

OPERATIONAL INSTRUCTION

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Subject: DEFERRAL OF BLOOD DONATION FROM PEOPLE WHO HAVE BEEN IN THE UNITED KINGDOM BETWEEN 1980 AND 1996

This information may help you in dealing with questions that some of your patients may raise with you, following recent media coverage of a decision by Australian Health Ministers to defer blood donation from people who have been in the United Kingdom. The decision was announced on 21 September 2000.

The deferral of blood donation applies to those who have lived or travelled in the UK for a cumulative period of 6 months or more between 1980 and 1996. This period coincides with the epidemic of Bovine Spongiform Encephalopathy (BSE) in cattle in the UK. Infection with the BSE agent through eating infected meat is thought to be the cause of variant Creutzfeldt-Jakob Disease (vCJD).

No cases of vCJD have been transmitted by human blood transfusion, but a recent article in *The Lancet* has provided preliminary evidence that the agent which causes vCJD may be transmitted by transfusion in experimental animals. The deferral of donations from those who may have been exposed to the BSE agent is, therefore, being implemented as a precautionary measure to protect the blood supply, even though the risk to transfusion recipients in Australia is likely to be very small.

It is important to reassure any of your patients who are concerned, either because they have visited the UK or because they have had a blood transfusion, that the possibility of their falling ill with vCJD is extremely remote.

The Blood Donor Deferral Facts Sheet provides answers to the most commonly asked questions about vCJD and blood donor deferral. You may find them useful for providing advice to your patients. You are welcome to photocopy the Facts Sheet to provide directly to your patients if you wish.

Copies of the Facts Sheet are available to the general public via the free-call **National Blood Information Line** on **1800 351 000** and on the website www.health.gov.au/issues.htm.

If any of your patients are blood donors and would like more information they should call the **Australian Red Cross Blood Donor Information Line** on **13 14 95**. Any patient who is considering withdrawing as a donor in response to the reports in the media should be encouraged to contact their local Australian Red Cross Blood Service to discuss the issue before taking this step. Self-deferral of a significant number of donors in the next 2 or 3 months has the potential to cause a crisis in the supply of blood.

Donor deferral will result in a substantial reduction in what is likely to be in Australia a very small risk to the blood supply. We can never eliminate all risk – only reduce it. Therefore, risk reduction demands that we balance the need to address the very small potential risk of someone transmitting vCJD against the real risk to the blood supply if current donors cease to donate immediately.

The Australian Red Cross Blood Service will be writing to all blood donors shortly to provide them with more information.

Bryant Stokes

CHIEF MEDICAL OFFICER

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Blood Donor Deferral Facts Sheet

Questions and Answers about Classical Creutzfeldt-Jakob Disease (cCJD), Variant Creutzfeldt-Jakob Disease (vCJD) and blood donor deferral in Australia.

Are people who lived in the UK between 1980 and 1996 at risk of contracting vCJD?

The risk of contracting vCJD through travelling and living in the UK in this period is considered to be very low, even among people who have eaten beef. It should be noted that in the UK, where millions of people were potentially exposed to vCJD through eating infected beef, there have only been 69 confirmed cases of the disease.

Why are blood donors who spent 6 months or more in the UK between 1980 and 1996 being deferred from donating blood?

There has not been a single documented case of vCJD transmitted by blood transfusion in Australia or anywhere in the world. However, some countries have taken this action as a precautionary measure in response to the possible risk of transmission of vCJD through blood. In light of recently published scientific data suggesting that vCJD can be transmitted experimentally by blood in animals, the Australian Health Ministers have agreed that persons who have lived for a cumulative period of 6 months or more in the UK between 1980 and 1996 inclusive should, for the time being, be deferred from donating blood.

What is donor deferral?

This is a procedure where donors are asked not to donate blood for a period of time in the interests of their safety and that of the blood supply. Sometimes donor deferral is for a short period, such as when a person is temporarily unwell or is on a course of medication. At other times, donor deferral is permanent, such as when a donor may be at risk of transmitting an infection to recipients (eg, Hepatitis or HIV) or when a donor's health may be compromised by donating blood (eg. Chronic anaemia).

