RESTRICTED

FIFTH MEETING OF THE HEPATITIS C LOOK BACK WORKING PARTY : 13 OCTOBER 1995

Note of decisions and actions.

Present

1.1 A list of those attending is attached.

1.2 Apologies were received from Dr Warren.

1.3 The Chairman introduced Mr Nash and Miss Towner who had joined the Secretariat.

Note of last meeting

2.1 There were no comments on the note of the meeting held on 25 May.

Matters arising :

- extension of look back to include DeFIX ? (para 8.1 of minutes)

3.1 The Chairman said that extending the look-back exercise to DeFIX was outside the terms of reference specified by Ministers. The term "blood transfusion" did not include blood products; Ministers would have to be consulted if any extension were proposed. He questioned the logic of extension only to DeFIX, particularly when it would probably be virtually impossible to track down recipients.

3.2 Dr Keel shared that view. The SNBTS medical and scientific committee had discussed the question recently but saw no reason to pick out DeFIX, although the Republic of Ireland had added a second stage to their look-back exercise to test for HCV all recipients of blood products prior to 1991.

3.3 The Chairman said that the Irish decision to extend the exercise had been a political one, taken against medical advice. It was for UK Ministers to decide if they wanted to extend their exercise to other groups, eg those who have had transfusion since the 1960s, or even more widely. The Chairman emphasised that the working group had done what was readily attainable. It was impossible to go through all records, and would be hard to track pre-1991 cases. A commitment had been given at the outset for anyone who was worried to have a test, and this must be upheld. The numbers of requests for test now seemed to be drying up after the

initial flood. Other members agreed it was important for tests to remain available; some requests were still being received.

3.4 Dr Gillon distributed copies of a letter from Ireland giving their figures. Dr Rejman suggested that since the proposed compensation payments were comparatively low and the benefits of treatment might also not be great, these might not outweigh disadvantages such as the effects on insurance. The Irish press release made it clear that, while anyone could ask to be tested, priority was being given to those who had received multiple transfusions.

3.5 It was pointed out that transfusion case numbers were small in comparison with total levels of infection in the community; intravenous drug misusers being the largest single infected group.

3.6 The Chairman summed up that test were available to anyone who requested them, particularly where there had been multiple transfusions. The group did not advocate extending the look back exercise beyond its original remit.

- **meeting with British Liver Trust (para 10 of minutes)**

3.7 Mr Pudlo reported on the meeting on 16 June between DH officials, led by the Chairman, and representatives of the British Liver Trust led by Alison Rogers, the Trust's Director. It was felt to have been a useful meeting, which might be followed by others.

3.8 Research, treatment with alpha interferon and counselling had been among the subject discussed. The Trust had argued that counselling for some groups was inadequate, and also suggested that GP awareness of Hepatitis C was variable. The Department had urged the Trust to co-operate with other groups with shared interests, such as the Haemophilia Society, and had since learnt that that contact had been made.

Updated progress reports from NBA and Territorial Health Departments on look back programme

4.1 . The Secretariat tabled a Paper (Paper 5.4) which attempted to unify the information submitted so far in the form of a matrix table.

England

4.2. Dr Robinson reported that the exercise was proceeding more slowly in London than elsewhere. Some hospitals experienced difficulty in finding records. Not many LBF3 forms had been returned but as laboratories would not be paid until they were this should provide an incentive. Neither had all hospitals returned the LBF1 forms. On balance, however, the exercise was going well and 146 patients had been counselled and tested. Much of the counselling work was falling on GPs

who in turn need to be coached on how to do it.

4. 3. Dr Robinson explained that the transfusion centres were responsible for identifying relevant donations and this information would be obtained to complete the empty cell on the matrix table attributable to England.

4.4 During discussion of the number of recipients still alive, the Chairman noted it was anecdotally reported that 50% of blood recipients die within one to two years after receiving blood, of their underlying disease, but good data on post transfusion survival was not available.

Scotland

4.5 Dr Keel added that she had received some more information from Dr Gillon and updated figures for inclusion in the table would be sent to the Secretariat shortly.

Wales

4.6 Dr Westmoreland reported that the approach of the Blood Transfusion Service in Wales was to find and identify all the recipients before commencing testing and counselling. There had been an element of slippage in progressing the exercise recently due to staff sickness and they had considered bringing in more staff to address this. The Chairman thought that Wales were doing quite well.

