJD patients have never stayed in the United Kingdom but extensive exportation of British meat to France has occurred.

The so-called Prnp-gene, the gene coding for prions, is likely to have a central role in the development of prion diseases. For vCJD the genetic background of the patient seems to play an important role because all patients with vCJD (100%) have the same gene variant. In the general population, this gene variant occurs at percentage of 38%. In the Netherlands no person with confirmed or suspected vCJD has been found.

Prion diseases and blood transfusion

For the natural TSE's, the presence of infectivity in blood is till now, never demonstrated in a documented and reproducible way, neither in animals nor in humans. On the other hand, "infectivity" in blood has been shown in a number of experimental animal studies. At this moment there is no test available to screen blood on classical Creutzfeldt-Jakob Disease (CJD) or vCJD. The screening test, which is used in Europe to test BSE in slaughtered cattle, is not suitable for screening human or animal blood.

Based on several epidemiological follow-up studies in patients receiving blood and blood products, classical CJD is considered as no risk for blood transfusion. Nevertheless like in the US, in many European countries including the Netherlands, precautionary measures have been taken to prevent transmission of classical CJD by blood transfusion by adding questions on the donor form for blood donors to exclude persons from donating blood who may be at risk for CJD. This includes donors who have a family member suffering from CJD or who have died from CJD. Persons, who in the past, have received medicinal products prepared from the brains of diseased persons and persons who have had cornea transplantation or a transplantation of the dura mater.

As yet, confirmed or suspected cases of transmission of variant CJD by blood transfusion have never been found. The possibility of transmission cannot be excluded absolutely, because vCJD is known only since 1996. This period is too short to offer absolute certainty. However, in the United Kingdom, with the highest number of BSE cases since 1987, no cases of vCJD have been found in recipients of blood products despite the administration of large quantities of blood and plasma products. In the United Kingdom 15 persons who died from vCJD have been blood donors. The blood cell products, prepared from blood of these donors have been administered to 20 recipients. None of these recipients have developed vCJD.

While vCJD is considered to be a food problem, for blood transfusion it is considered a theoretical problem, because it not known whether or not a risk really exists and an eventual risk cannot be excluded completely.

The following measures have been taken to prevent the theoretical transmission of vCJD by blood:

1. Blood products prepared from donations of a (ex-) donor who later was diagnosed with vCJD will be recalled from hospitals and pharmacists as a precautionary measure.
2. Similar to the United States, Canada, Australia and Japan, in several European countries donors who have stayed in the United Kingdom more than six months in

the period of 1980 till 1996 are excluded from donating blood. This precautionary measure is called the “Ban on British Donors”.

3. In several European countries leukocytes are routinely removed from all blood cell products by filtration, in other countries this measure is under consideration.

In the Netherlands, the “Ban on British Donors” has been issued for donors whose blood cells are being sent to the New York Blood Center. On February 1, 2001, the Dutch National Health Council has advised to the Minister of Health to introduce leukodepletion of all cellular blood products. The reason to advocate leukodepletion of all cellular blood cell products is the fact that scientific research in experimental animal models appears to show that if vCJD prions should occur in blood, they are most likely transported by white blood cells. Removal of leukocytes from blood cell products where these cells have no function, is being considered as an extra general precautionary measure. Since leukodepletion has also other medical advantages like preventing transfusion reactions, the CLB Blood Bank is preparing the introduction of leukodepletion as precautionary measure.

Conclusion

In Europe, vCJD/BSE is a food problem, while for blood transfusion vCJD/BSE is considered as a theoretical risk. The current safety of blood in the Netherlands is achieved by a policy based on taking precautionary measures to exclude all established and potential risks. This policy has been followed also regarding the occurrence of the theoretical risk of vCJD. Since these measures have been taken by blood transfusion organizations and authorities in several European countries and the US, based on scientific evidence, it is unlikely that there is a difference in the current safety of blood, in the United States versus in Europe. It is uncertain if the extreme proposal to introduce a policy aiming to “Ban all Western European Donors” will affect the safety of blood regarding the theoretical risk of vCJD/BSE. The proposal will most likely introduce a real risk for patient care by endangering the supply of red cells in the US.