

Chairman's brief

Meeting to Discuss CJD Incidents Panel Draft Framework Document: Management of Incidents Involving Blood and Blood Products

Thursday 2 August 2001, 2.00pm, Royal College of General Practitioners

A Chairman's briefing meeting will be held at 12.00 in president's flat at the RCGP

Attendees

Dame Lesley Southgate

Dr Philippa Edwards

Dr Nicky Connor

Miss Claire Mills

Agenda Item		Lead Speaker	Paper Numbers
1.	Welcome and introductions	Southgate	2
	Unlike the situation with surgical instruments, systems are already in place for the tracking of the various products produced from blood donations and for identifying the recipients of some of the products. We therefore need to understand the systems currently in place and identify the changes the Panel proposes to make the system for blood equivalent to that proposed for surgical instruments. For this reason, we have invited specialist advisors who are familiar with, and responsible for, current systems to attend the meeting to assist in developing the framework document. You may wish to ask all participants to introduce themselves.		
2.	Purpose of the meeting	Southgate	
	The purpose of the meeting is:- <ol style="list-style-type: none">1. to inform the Panel drafting group of the current systems in place for investigation and management of incidents involving blood donations2. to inform those currently involved in the management of incidents involving blood donations of the CJD Incidents Panel's principles, as set out in the draft framework document3. to identify any changes in current systems for the management of blood incidents needed to involve the Panel in the process3. to agree a proposal for drafting the relevant sections of the Panel's framework document to set out the system for investigation and management of incidents involving blood donations.		
3.	Summary of framework risk assessment and management proposals	Edwards	4, 5

	<p>This is largely for the benefit of the specialist advisors, so they are aware of the Panel's thinking on the management of risk</p> <p>The risk assessment for blood components is relatively simple and will remain as written in the current draft of the framework document. The risk assessment for plasma derivatives is much more complicated. The most recent drafted version has been criticised following its presentation to the MSBT, an expert committee that advises on the safety of blood. In the light of this, the Secretariat advises that an expert group is established to provide a thorough risk assessment for plasma derivatives that will be acceptable to experts in the field. However, it is expected that at least some recipients of plasma derivatives will fall into each of the risk categories identified:- "contactable" "database" "no action" so the mechanisms for obtaining the information necessary to carry out the risk assessment and for managing the groups will be required.</p>		
4.	Outline of existing system for follow-up for plasma derivatives	Lister	6
	<p>Charles Lister will outline how the potential for vCJD contamination of plasma derivatives is found out and followed up. We want to tease out from this the incident investigation side of the process.</p>		
5.	Discussion of how this might be modified to input Panel advice	Edwards	7
	<p>The Secretariat has suggested the information the Panel will need in order to provide advice. You may wish to ask:</p> <p>Does the drafting group agree with this list?</p> <p>Can Charles Lister/Lincoln Tsang/Nigel Goulding suggest how this can be achieved?</p>		
6.	Outline of existing systems for management of products	Tsang/ Goulding	8
	<p>Mike Goulding wrote the paper, I am not sure whether he or Lincoln Tsang are going to present it to the meeting. You may wish to point out to Panel members that plasma derivatives are medicinal products that are regulated under European Commission Regulations.</p>		
7.	Any changes required?		
	<p>One key issue is to ensure that information is provided to the Panel and that recipients can be identified if necessary, in incidents in which there is not need to withdraw batches of product.</p>		

8.	Outline of existing systems for follow-up of blood component recipients	Hewitt	10
	<p>You may wish to point out to members that blood components are not authorised medicinal products. They normally have a very short shelf life and the number of recipients is small.</p> <p>A system is already established that allows the long-term follow-up of recipients of blood components. Although Pat Hewitt has kindly provided summary charts which she will want to introduce to the meeting Bob Will and the NCJDSU are key players in the system and you should invite Prof Will to comment.</p>		
9.	Discussion of how this might be modified to input Panel advice	Edwards	9
	<p>Blood components</p> <p>As the risk assessment for blood components indicates that all recipients or all such components will always be in the “contactable group”. This advice need only be provided once.</p> <p>Questions are:- To whom should the advice formally be given? Does the advice raise any problems? Prof Will and Martin Donaghy may wish to contribute.</p> <p>Are the Panel content that the database for recipients is run independently of the surgical instrument database.</p> <p>Plasma Derivatives</p> <p>To whom should the advice of the type given in Paper 7 be given? How will it be disseminated to those who need to receive it?</p> <p>How should a database be established – either with the surgical instrument database or with the blood component recipients database?</p>		
10.	Next steps	Southgate	
	<p>You may wish to :-</p> <p>Ask if there are any outstanding issues for discussion, in particular, ask Bob Will if he wishes to raise any points for the NCJDSU.</p> <p>Ask the devolved administrations if they wish to comment at this point</p> <p>Depending on the outcome of the discussion, it would be helpful if the ACTIONS could be agreed as well as the PERSON who is responsible for taking each action</p>		