Note of the meeting to review management and communication strategies:
vCJD and plasma derivatives

Wednesday June 9th, Skipton House

Chair: Dr Ailsa Wight, Department of Health

Attendees

Ed Davis	DH
Carole Fry	DH
Nathan Moore	DH/MHRA
David Daley	DH COMMS
Noel Gill	HPA-CDSC
Angie Bone	HPA-CDSC
Nicky Connor	HPA-CDSC
Mike Painter	HPA/CJDIP
Anna Molesworth	HPA-CDSC
Emily Collins	HPA-COMMS
Helena Janecek	HPA-CDSC
Katie Oakley	HPA-CDSC
Frank Hill	UKHCDO (Chair)
Hester Ward	NCJDSU/SCIEH
Peter Christie	SEHD
Jane Martin	BPL
Rakesh Vasishtha	NBS
Alan Slopecki	NBA(NBS)
Mark Turner	SNBTS
Matthew Helbert	PIA
Geoff Ridgway	ACDP WG (Chair endoscopy sub-group)
Don Jeffries	ACDP TSE WG (Chair)

1. Introductions/overview
The background to the meeting was the assessment of the risk to recipients of blood products from donors who had subsequently gone on to develop vCJD, following on from the announcement in December 03 about risk to recipients of whole blood.

In particular, there were key implications for the individual patient management, for the management of public health risk for haemophiliacs and primary immunodeficiency patients, and for management of surgical instruments, particularly endoscopes, used on these groups of patients.

The risk assessment looked at blood donations from 9 donors who had subsequently developed vCJD. These donations resulted in 176 derived blood products. These were Factor XIII/IX;antithrombin, intravenous

immunglobulin G; albumin; normal immunoglobulin and Anti-D. Each of these products was categorised according to risk of infection: high, medium, low-medium and low, although it may have been better expressed as the number of doses needed to exceed the theoretical threshold for the study – the recipient had a 1% or greater chance of being infected.

The risk assessment had taken an extremely precautionary approach as agreed by the panel previously, and the meeting accepted the limitations of the assessment as well as the summary of risk.

No further sensitivity study had been done apart from the original DNV study.

Although shelf life of the products might remove some of them from use, the problem would remain as future donors who cannot be screened for vCJD at time of donation might still go on to develop vCJD.

Numbers of people were not available for all the different categories of recipients, but approximate numbers of patient who were ~~particularly~~ potentially at risk as a recipient of implicated blood products were:

Haemophiliacs	~ 2500
PID patients	~ 200

Other patients potentially at risk from the medium/low-medium products needed to be born in mind – for example plasma exchange patients could use 5 litres at a time.

Haemophiliacs

Discussion centred on the merits of an individual risk assessment as set out by the panel. Haemophiliacs are a particular group with a high usage of blood products, who are used to receiving sensitive information about risk, for example in relation to developing HIV or Hepatitis C for example.

It would therefore be desirable to inform all patients with clotting disorders that they may be at additional risk of vCJD because they may have been exposed to infection even though they may not have received product identified in the current batch as they receive repeated frequent treatment with product.

Discussion therefore centred on whether all haemophiliacs should be considered 'at-risk' patients in terms of management of the public health risks or whether patients should only be considered at-risk where the implicated batches had been traced to the patient.

It was agreed that the proposed strategy should be to notify all haemophiliacs, via the treatment centres, that they may be potentially at risk of vCJD, and to set in place a careful counselling strategy on the implications of this. All patients who were assessed to be at additional risk because they had received implicated batches would be counselled and the public health risk managed accordingly ie they would be treated as an at-risk patient for a surgical or endoscopic procedure

The meeting acknowledged the potential risk associated with this strategy – that there could be transmission of vCJD to subsequent patients following surgery or endoscopy from a patient who may have received implicated products, though not currently identified as such.

It was agreed that if the number of haemophiliacs who were traced as receiving implicated batches was more than 90% of all haemophiliacs, there may need to be urgent reconsideration of classifying all haemophiliacs as at-risk patients for surgical or endoscopic procedures.

PID patients
This is a smaller group of patients (~200) who are also treated at dedicated centres. They also receive fractionated blood products that may carry a reduced risk **[DN – can we clarify this? How much is the risk reduced?]**.

It was considered that most patients would not have received sufficient products to put them at risk. A best-guesstimate was that ~50 patients in this group may have received sufficient implicated products to put them at-risk.

The meeting agreed that in terms of pubic health risk, PID patients would be treated on an individual risk-assessment basis.

Other patients
It was agreed that other patients, such as secondary immunodeficiency and plasma exchange patients, might have had sufficient exposure to implicated batches to put them at-risk. The numbers were very uncertain **[DN – but could be of the order of?]**

There was considerable doubt around the feasibility of tracing implicated products to these patients as product would often have been dispersed in a pharmacy to wards with limited record keeping, apart from particular groups like plasma exchange patients. There were also complications in that during the period 1987-98, some NHS centres acted as wholesale dealers for blood products to the NHS, which would make traceability extremely resource intensive.

It was agreed that the NHS should be asked to make every effort to trace these products where possible to patients. BPL would be able to quickly provide distribution information down to pharmacy level.

Endoscopy
The meeting acknowledged particular concern over possible iatrogenic transmission of vCJD following endoscopy procedures for haemophiliacs and PID patients. It was establishes that both these groups often underwent endoscopy, and sometimes biopsy.

Current guidance for endoscopes following their use on patients who are at high-risk of subsequently developing vCJD is that they should be quarantined.

The agreement at the meeting that endoscopy for haemophiliacs should continue to use the individual risk assessment path prior to endoscopy – an 'umbrella' at-risk category for ~2500 haemophiliacs would quickly take out of use a large number of endoscopes. PID patients would continue with individual risk assessments prior to endoscopy.

The forthcoming meeting on 22 June of the Endoscopy sub-group of the ACDP would consider these issues further.

Communications
A clear communications strategy needed to accompany next stage – ie detailed individual risk assessment. DH would need to clear with Ministers any dissemination of information.

It was agreed that there should be a transparent communication exercise for any member of the public to have access to information about the risk assessment associated with blood products.

In addition, some blood products from UK went abroad (including countries outside of EU). Europe and FCO would be notified of the potential risk, and BPL would provide as much information as possible to assist with traceability.

Actions

- Submission to ministers to update handling of key risk group patients and the associated risks of this strategy (**DH policy**)
- Communication strategy with haemophiliac and PID groups to inform firstly clinicians and secondly via the clinicians, patients of risks and current actions (**HPA/UKHCDO/PIA/DH COMMS**)
- Communication strategy to NHS Trusts (via Medical Directors) to trace implicated blood products for all patients where possible (**HPA/NBA/NBS/DH COMMS**)
- Notify Europe and FCO on implicated products sent abroad (**HPA/NBA/NBS/FCO/DH COMMS**)
- Endoscopy working group to review recommendations following the outcomes of this meeting – June 22.