CJD 6317

file: CJD Incidents Panel: Blood + blood products.

Philippa Edwards
26/07/2001 08:10

Sent by: Philippa Edwards/PH6

To: Claire Mills/PH1/DOH/GB
cc:

Subject: RE: CJD Incident Panel: Draft Framework Document

Claire
Oh bother! This means we will need to collect a list of consultees from the devolved administrations.
pip

---------- Forwarded by Philippa Edwards/PH6/DOH/GB on 26/07/2001 08:06 ----------

Martin.Donaghy@GRO-C on 25/07/2001 16:47:50

Sent by: Martin.Donaghy@GRO-C

To: Philippa Edwards/PH6/DOH/GB
Anne.Grinton@GRO-C
glenda.mock@GRO-C
Martin.Donaghy@GRO-C
Janet.Angel@GRO-C
Gaynor.Legall@GRO-C
cc: Charles Lister/HSD2/DOH/GB
Claire Mills/PH1/DOH/GB
Peter Jones/PH6/DOH/GB
Alan Harvey/PH6/DOH/GB
Nicky Connor/PH6/DOH/GB
patricia.hewitt@GRO-C

Subject: RE: CJD Incident Panel: Draft Framework Document

Philippa

I would prefer the consultation in Scotland going through the Panel secretariat with the ability for us to pull off a sub-set of Scottish Reponses.

Martin

-----Original Message-----
From: Philippa.Edwards@GRO-C
[mailto:Philippa.Edwards@GRO-C
Sent: 05 July 2001 15:27

To: Anne.Grinton@[GRO-C]; glenda.mock@[GRO-C]
martin.donaghy@[GRO-C]; Janet.Angel@[GRO-C];
Gaynor.Legall@[GRO-C]
Cc: Charles.Lister@[GRO-C], Claire.Mills@[GRO-C]
Peter.Jones@[GRO-C]; Alan.Harvey@[GRO-C]
Nicky.Connor@[GRO-C] patricia.hewitt@[GRO-C]
Subject: Re: CJD Incident Panel: Draft Framework Document

Thank you for your message and apologies for the delay in replying. I have already discussed with Charles Lister the need to consult with Haemophilia Societies before the wider consultation process. I expect that Martin Donaghy and Glenda Mock prefer the consultation with the Scotland and Northern Ireland Haemophilia Centre Directors Organisation to go through them, rather than the Panel Secretariat taking this on directly but let me know when the time comes if you prefer the latter. Is anything analogous required for Wales?
There is still quite some work to do on the framework document, particularly the section on blood and plasma derivatives before it is ready to send out.
regards
Pip

Anne.Grinton@[GRO-C] on 18/06/2001 16:21:20
Sent by: Anne.Grinton@[GRO-C]

To: Charles Lister/HSD2/DOH/GB
cc: Philippa Edwards/PH6/DOH/GB
Bob.Stock@[GRO-C]
Sandra.Falconer@[GRO-C]

Subject: CJD Incident Panel: Draft Framework Document

1. CJD Incident Panel: Draft Framework Document
2. Interim Guidance on Blood Products

1. As I mentioned when we spoke on the telephone last week I briefed Scottish Haemophilia Directors on both of these documents when we met last Wednesday. I pointed out that the Interim Guidance had gone to UKHCDO, but it appears that relations within that organisation are not particularly amicable at the moment, especially between the different parts of the UK. Christopher Ludlam and Gordon Lowe were therefore very keen that they be consulted separately as joint chairs of the Scotland and Northern Ireland Haemophilia Centre Directors Organisation! On this occasion I think it is fair enough that I send them a separate copy of the Interim Guidance once you have further amended it. However, I would be reluctant to sign up to a separate consultation process in perpetuity, given that at least in name they are meant to be a UK organisation. Grateful therefore if I could have
sight of the revised Interim Guidance as soon as possible.

