RESTRICTED - POLICY

NOTES OF DECISIONS AND ACTIONS FROM THE FOURTH MEETING OF

HEPATITIS C LOOK BACK WORKING PARTY

Held 25 May 1995

Present

1.1 A list of those attending is attached.

1.2 Apologies were received from Dr E Mitchell, Professor J D Williams and Mr R Scofield.

Minutes of third meeting

2. Agreed.

Matters arising

3. It was decided that discussion on Professor Zukerman's four points in paragraph 14 of the minutes could be dealt with later in the meeting (see section 9.7).

Reaction to CMO's letter of 3 April

4. Comments had been received but overall were less critical than anticipated.

Progress reports from NBA and Territorial Health Departments on Look Back programme

5.1 Wales (Paper 4/1) reported that the exercise is going well.

5.2 Scotland (Paper 4/2) recorded pressure from haemotologists for extra funding. Many haematologists and GPs had declined to do any counselling and much of the work was falling back on RTCs. All donations had now been traced.

5.3 Northern Ireland tabled a paper outlining their progress to date (Paper 4/3).

5.4 For England (Paper 4/4) Dr Robinson reported on the number of components identified. The NBA still expected to be able to identify 3,000 live recipients from around 11,000 components. There was no evidence so far that the numbers would be higher. Some components had not been traced. Each transfusion centre is

monitoring costs on a quarterly basis but it was early days to estimate workload. The majority of counselling could be done by transfusion centre consultants. Hospitals had raised concerns about interferon funding. Some records were irretrievably lost, eg at Southampton. It was also reported that some GPs in Bristol were not even aware of CMO's letter.

Matters arising from experiance so far, correspondence etc and review of likely completion date.

6.1 Chairman noted a degree of success and suggested that after six months into the exercise it would be right to report back to Ministers. He noted some difficulties in tracing records and the problem of funding interferon and the increases in workload at some haematology departments and at large liver units. The NHS central register accessed via OPCS could be used for cause of death rather that GP or hospital records. The feedback so far had generally indicated that GPs saw the CMO letter as helpful.

Action:

Secretariat to prepare progress report for Ministers.

6.2 Professor Thomas wondered whether the doctors underestimated the transmission rates. Tabled papers (Papers 4/5 and 4/6) suggested UK population infected by blood transfusion may be as many as 40,000. Dr Nicholas asked to see the basis on which these figures were calculated. Professor Thomas agreed to go back to the authors asking for an explanation of the mathematical modelling used.

Action:

Professor Thomas

6.3 Professor Thomas considered that the main issue was how to deliver treatment once patients had been identified and outlined the broad treatment protocol. Interferon treatment would cost about £5,000.

6.4 Chairman recognised that there were implications for both haematology and hepatology departments. Action might be needed but the Look Back Working Party's task was to simply identify the problems. It would then be for Health Departments to decide what needed to be done.

Testing of Stored Samples

7.1 Chairman thanked Dr Gillon and Dr Robinson for their papers (Papers 4/7 and 4/8). Dr Gillon said that it was impossible to separate out and test stored serum samples for the period January 1990 to August 1991 where

donors had not returned. All samples would therefore need to be tested which would be very expensive. The extra cost related to the testing kits rather than staff time. Dr Robinson agreed that the position was the same for the stored samples held at North London Blood Transfusion Centre.

7.2 Chairman said that only North London and Scotland held substantial numbers of samples. Testing in these centres did not offer a level playing field with the rest of the UK. If all the samples were not to be tested, it was necessary to find some other way forward. There were three options which could be put to Ministers:

1. do nothing

2. test all the samples, which was costly for numbers involved, and unfair to other parts of the country

3. Not to test, but to assume in positive patients who had a blood transfusion that the transfusion was the source of the hepatitis C infection.

7.3 Dr Robinson asked whether, if samples were tested, they would be lost or whether they could be returned to the store. Dr Gillon said that depending on sample size, samples could be refreezed, but refreezing would be less secure.

7.4 Dr Keel said SHHD lawyers position was that it would be difficult not to go back and test the samples, despite the cost.

7.5 The Chairman was concerned about the public perception of high cost against a payoff which from the Scottish and North London data seemed remarkably small, and asked members views for a working party position.

7.6 Dr Mortimer advised against testing and pointed to the cost of counselling. Professor Zuckerman agreed that testing all the stored samples was inappropriate. Dr Westmoreland supported this view.

7.7 The Chairman expected DH lawyers to take the same view as SHHD lawyers. The working party needed to offer an alternative way forward. Part of the argument would be the cost of testing all the stored samples against using the £2m plus for other health services.

7.8 The working party discussed whether HCV screening might be offered to anyone who has had a transfusion. Members thought that to announce that testing was available to any blood transfusion recipient who was concerned they might be HCV positive could be very costly for the diagnostic services, although many of those who are concerned may already have gone to their GP and their GP may have done a test.

7.9 It was agreed to discuss this item further when more experience of the Look Back was available.

Action:

Secretariat to inform members.

Other transmission routes

8.1 Dr Keel had received a letter from Dr Ludlam suggesting the Look Back be extended to DeFIX. He also suggested that a pilot study could be undertaken in Scotland. Dr Gillon said that no central records existed to identify those who have had DeFIX in the period prior to 1986 which could involve a huge exercise with potentially little outcome. Many would no longer be under the same consultant. The working party agreed that there was a strong argument against extending Look Back to DeFIX.

