Minister to note. The FDA's TSEAC group is meeting on 3 + 4 June and officials will provide an update next week. Dr McGovern feels the recommendation restricting blood donors (para 2) will not be accepted as it would knock out ≃ 75% of all donors (the military who have been based in the UK). Dr Metters has been dealing with media bids.

No new line to take - para 7.

Jeremy Metters

Mike McGovern

Date: 2 June 1999

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The FDA, CJD and possible deferral of US blood donors visiting or resident in the UK.

Introduction

The FDA's group on Transmissible Spongiform Encephalopathy Advisory Committee (TSEAC) is considering what advice it should give to their Advisory Committee on Blood Safety and Availability. TSEAC meets 3 June to consider the options and the impact of this on availability of blood in the US. This is one in a series of upcoming high level US public health committee meetings on the safety of the US blood supply.

2. There is a possibility that TSEAC will advise that all potential blood donors who visited the UK from 1980 to 1992 for a period of 28 days or more should not donate blood. Potential plasma donors are also likely to be deferred no matter how long they visited the UK for. You will remember that 18 Decemebr 1998, TSEAC voted 6 to 3 in favour of introducing restrictions reflecting concern about transmissability of vCJD through blood and blood products. This note summarises current intelligence and provides lines to take.

Intelligence

3. Briefing from a senior FDA official last week suggested that there are three possibilities:

a) that the new restrictions on blood and plasma donors will be introduced with immediate effect. According to the US Advisory Committee on Blood Safety and Availability the expected 11% drop in blood donors (1 million units) could be balance by allowing the 1.5 million US citizens with assymptomatic haemochromatosis (an iron overload condition) to donate their blood for the first time. Up to now they could not donate blood despite having to have it removed every three to six weeks at a fee

ranging from $11to $130. Donation would be free and therefore an incentive for this very powerful lobby to donate.

b) that TSEAC might refer the issue to a further Public Safety Advisory Committee which meets 26/27 August for a decision. However this committee is unlikely to take action on the basis of the information available so far. In addition the US Defense Department is represented here and is strongly against the introduction of the proposed new donor deferral measures as it would involve very large numbers of military personnel and would `effectively cripple the Air Force donor programme and significantly reduce the donor pool of the Army and Navy'.

c) the position might be referred to the Surgeon General, who is unlikely to oppose the powerful arguments from the Assistant Secretary of Defense for Health Affairs. We are advised that this view is likely to prevail and that it would be difficult for TSEAC to act independently, though the meeting is public and there may be media activity. It is likely therefore that the Department of Health and Human Services Blood Safety Committee will discuss the advice when it meets 7 June.

What is likely to happen?

4. The TSEAC will almost vote for donor deferral as described above and by the same and if not a greater majority than 18 December. There is likely to be some media activity around the issue though the advice may be referred to the more senior US decision making health committees. Given the Balkan conflict, the antipathy of the Department of Defense to the proposition on the basis of lack of evidence and negative impact on blood and plasma supplies, and the questionable use of blood from people with haemochromatosis the TSEAC advice may not be acted on.

5. One way or the other there may be significant media interest in the advice from TSEAC whether or not is implemented. Haemo Quebec have already implemented donor deferral as described and though their blood supply is adequate at the moment they are almost certain to need to ask the US to supplement their stocks.

Implications for the UK

6. Apart form the media implications there may be some knock on effects on the UK blood product programme. Currently England imports all its plasma from which blood products are processed from US sources. Any reduction in this supply could put pressure on that supply or increase prices. The effect may not however be immediate and manageable as US stocks are currently very good.

Line to take

7. There is no evidence that CJD or vCJD are transmitted by blood transfusion or blood products. It is for individual countries to consider what action they think necessary to ensure the safety of their blood supply. Like the UK, the US (and Canada) will need to consider the balance between the real risks to patients from restricting the blood supply and the theoretical and unquantifiable risk of transmission of vCJD through blood and blood products.

Dr Mike McGovern

General Lines to Take

What exactly is the US planning to do: There is a possibility that TSEAC will advise that all potential blood donors who visited the UK from 1980 to 1992 for a period of 28 days or more should not donate blood. Potential plasma donors are also likely to be deferred. This will result in a reduction of 11% in the US blood supply.

Will this action make the US blood supply safer: The TSEAC consider that this action will reduce the unquantifiable and theoretical risk of transmitting vCJD through blood and blood products. There is no evidence world wide that CJD or vCJD have ever been transmitted through blood or blood products. The US (and Canada) will need to consider the balance between the real risks to patients from restricting the blood supply and the theoretical and unquantifiable risk of transmission of vCJD through blood and blood products.

Why isn't the UK taking the same measures: This is not an option for the UK as we use 2,5 million units of blood every year and this cannot be replaced. There is no ready market for blood. A reduction of 10% in the UK blood supply would compromise the care of patients especially those suffering severe accidents, patients with cancer and leukaemia, and those needing surgery.

Is UK blood safe: Almost every medical treatment including blood transfusion is associated with some risk. Two recent major studies from SHOT (Serious Hazards of Transfusion) have demonstrated that blood transfusion is very safe and that it is becoming even safer with improving technology. There is no evidence world wide that CJD or vCJD have ever been transmitted through blood or blood products.

But what about the risk of CJD from UK blood: There is no evidence world wide that CJD or vCJD have ever been transmitted through blood or blood products. We need to consider the balance between the real risks to patients from restricting the blood supply and the theoretical and unquantifiable risk of transmission of vCJD through blood and blood products.

What have you done about reducing the risk from vCJD from UK blood: As the experts have advised we have 1) instructed our laboratories to make blood products only from plasma imported from countries where there is no evidence of vCJD and 2) instituted universal leucodepletion of the blood for transfusion [which will be complete by 31 October 1999 as planned]

Patients will be worried: There is no evidence world wide that CJD or vCJD have ever been transmitted through blood or blood products. We need to consider the balance between the real risks to patients from restricting the blood supply and the theoretical and unquantifiable risk of transmission of vCJD through blood and blood products. We are doing every thing the experts have recommended -importing plasma and leucodepletion -to reduce any possible risk.

Why can't the UK import blood from abroad: This is not an option for the UK as we use 2,5 million units of blood every year and this cannot be replaced. There is no ready international market for blood nor are there viable replacement products.

Do donors continue to need to give blood : The NHS needs blood donors more than ever before to support the rising demand for blood associated with the increasing number of operations and treatments we carry out in our hospitals.