Northern Ireland

4.7 Dr Mitchell reported difficulties in summarising the information in the way needed for inclusion in Secretariat's the matrix table. The recent summer holiday period impacted severely on the exercise and not much progress took place. Difficulties were also being experienced in tracing donations, and with funding.

General

4.8 Recognising the need to provide accurate, up to date and uniform information to Ministers, Dr Rejman suggested that the completed matrix table be send to the NBA and the Territorials for checking prior to being submitted to Ministers. He expressed a desire to have the exercise completed within the next couple of months.

Action: NBA and Territorials to provide information to the Secretariat to update and complete each cell in the matrix table. Secretariat to incorporate and refer updated table for checking.

Funding of interferon treatment

5.1 Mr Pudlo reminded the group that at the end of the last parliamentary session Ministers had said that, while they were

not intending to pay compensation to those who had contracted Hep C through blood products, they would look into allegations of problems of patient access to treatment. This had been in response to suggestions that some haemophilia patients were not being given alpha interferon when this was clinically appropriate. Officials were in touch with haemophilia centre directors seeking further information about the nature and extent of any problem. If the working group had any such information officials would welcome it.

5.2 Professor Thomas said that KCW had agreed an algorithm of treatment with providers. This recommended treatment based upon the results of a liver biopsy. A data base was being used. KCW also had an agreed allocation of funding for alpha interferon treatment, but other purchasers were still considering the position. Given the competition for funds, he suggested NHS Executive action might be needed to ease the situation. Professor Zuckerman pointed out that funding was a particular problem because treatment was so expensive.

5.3 The Chairman reiterated Mr Pudlo's request for any relevant information to be sent to him, to enable the Department to deliver on the undertaking Ministers had given to the House.

ACTION - Members to send any relevant information to Mr Pudlo

Testing of stored samples

6.1 Research in Scotland on testing of stored samples not included in the look-back had shown that the number still alive after five years is small, which suggests that it is not worth attempting to do.

6.2 Professor Thomas considered this to be an unique opportunity to see if all patients who are exposed become infected.

6.3 Dr Gillon confirmed that the Scottish experience had shown that if the donation is infected then 100 per cent of recipients become infected.

6.4 The Chairman said that he had asked lawyers for advice and was awaiting their reply.

Indeterminates (paper 5/3)

7.1 Dr Robinson said that despite efforts to be clear in the original instructions on the exercise, there had been inconsistency between centres in whether or not indeterminates had been included. This might be part of the reason for the differences between the results being reported. The NBA wanted try to bring consistency and credibility to the exercise by the inclusion of those indeterminates likely to be true positives. Professor Tedder had estimated that this might add some 10% to existing numbers.

7.2 Dr Robinson said that England had not been funded for PCR testing. They felt there was a gap we were legally obliged to fill, but wanted first to finish the original exercise and then start the additional work about next spring.

7.3 Various views were put forward on the proportion of indeterminates likely to be truly positive.

7.5 The Chairman agreed that consistency was needed - indeterminates seemed to have been included in a all cases in Scotland but only some 2/3rds in England. Serological testing was crucial to case definition, which must be uniform. This was not helped when tests were done in a number of different laboratories. (Dr Mitchell said that in Northern Ireland local testing was confirmed centrally.)

7.6 Dr Zuckerman said that if it were practicable all testing should ideally be carried out by the same reference laboratory at the same time and under the same conditions. The Chairman agreed that, if the group decided that indeterminates should be included in the exercise, the fewer laboratories involved the better.

7.7 There followed discussion on the quality control of the various tests. Dr Robinson stressed that reports must be based on test results at the time of the original testing.

7.8 The group agreed to amend the first sentence of paragraph two of the paper to read "Donors with indeterminate serology that was reported to show a very clear band of 3 + .. ".

7.9 The Chairman summarised the Working Groups view that there was support for including indeterminates, using the criteria proposed by Dr Robinson. This would be a second wave exercise after hospitals had dealt with the first wave.

Research

8.1 Mrs Griffin spoke to paper 5/1, which listed in broad terms the issues that had been identified as priorities for research. RD had met with the Medical Research Council and colleagues involved with the NHS R & D programme to obtain information about current research projects and to co-ordinate future plans. DH had identified modest funds available for research in the area of Hepatitis C, and this would complement MRC funding and NHS funding likely to be directed at research on the effectiveness of treatment.

