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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 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 VIII/IX;antithrombin, intravenous

immunglobulin G; albumin; intramuscular 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 having 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 the limited shelf life of the products had removed some of them from use, the problem would remain as donors, who cannot be screened for vCJD, may still go on to develop vCJD.

Numbers of people affected were not available for the different categories of patient, but approximate numbers of patients who were potentially at additional risk of vCJD as a recipient of implicated blood products were estimated to be:

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 2.5 litres at a time and may have 10 exchanges over a couple of weeks.

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 have in the past received sensitive information about risk, for example, in relation to developing HIV or Hepatitis C.

The UKHCDO proposed informing all patients with clotting disorders who had received UK sourced products between 1980 and 1988 that they may be at additional risk of vCJD because they may have been exposed to infection, even though they may not have received products currently known to be implicated.

Discussion centred on whether this wider group of 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 if they have received UK sourced products in the specified time period. Advice and support would be given to all patients who are assessed to be at additional risk because they have received implicated batches. The public health risk

would be 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 a large percentage of haemophiliacs are traced as receiving implicated batches and are placed in the 'at risk' group, then this strategy should be reconsidered.

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; this group of patients will need to receive several doses in order to fall into the 'at risk' group.

It was considered that most patients would not have received sufficient implicated products to put them at additional risk of vCJD. A best-guesstimate was that fewer than 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.

There was considerable doubt around the feasibility of tracing implicated products to these patients as products would often have been distributed by pharmacies 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 NBS centres acted as distributors for blood products to the NHS, which would make traceability extremely resource intensive.

It was agreed that the NBS 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 for products where NBS was not the consignee.

There would also be a communication strategy to NHS Trusts (via Medical Directors) to trace implicated blood products for all patients where possible.

Endoscopy
The meeting acknowledged particular concern over possible iatrogenic transmission of vCJD following endoscopy procedures for haemophiliacs and

PID patients. It was established that both these groups often underwent endoscopy, and sometimes biopsy. It was estimated that PID patients might have a biopsy approximately once in every three patient years.

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

It was agreed that endoscopy for haemophiliacs should continue to use the individual risk assessment path prior to endoscopy asan 'umbrella' at-risk category for ~2500 haemophiliacs could have a greater effect on the availability 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 the next stage – ie detailed individual risk assessment. DH would need to clear with Ministers the notification strategy outlined above.

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.

Position paper: biopsy/non-biopsy risk assessment for haemophiliac and Primary Immunodeficiency Disease patients

Background

- Meeting of 9 June looked at risk assessment of blood plasma products
- Haemophiliacs and PID patients were identified as key groups potentially affected by the risk assessment outcomes
- Risk of patient-to-patient transmission of vCJD following surgery or endoscopy among these risk groups was reviewed
- Haemophiliacs and PID patients do routinely undergo gastro-intestinal tract endoscopic procedures

Outcome of the blood plasma risk assessment

- UKHCDO proposed informing all patients with clotting disorders who had received UK sourced products between 1980 and 1988 that they may be at additional risk of vCJD because they may have been exposed to infection
- It was agreed that endoscopy for haemophiliacs should continue to use the individual risk assessment path prior to endoscopy, as an umbrella at-risk category for ~2500 haemophiliacs could have a profound affect on the availability of gastro-intestinal endoscopes.
- PID patients (~250) would not generally be exposed to the hig-risk blood plasma products would continue with individual risk assessments prior to endoscopy. The 9 June meeting considered that tracing implicated blood plasma products to PID patients might identify around 50 patients who would needed to be treated as 'at-risk'.
- Haemophiliacs who are assessed to be at additional risk because they have received implicated batches would then be treated as an 'at-risk' patient for a surgical or endoscopic procedure.

Issue

- Unless haemophiliacs have been identified as specifically receiving an implicated blood product, they are not treated as an 'at-risk' patient for endoscopy.
- There is a risk attached to this. As they routinely receive blood products that are in a 'high risk' category from the blood plasma risk assessment, they may well have been exposed to implicated blood.

Proposal

- Haemophiliacs will not be treated as high risk patients unless they are known to have received implicated blood products. The proposal is that there is a differentiation of endoscopic procedures between those with biopsy, and those without.

    - If endoscopic biopsy is carried out on a haemophiliac, this should be considered a 'high-risk' procedure and current guidelines on quarantine should be followed.
    - If routine endoscopy is carried out, the 'scope does not need to be quarantined.