2. As far as the draft framework document is concerned, I would prefer to share it with them once section 2.59 has been amended to replace "risk" with "contactable" group. I would therefore be very grateful if Philippa could forward this to me once that, and any other relevant amendments have been made, for onward transmission to Scottish Haemophilia Directors.

Regards,

Aileen

CJD 6317

file: CSD Incidents Panel, Blood + Blood products.

Philippa Edwards
24/07/2001 09:53

Sent by: Philippa Edwards/PH6

To: Alan Harvey/PH6/DOH/GB@GRO-C
cc: Nicky Connor/PH6/DOH/GB@GRO-C
Peter Bennett/EOR4/DOH/GB
Claire Mills/PH1/DOH/GB

Subject: CJD Incident Panel Framework document

Alan

Just a note to put on the record the outcome of discussions with EOR in response to criticisms made of the framework document from MSBT. The key points are as follows:-

1. The risk assessment for surgical procedures in the framework document is based on the EOR risk assessment which has been endorsed by SEAC and very thoroughly considered by relevant experts on the CJD Incidents Panel.
2. The risk assessment for blood components (whole blood, red cells, plasma) is relatively simple and goes in parallel with the risk assessment by EOR on the effect of recipients of these components giving blood donations.
3. In conrast, the risk assessment for plasma derivatives is new. DNV carried out a risk assessment for some of these products but the analysis was not very clearly presented and was also incomplete. The CSM have also carried out an analysis but this was qualitative, rather than the quantitative analysis required for the Panel and was also carried out under the restrictions of the Medicines Act.
4. The orginal risk assessment was prepared at short notice by Nicky and Pat Hewitt from the Panel under pressure from above, rather as an add-on. It was accepted without comment by the Panel but subsequently challenged when a sub-group of the Panel attempted to use it to assess the risks in individual incidents.
5. A revised risk assessment prepared by myself and Don Jeffries was similarly accepted by the Panel and the ACDP/SEAC JWG with little comment. It has subsequently been challenged by members of the MSBT, who have expertise in this area than any of those who developed or previously approved the risk assessment. Some of the criticisms raised MSBT are obviously valid and arise from a lack of understanding, by those who developed and approved the risk assessment, of the processes involved in the production of plasma derivatives. Other criticisms reflect differences in expert interpretation of experimental data, some of which is new.
6. EOR consider that they do not have the expertise required to endorse or revise the current risk assessment for plasma derivatives included in the Panel framework document.
7. The areas under dispute could change the categorisation of some recipients of plasma derivatives, including haemophiliacs, to remove them from the "contactable risk".
8. I am concerned that the CJD Incidents Panel is reaching conclusions that are outside its area of expertise and are not sufficiently supported by analysis of the experimental data by relevant experts. There are also areas where expert opinion may differ and this needs to be thoroughly thrashed out.
9. The Panel has been specifically asked for advice on the management of patients who were treated with products known to have been prepared from plasma pools containing a donation from a donor who subsequently developed CJD.

The areas of concern were - orthopaedic surgery

dental surgery
endoscopy

10. Advice has been provided only in relation to orthopaedic surgery, as this is independent of the final conclusion on the risk category for the recipients of the plasma products of concern.

11. In the absence of advice, the treatment of recipients of possibly contaminated plasma derivatives is highly variable.

12. We agreed that it you would propose to DCMO that the risk assessment for plasma derivatives should be deleted from the draft framework document to allow time for discussion with a group of the relevant experts.

13. I agreed to propose the same action to the Chairman and Deputy Chairman of the CJD Incidents Panel.

14. Discussions with patient interest groups would be deferred until after the risk assessment was on a more solid base.

15. The meeting to discuss the mechanisms for investigating and management of incidents would proceed in the meantime as planned.

16. We agreed that the submission to obtain approval to proceed with arrangements for the public consultation of the framework document and for the publicity campaign proposed by the Panel should be prepared separately form the submission proposed on the issue of plasma derivatives.

17. I would be grateful if you could forward this e-mail to Charles Lister if you are in agreement with the proposals.

Pip