CJD INCIDENTS PANEL

BPL's COMMENTS ON:

"Management of possible exposure to CJD through medical procedures
A consultation paper"

1. General comments

Then overall approach proposed appears, in general, to be scientifically and ethically sound. However, we need to safeguard the interests of individuals and the general public without being too alarmist.

In some instances, the distinction between maintaining the current health of the individual patient and protecting the general public in the future has been misplaced in this very uncertain situation. To initiate a programme which could put many patients under undue stress is not in their best interests and is likely to have to be diluted in the future after damage has been done.

2. Specific questions raised

Q1 Do you agree with our proposals for investigating and managing incidents?

A1 The idea is laudable, the implementation may be difficult, but others closer to the action would be more able to confirm or otherwise the practicalities. The main issue for me is the time interval between the intervention and the diagnosis of clinical disease and the traceability of instruments and patients.

Q2 Do you agree with our proposal that the instruments used on infective tissues of patients who later develop CJD may continue to be used if they are judged to have undergone a sufficient number of cycles of use and decontamination?

A2 This proposal seems to adequately balance possible risk against cost. It is probable that with the likely time between intervention and diagnosis of the index case, a long interval would have passed and all instruments would have been subjected to the recommended number of cycles of washing and decontamination.

Q3 Do you agree with our proposal that instruments that have not undergone a sufficient number of cycles of use and decontamination, should be permanently removed from use (either destroyed or used for research)?

A3 Yes. They should be used for research unless there is a good reason for them not to be so used *i.e.* a more positive statement, as implied in 4.6. Do we know the likelihood of different instruments retaining *protein* from tests, for example, which stain for protein? The quality assurance of mechanical cleaning and autoclaving has been challenged recently in the media. A concerted effort must be made to improve that situation, but such a recommendation does not appear anywhere in this report from the CJD Incidents Panel.

Q4 Do you agree with our proposals to reduce the risk of further spread of CJD via surgery and donated blood and organs?

A4 The proposals have a large disadvantage, which outweighs their advantages. Marked psychological trauma will be caused to a significant proportion of the 'exposed' patients. Counselling will help some at the initially, but many will dwell upon the possibility of a future severe disease. They will worry over whether they were the first patient to have the intervention after the index case or the tenth. The fact that they are being told will 'confirm' to them that the risk is real and actual. Trying to assure them that the action is precautionary and the risk theoretical will not wash with the suspicion about science, medicine, government *etc.*

Patients who have interventions abroad will not be included in this database, yet the stringent hygiene decisions suggested in this report by the CJD Incidents Panel will not have been followed. With the publicity around the use of other EU health care systems to reduce the UK waiting lists, this could be a growing problem, even though most operations will still be undertaken in the UK.

Q5 Do you agree with our proposals to contact these exposed patients so that public health actions may be taken to protect others?

A5 As mentioned in 4, above, the recommendations are fraught with difficulties and ongoing health care issues with the 'contactable' group. As individuals, they have the right to 'not know' in this uncertain situation. We cannot offer them any release from their worries in the future, so they will continue to brood over the question about whether they are destined to contract the disease or not. Some of them will feel like 'lepers' of old. Some may not be offered treatments for other conditions in the future because of the extra precautions that need to be assured following the intervention. Therefore, their individual rights will be undermined.

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needs to refer also to Table 9.

Paragraph 4.12 refers to Table 8, which only mentions plasma-derived products, not the "source tissues" mentioned in this paragraph. ~~However, looking~~ at that table emphasises the point in the first paragraph of this answer to question 5. Patients with haemophilia A will be split into two groups: those who have or had a "crude" factor 8 and those who have a "highly purified" factor 8. Likewise, patients receiving intravenous immunoglobulin (IVIG) will be separated as a high risk group, but not all patients receiving IVIG need it lifelong. Some only have a single short course of one day or up to

PTO re "crude" factor 8.

5 days. There are conditions where exposure is between these extremes. If patients receiving a few doses are 'contactable', how much more worried the regular users will be and these are the ones who need the product lifelong and have no alternative management (the primary antibody deficiency group).

Actually, the term "crude" factor 8 is not a recognised description. It could even be interpreted as cryoprecipitate, but it probably means intermediate purity factor 8.

Q6 Do you agree with our proposals not to inform possibly exposed people (except for those in the contactable group) of their possible exposure?

A6 Yes, but as mentioned above (see response to Q5), no possibly exposed persons should be told as a routine procedure.