8.2 Mrs Griffin tabled Paper 5.2, prepared by Dr Julia Heptonstall of the Public Health Laboratory Service, proposing a central national registry of hepatitis C infection.

8.3 Dr Mortimer regarded the setting up of a national register as a fundamental step to take. However, it was necessary to avoid contravening the Data Protection Act.

8.4 The Chairman noted that unless there was positive

consent given by a data subject at the time of collection, researchers may not test the sample for any purpose other than that for which it was collected. The same principle applied to use of data for purposes other than those for which it had been collected.

8.5 Professor Thomas viewed the national register as an opportunity to assess the numbers affected and develop a comprehensive model that allowed researchers to predict the rate of progression of hepatitis C and the consequent cost of providing treatment.

8.6 Professor Zuckerman thought the scientific case for a register was overwhelming.

8.7 Dr Gillon thought it an excellent proposal which he would discuss with colleagues in Scotland. He remained concerned, however, about the issue of consent.

8.8 Dr Mortimer reflected that the amount of information held on the data base and available to researchers will be limited without going back to clinicians.

8.9 The Chairman summed up by saying that the Working Party overwhelmingly supported an archive, which would be given high priority when funding was being considered. He reaffirmed that it would be important to avoid contravention of the Data Protection Act, eg by obtaining consent prospectively. Mrs Griffin said that proposals for research in those areas agreed to be a priority for DH would be taken forward by open competitive tendering.

ACTION - Mrs Griffin to set in hand tendering exercise to commission research on priority issues, and take forward consideration of proposals for an archive.

Number of infected recipients

9.1 Professor Thomas explained the figures for transmission rates he had cited at the last meeting (para 6.2 of note) had been calculated by Dr Adrian Renton. They were based on estimated figures, for non-A, non-B cases over the last 20-30 years. The look back group was looking at a more limited period; the incidence in the population generally was likely to be much higher. A French study showed a 6% rate in all transfused patients. [The French were keen for other countries to carry out checks too.] Professor Thomas would send a copy of the relevant papers to the Secretariat.

ACTION - Professor Thomas to send a copy of paper justifying the estimates of Hepatitis C following blood transfusion to the Secretariat.

Other points arising from experience of the exercise

9.2 Dr Robinson mentioned that the NBA had been asked to

advise on whether the next-of-kin should be informed when infected cases were identified but the individual was not thought suitable for counselling (eg because of their age). The NBA's legal advisors considered their was no medical or legal obligation to take such action, unless a "need to know" existed.

9.3 Dr Robinson also mentioned that some GPs were wanting to invoice the NBA for the role they played in dealing with those identified through the look back exercise.

9.4 Dr Robinson highlighted the need for results of tests to be provided quickly, as subjects could become very anxious in the meantime.

9.5 Dr Gorst said that the exercise had tested various parts of the NHS system. Some had worked well, but others - especially the medical records system in hospitals - had proved very poor. He thought that attention should be drawn to this.

Conclusion of exercise

10.1 The Chairman thanked the working group for their contribution to the exercise. Officials proposed making a report to Ministers when the figures had been tidied up. They would recommend that stored samples which did not relate to previous donations of donors found to be positive since 1991 should not be included, or the exercise extended to DeFIX or to other blood products. It would be important to underline the continued availability of tests to those who asked for one. Officials would also raise with the Executive the problems with medical records which had been encountered.

10.2 The Chairman suggested that the working group would not need to meet again. Any further discussion of the subject would be in the full MSBT, when all members of the working group would be invited to attend for the relevant part of the meeting. He thanked all members of the Group for the excellent contributions they had made to the task given them by Ministers and the despatch with which it had been accomplished.

FIFTH MEETING OF THE HEPATITIS C LOOK BACK WORKING PARTY
13 October 1995

Attendance list

Dr J S Metters (Chair)

Dr J Gillon
Dr D Gorst
Dr E A Robinson
Professor H Thomas
Dr D Westmoreland
Professor J D Williams
Professor A Zuckerman

Dr J Gillon
Dr A Keel
Dr E Mitchell
Dr D Westmoreland

Dr P Mortimer was also present

DH officials

Dr P Doyle
Mrs J Griffin
Mr J Nash
Dr H Nicholas
Mr P Pudlo
Dr A Rejman
Miss A Towner