What is significant about the period 1980 to 1996?

vCJD is related to Bovine Spongiform Encephalopathy (BSE). This period covers the period of the epidemic of BSE in cattle in the UK. The first cases of BSE were reported in 1986. Scientists believe the incubation period for the disease is about five years, so BSE most likely first appeared in cattle around 1980. It is thought that BSE occurred in cattle that were fed with offal from other animals. The UK introduced a ban on feeding offal to cattle in 1988, and subsequently introduced a series of measures to reduce the risk of humans being exposed to BSE. These measures have been fully implemented since 1996.

Why is 6 months the cut-off for deferring donors?

This approach is identical to that implemented by regulators in the United States of America, Canada and New Zealand. The period of 6 months was chosen because it will greatly reduce the exposure of donors to the risk of BSE. The policy is expected to reduce the theoretical risk of vCJD without jeopardising the continuing availability of supplies of blood and blood products to people who need them.

If I recently received a blood transfusion in Australia, should I be concerned?

No, there is no need to be concerned about your health. There have been no cases of vCJD in Australia and no cases of vCJD associated with human blood transfusions anywhere in the world.

When will the policy of deferring donors who have lived or travelled in the UK commence?

The policy will be phased in progressively over the next three months.

Should people who believe they will not be able to give blood under the new rules continue to give blood now?

Yes. Donors should continue to donate until advised by the Australian Red Cross Blood Service they can or cannot donate under the new rule. There is no risk to donors from giving blood. Anyone who wants more information about whether they should donate should phone the Australian Red Cross Blood Donor Information Line on 13 14 95.

Why isn't the new donor rule being implemented immediately?

Some steps will be taken immediately. However, all countries which have implemented similar policies have had an implementation period of three months or more. This time is needed to fully implement the necessary procedures involved in donor deferral, including logistical issues and training of staff. It is also needed to implement an integrated plan for ensuring that there is enough blood available for patients who need it. This is a balanced approach that protects patients from a 'theoretical' risk without exposing them to the "real" risk from a shortage of blood.

How are donors being informed about this?

Through media announcements, through letters to all current Australian donors and through information at blood centres.

What is classical Creutzfeldt-Jakob Disease (cCJD)?

cCJD is a rare protein disease affecting humans. The disease was first identified by German psychiatrist, Dr H.G Creutzfeldt, and German neurologist, Dr Alfons Maria Jakob, in the 1920s. It is caused by abnormal proteins, known as prions, in the brain. Prion diseases lead to the degeneration of the central nervous system. The symptoms of cCJD disease include a rapidly progressive dementia, loss of motor control and involuntary movements. Symptoms may not appear for many years after the disease process begins, but once they do, death usually occurs within 3 to 12 months. At the moment, there is no effective treatment and no reliable test to identify the disease while the patient is alive.

Approximately 85 percent of cCJD cases occur spontaneously without any known cause. A small proportion of cases occurs in families who have specific genetic abnormalities. Other causes include certain medical treatments that are no longer used, such as growth hormones obtained from human pituitary glands and dura mater (brain membrane) grafts. cCJD occurs naturally at the rate of approximately one case per million people per year. It rarely occurs in young people and is most commonly seen in the 65 to 79 year age group.

What is variant Creutzfeldt-Jakob Disease (vCJD)?

vCJD is a new and more aggressive strain of the disease, which was first reported in the United Kingdom in 1996. It produces similar symptoms to classical CJD, although vCJD progresses more rapidly. vCJD is thought to be contracted by eating meat infected with the prion which causes bovine spongiform encephalopathy (BSE), more commonly known as “Mad Cow” disease. So far, people who have been ill with vCJD have been aged between 16 and 52 years, with most in their twenties and thirties. However, there have been no cases of “Mad Cow” disease in Australian cattle and there have been no cases of vCJD in Australia.

What are the differences between cCJD and vCJD?

cCJD tends to affect people aged 60+ and symptoms may take 30 years to develop from the time that exposure to the prion occurs, whereas vCJD has been found in teenagers and young adults and it develops more rapidly following exposure.

Have there been any cases of cCJD or vCJD in Australia?