Q7 Do you agree with our proposals to set up a database to follow up all possible exposed people, with the aim of increasing our knowledge of the risk of transmitting CJD through medical interventions?

A7 Yes. It is crucial to have an ongoing opportunity to understand more. As we really do not have a strong scientific basis for our assumptions, we need to develop a suitable system but not cause harm to anyone in the process.

Q8 Do you agree with our proposal that informed consent should not be sought from individuals before recording their details on the database?

A8 Yes, without doubt.

Q9 Do you agree with our proposal that the database should be publicised so that individuals can find out whether they are on it, and about their possible exposure?

A9 Yes. This is very important so that the exercise is not construed as secretive (although obviously highly confidential). However, the general public must be made aware that anyone who knows they are on or have been on the database may have their life insurance policy weighted against them.

Q10 Do you agree with our proposal that individuals (except for those in the contactable group) should be able to remove their names from the database, without having to find out whether they have been put at risk?

A10 We assume that this means that anyone can ask the database administrator to make sure their name is not there. If this is the interpretation, it is agreed, but we should

extend this to the 'contactable' group, who should not be contacted (see reply to Q5, above). See also the response to question 9 above.

Q11 This seems to be missing.

Q12 Do you agree with our proposal to include people who have received blood components donated by people who later develop CJD, in the contactable group?

A12 This question relates to vCJD. As mentioned above (reply to Q5), there should not be a 'contactable' group. Clearly, such people should be recorded as 'exposed'.

Q13 Do you agree with our proposals to manage people who have received plasma products derived from blood donated by people who later develop CJD?

A13 This question also relates to vCJD. The patients should have the opportunity to decide whether they wish to know or not. This is easier for the regular users such as those with haemophilia A and B and patients with primary antibody deficiency, because the batch records for these diagnostic groups is generally superb. For other patients and other diagnostic groups and products it can be very difficult. This creates a potentially large hole in the data likely to be available to determine whether there is any risk or not. Much effort need to be made to ensure that Trusts, Pharmacies and other users do have a central record of who received which batch of each product. We agree that all recipeints of implicated batches should be entered on the database. In principle, no distinction should be made between those who received different plasma-derived products. We do not know the risk, if any, of any of these products, so to differentiate between them on the basis of uncertain and changing assumptions is not in the best interests of patients. Products will be categorised as 'safe' or 'unsafe' by patients and the media. This risk must be avoided.

Recipients of plasma-derived products should not be divided into two groups of risk as this will alienate some patients and some products. To omit a 'contactable' group and record all patients as 'exposed' would be sufficient. The DNV risk assessment used data which is now regarded as pessimistic. The risk would now appear to be significantly lower. Therefore, to initiate actions based upon aged premises would not be in the best interest of patients.

Paragraphs 5.16-5.18 are sufficiently flexible to allow a logical, scientific approach to taken and to allow the most recent information to direct decisions.

We agree that the use of a single agency, the CJD Incidents Panel, should encourage a consistent approach to the assessment of risk of vCJD transmission by plasma products in the UK. I assume reference to systems outside the UK is not part of the remit of the CJD Incidents Panel.

Paragraph 5.6 is at variance with current activity in which BPL has been told to inform Department of Health in countries where product(s) have been sold even though the shelf-life has expired. The recommendation proposed in 5.6 is preferred.

Q14 Do you agree with our proposals for a national publicity campaign to raise public knowledge and awareness about these risks?

A14 Paragraphs 6.7 to 6.10 agreed.

Q15 Do you agree with our proposals for local publicity campaigns for each incident?

A15 This proposal is better than having a 'contactable' category and would serve as a reasonable substitute without raising undue worries and allowing individuals to ask if they wish to know. The last bullet point in paragraph 6.11 will not achieve the target to which it is aiming. If a person is "especially concerned" after the previous measures, unless the person is not on the database and therefore not affected, the worry will not disappear and may well escalate. Sufficient resources need to be readily available for any such persons, even a specific telephone number, separate from NHS Direct, similar in principle to Alcoholics Anonymous.

Q16 Do you agree with our proposals for enabling concerned individuals to find out about their possible exposures and whether they are on the database.

A16 In principle, yes. The flow chart in Annex 6 only deals with CJD and surgery so needs to be modified to include recipients of blood components and plasma-derived products. As mentioned in the reply to question 9, everyone should be made aware of possible consequences of knowing that they are included on the database.

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