8.2 Chairman said that the working party was set up to look at hepatitis C in blood, not organs; the working party had noted other transmissions, eg intravenous drug abuse. There is no data bank for tissue/organ recipients, although it might be possible to obtain information through UKTSSA.

8.3 The working party discussed HCV infection through haemodialysis. Some haemodialysis patients may have been infected through blood transfusion, others through haemodialysis equipment. Professor Zuckerman said that a lot of data existed on haemodialysis. Chairman said that he had received a letter from Dr Walford agreeing that the PHLS should revisit the Rosenheim report and would be discussing method, timetable and involvement of the Royal Colleges. The working party agreed the PHLS initiative was the best way of carrying this forward.

Research

9.1 Professor Zuckerman said that virologists and hepatologists were concerned about the lack of support for research into hepatitis C. Professor Thomas referred to the difficulty of competing with HIV research for funding (research support for hepatitis C research was £300.000 compared with £18m for HIV). It had not been possible before to tell how long those with liver disease through hepatitis C had the infection. The Look Back provided the opportunity to find this out. Instead of treating 100% of patients, clinicians would know which 20% to treat. There is a need to address three or four issues set out in the paper tabled (Paper 4/9).

9.2 Professor Zuckerman added that he wouldn't want this lost in a mass of papers. Wanted to stop passing the buck from one committee to another. Meeting on hepatitis C between British Liver Trust, Childrens Foundation, Wellcome and others misfired badly.

9.3 Chairman stated that in the working party's view this was a unique opportunity to investigate epidemiological questions, routes of transmission, and disease management and treatment. There is a strong case for bringing together a series of research activities on hepatitis C. The Working Party is not a funding body and

not the only DH Committee with an interest in this (Advisory Committee on Hepatitis) but can make recommendations. Put in hierarchy and urge on Minister and ask RDD to pursue. Can't guarantee would be funded.

9.4 Dr Warren suggested that quicker benefits from this than from long-term research with quick pay back on investment.

9.5 It was accepted that a national register be created with archive samples of serum and clot (to allow DNA storage). Joint NBA /PHLS code may be a starting point. Specimens should all be gathered together for series of research exercises. Samples from recipients identified should also be kept at a central venue.

9.6 Chairman reminded members that if the Working Party goes back beyond the Look Back they could be accused of taking on what properly belongs elsewhere.

9.7 Professor Zuckerman said that the first three of his points raised at the previous meeting were covered. Last item - research into new viruses- he tabled a preprint of an article in Lancet (Paper 4/10) ''new'' hepatitis viruses transmitted by blood, products and parenteral routes with a prevalence of 1.2%.

9.8 Mrs Griffin said that there were budgets in DH and NHS for research. RDD would take away to consider what is being considered today.

9.9 Dr Warren said that when looking at issue of transmission to spouses or vertically, it is important that material is systematically collected. This could be important in public health terms.

9.10 The Chairman reminded members that in investigations of sexual transmission there could be problems of consent.

9.11 Dr Gillon offerred to discuss with colleagues in Scotland about cooperation on research between SNBTS and NBA and PHLS. SNBTS may have more history.

9.12 Dr Gorst then spoke about psychological morbidity from Look Back. A lot of anxiety is being created. Opportunity to see if counselling works not to be overlooked. This had possible implications for the BTS.

9.13 The Chairman summarised by saying:

1. research should be included in the report to the MSBT and Ministers

2. the various items should be put into hierarchy

3. the archive was the most important

4. other items follow naturally.

9.14 The Archive itself was not yet a formal proposal. This needed to be prepared.

Action:

1. **Dr Robinson** and **Dr Mortimer** and **Dr Gillan** to prepare a formal proposal on behalf of NBA, PHLS and SNBTS. This proposal should then be passed for consideration onto RDD.

2. Subsidiary items should then be ranked in order of priority and separate proposals should be prepared - **All members.**

British Liver Trust

10. Chairman informed the working party that Alison Rogers, Director of the British Liver Trust, had written to CMO about the Look Back exercise and that a meeting between DH and BLT would be held in June. Chairman would lead the DH contingent.

Any Other Business

11.1 Chairman considered a Letter submitted by Professor Tedder - concerning indeterminates - not all PCR tested. Professor Tedder proposes a way of defining a particular group of indeterminates likely to be truly positive and thereby avoiding testing all indeterminates.

11.2 In Scotland PCR performed on indeterminates since the start, approximately 5 - 6% of the repeatedly reactive samples, were positive.

11.3 This was felt to be an important issue but more information was required on the numbers involved and the costs. Any identified would lead to identification of recipients over and above the 3,000 predicted. Some members were not keen upon this proposed extension since most of the indeterminate positives would not be truly HCV positive and to approach donors to retest them in such circumstances would be causing worry with little benefit.

Action:

Dr Robinson to obtain more information on the numbers and costs involved and to discuss with **Professor Tedder** about feasibility of identifying those indeterminates likely to be true positive.

Date of next meeting

12. It was agreed that the next meeting would be arranged in September on the same day as the meeting of MSBT.

FOURTH MEETING OF HEPATITIS C WORKING PARTY

25 May 1995

Attendance List

Dr Metters (Chairman)

Dr D Gorst
Dr E A Robinson
Prof A Zuckerman
Dr R Warren
Dr J Gillon
Dr D Westmoreland
Professor Howard Thomas

Departmental officials

Mrs J Griffin
Dr H Nicholas
Dr A Rejman
Mr P Pudlo
D E Burrage