In 1993 a Case Registry was established in Australia. The Registry is similar to those operating in the United Kingdom and New Zealand. The Registry actively searches for cases of CJD and reviews and investigates all reported cases to ensure consistent diagnosis and risk factor identification. Following completion of a look back study to 1970, there are currently 482 cases of cCJD on the register. There have been no cases of vCJD reported in Australia.

Has anyone within Australia who has travelled to the UK developed vCJD?

No. There is no evidence that travellers to the UK, even those who may have eaten beef while travelling there, have developed vCJD.

Is there a test for cCJD or vCJD?

There is currently no test that is conclusive in detecting cCJD or vCJD in a person who is still alive. Sometimes, vCJD can be detected in the tonsils or in the appendix in a person who has all the other symptoms of vCJD, but there is no routine test that could be done on the general population. Work on this continues, but a test may be years away.

How many cases of vCJD have there been in the United Kingdom?

There have been 69 confirmed cases of vCJD in the UK between 1996 and September 2000.

Have there been any other reports of vCJD internationally?

There have been two confirmed cases reported in France and one in Ireland.

A small number of cases of vCJD have been reported from France. Why is there no deferral policy for people who have lived or travelled in France?

The number of cases of BSE occurring in France has been small and only 2 confirmed cases of vCJD have been recorded there. However, the issue is under active consideration by public health authorities in a number of countries, including Australia.

vCJD was first identified in the UK in 1996, and other countries have already introduced similar measures, so why has it taken Australia so long to take this step?

Countries which have already introduced similar measures include the USA, Canada and New Zealand. Although announcements were made in these countries in 1999, the measures did not take effect until 2000. Before similar steps could be taken in Australia, the Australian Red Cross Blood Service needed to assess the impact that such action would have on the availability of blood. Health authorities have been mindful of the potential impact on the supply of blood of deferring around 30,000 blood donors. Until recently there was no substantive scientific evidence that vCJD could be transmitted through blood and it is for this reason that Australian Health Ministers put on hold making such a drastic decision when they met in July 2000. However, work has been underway to assess the impact that such action would have on the availability of blood and to establish contingency plans for ensuring the availability of blood should a decision to defer donors be made.

What effect will donor deferral have on blood donations?

It is anticipated that there will be an initial reduction of 5-10% in donations and that eventually about 30,000 donors will be deferred.

What are health authorities and the Australian Red Cross Blood Service doing to be sure that blood centres will have adequate supplies?

There is a range of strategies some of which can be introduced immediately and others which will be phased in over the next 1 to 3 months. Tele marketing of donors will commence immediately. Other strategies will target lapsed donors to encourage them to resume donating and donors who donate 1, 2 or 3 times a year will be encouraged to make more donations. Longer term plans include the introduction of Youth Donor Programs to educate and motivate students to become regular donors.

Will existing supplies be destroyed?

No, this is not necessary. There have been no cases of vCJD in Australia and donor deferral is purely a precautionary measure to safeguard the blood supply.

Can vCJD be transmitted from mothers to babies?

There have been no documented cases of transmission of vCJD from mothers to babies. There have been media reports in the UK of neurological symptoms developing in a baby who was born to a mother who later died of vCJD, but there is no scientific evidence at this stage that the baby has vCJD.

Some countries have introduced leucodepletion. Will Australia do that too?

Australia is not introducing universal leucodepletion at this stage. It has yet to be determined whether this procedure does reduce the risk of vCJD. The Commonwealth Government is funding a scientific assessment of leucodepletion, in collaboration with State & Territory Health Departments and will consider the issue when the report from this study is available.

What is leucodepletion?

Leucodepletion is a filtering process which removes white cells prior to transfusion.

What other countries use leucodepletion?

The United Kingdom, some other European countries, Canada and New Zealand have introduced leucodepletion. It is still under consideration in the USA.

Is more information available?

For more information, refer to the Internet website www.health.gov.au/issues.htm or contact the **National Blood Information Line** on **1800 351 000**.

Blood donors who would like more information should contact the **Australian Red Cross Blood Donor Information Line** on **13 14 95**.