Minutes of meeting of Panel subgroup held on 21st April 2004 at the Royal Society of Medicine, London, to discuss three incidents involving patients 'at risk': PI 07, PI 259 and PI 262

Present

CJD Incidents Panel
Mr John Barker
Dr Gerry Bryant
Ms Patricia Cattini
Dr Pat Hewitt
Professor James Ironside
Professor Don Jeffries
Professor John Lumley
Dr Mike Painter (Chair)
Dr Geoff Ridgway
Dr Hester Ward

Visitor
Dr Geoffrey Thould

Health Protection Agency
Dr Nicky Connor
Professor Noel Gill
Ms Helen Janecek
Ms Katie Oakley

Apologies
Dr Roland Salmon

PI 07

Background

Dr Thould presented this incident to the subgroup. Following the death of a 45 year old man with suspected CJD in 1998, a diagnosis of vCJD was confirmed. An appendicectomy had been performed in 1995 and tissue samples from that time tested positive for abnormal prion protein. The local manual surgical instrument tracking system would enable the first 10 patients on whom the appendicectomy set had been used to be traced ('the 10 patients'). However, it was not possible to identify any patients who might have been exposed as a result of potential cross-contamination during the decontamination process.

The initial advice from SEAC and the then SEAC/ACDP Joint Working Group on TSEs was that nothing need be done. The Department of Health suggested a flagging exercise involving the 10 patients so as to enable any deaths from vCJD to be traced back to this incident as part of a formal scientific study. However, the LREC refused approval for the study on the grounds that it would be unethical to conduct it without obtaining the consent of the 10 patients. The Department of Health therefore requested that the NHS Trust identify the 10 patients and keep their personal details confidentially and securely.

In the light of the recently reported possible case of vCJD transmission by blood donation, Dr Thould, the local CCDC, had written to the Panel requesting advice as to whether or not any further action now needed to be taken in respect of the 10 patients.

Discussion

Dr Thould reported that the 10 patients could be identified sequentially ie in the order on which they had been operated on following the appendicectomy on the index patient. It would be possible to identify the first two patients.

Panel members accepted that there would be some migration of instruments between sets, and that only a few of the instruments would have been exposed to medium risk tissue. Panel members agreed that identifying patients exposed to the implicated instrument set was sufficient, and that it was neither necessary nor possible to identify who had been exposed to a particular instrument.

Panel members agreed that it is unlikely that, under wet conditions during decontamination processes, the abnormal prion protein would cross-contaminate other instruments.

Panel members agreed that instrument trays are unlikely to pose a risk of transmitting vCJD and, in addition, are lined with disposable material.

Advice

Panel members advised that the first two of the 10 patients to be operated on should be informed about their exposure and the possible risk of developing vCJD. They should be advised not to donate blood, organs or tissues. They should also inform their doctors in order that infection control measures could be taken should they require surgery. This was consistent with previous Panel advice in relation to surgery on medium risk tissue.

Dr Thould reported that there was considerable local concern about the impact on the two individuals and asked whether it would be possible for public health measures to be taken without their knowledge. The subgroup advised that both the Panel and the National Blood Service consider that this could be unethical and that this was not Panel policy. The National Blood Service (NBS) is no longer able to discard donated blood without informing the donor about the reason. It could be considered to be assault if the NBS discarded blood donations from individuals without their knowledge.

The NHS Trust was also concerned about holding the personal details of the 10 patients in contravention of the GMC guidance. They were advised to pass the names of the remaining eight patients to their health protection team to hold locally, since the HPA is licensed to do so by the Patient Information Advisory Group under section 60 of the Health and Social Care Act 2001.

It was agreed that the Panel's advice should be couched positively, commending the local arrangements for tracking surgical instruments, and recommending that the two individuals to be contacted receive appropriate support at local level, including counselling if necessary. The HPA CDSC team are available to support local teams, and can provide literature as well as access to expert support for health professionals.

PI 259 and PI 262

Background

Dr Connor introduced these two recently reported incidents, both of which involved contact with medium and high risk tissues in 'at risk' patients, and where the surgical instruments could be traced:

PI 259: a recipient of blood donated by an individual who subsequently developed vCJD underwent cataract surgery between receiving the implicated blood transfusion and being placed in an 'at risk' group

PI 262: a recipient of human growth hormone considered at high risk for iatrogenic CJD underwent neurosurgery without special precautions being taken.

Issues for consideration

In both cases, Panel members were asked to consider whether patients subsequently operated on should be contacted, with a view to developing general principles to guide advice in future incidents involving 'at risk' patients. In the past, the Panel had not focussed on these general principles as such, since the detailed facts of particular incidents had warranted pragmatic decisions not to contact potentially exposed patients, for example, because it was not possible to trace the instruments used. However, the fact that the instruments used could be traced in relation to both incidents provided an opportunity to think through the implications of the Panel advice to be given.

Relevant factors to be taken into consideration included:

- The relatively high number (potentialy several hundred) of individuals likely to be put into an 'at risk' category as a result of the forthcoming patient notifications in relation to the receipt of implicated plasma products. This, potentially, would have a knock-on effect on the number of patients subsequently operated on who would need to be contacted. Does the increased risk of developing vCJD warrant notification of this large group of individuals?
- The possible need to quarantine surgical instruments which had been used on medium and high risk tissue in 'at risk' patients.
- The possible requirement for local teams to obtain the past surgical histories of 'at risk' patients.

In summary, the issue was whether the Panel subgroup could provide advice both specific to these two incidents and as broad principles for incidents involving individuals 'at risk' of CJD.

Discussion

There were a number of factors with uncertain consequences which made it difficult to extract general guiding principles for Panel advice at this stage:

- A dilution effect pertains to these 'contacts of contacts'.
- The need for more modelling in relation to a dilution effect for vCJD.
- The timing of surgery in relation to exposure of the 'at risk' patient, for example, following an implicated blood transfusion.
- The degree of risk posed by individual batches of blood components.
- The likelihood of the index patient developing CJD.
- Given the current lack of approval for a database of the 'primary' group of contactable patients, it was unlikely for a database of a 'secondary' group of contactable patients to be approved in the near future.

Advice

Panel members advised that there was no need to contact the exposed patients and that there was no need to quarantine the instruments.

PI 259

Panel members asked that further information should be sought concerning the use of disposable tips for the instruments.

PI 262

Panel members noted that, of 1900 patients who had received implicated human growth hormone, over 40 had died from CJD, the longest incubation period being 13 years. The risk of the index patient developing CJD is therefore small. Panel members therefore advised that the patients subsequently operated on should not be contacted, but that a information be retained locally. Those instruments that were traceable locally had already been quarantined and were to be sent for research. Panel members did not seek to change this local decision.

Panel members recognised that patients at risk of familial forms of CJD were at a higher risk of developing CJD. The subgroup did not agree whether patients exposed to instruments used on these 'at risk' patients should ever be contacted.

Next steps

It was agreed that general principles were needed to guide the informing of patients and subsequent actions for the forthcoming notification of recipients of implicated plasma products. Therefore Dr Connor would prepare a paper for the Panel outlining the form these might take, circulating a draft to the subgroup for their comments within the next few days.