

UK Haemophilia Centre Directors

Home Therapy Working Party

Minutes of meeting held in London on Wednesday, 11 October 1978

Present: Sister Maureen Fearn
Dr Charles Forbes
Dr John Stuart
Dr Peter Jones (Chairman)

1½ Matters arising from Minutes of the meeting held in Newcastle,
October 14th 1977.

Funding (item 3): PJ reported that the request for consideration to be given to central funding of research and development by the Haemophilia Society had been reported in the Society Bulletin. It was suggested that the matter be raised again at the Directors meeting in November and a progress report requested. Because of the relatively small size of the Society suggestions of possible link-ups with other charities were made - for instance Action for the Crippled Child, and Charities with an appeal to those interested in disorders of blood clotting (thrombosis).

UKHT Returns 1976 (item 4) Dr Forbes reported that the position in Scotland with regard to delayed development of a home therapy programme because of lack of NHS concentrate remained the same. For reasons as yet unexplained too little AHG concentrate was being produced in Edinburgh, even for Scottish patients.

HT Register (item 6) The question of how to simplify annual returns and registration of patients had been raised at the Reference Centre Directors Meeting and was to be discussed again at the Directors meeting in November.

A.O.B; comparison of work in Centres abroad (item 9b). It was agreed that there was no call at present to attempt to arrange visits to European and other Haemophilia Centres. With the completion of the Employment Study it might prove rational to approach colleagues abroad.

3a Projects PJ presented interim figures for home therapy in the UK in 1977. Three Centres had yet to report.

The returns suggested that, rather than the improvement expected in the use of British AHG concentrate for HT, there had been further erosion with increased use of cryoprecipitate and commercial concentrate. The figures relating to this finding and to the other subjects covered in the returns would be checked again once the remaining Centres had

reported, and correlated with the Oxford returns, before presentation at the November meeting.

JS suggested that a breakdown be made between children and adults in order to see if there was a difference in VIII usage.

PJ reported that some Directors had included GP administered therapy in their returns on HT; this was to be raised in November.

It was pointed out that 22 Directors had specifically mentioned the value of having a nurse as a member of the haemophilia team, and suggested that this be recommended to the DHSS as "official policy". CF said that a recommendation was to be made at the November meeting.

- 3b Prophylaxis MF commented on the poor quality of the returns and stressed the need for a redesigned form. It was agreed that this and the other forms should be redesigned in order to present firm proposals to Miss Spooner to include in the package to be mailed from Oxford relating to 1978.

MF reported interim figures for prophylaxis; 3 Centre Directors were still to report. To date 24 Directors prescribed prophylaxis for 72 patients. JS asked for breakdown by age in the final analysis.

- 3c Low dose therapy. There was considerable discussion on the value of designing a double blind cross-over trial of different VIII concentrates doses. JS had tabled the draft of a paper which, in describing a Birmingham study of 27 severely affected HT patients, showed that a reduction of 32% in the use of concentrate could be achieved without increased morbidity. Doses used had been 9.1 and 6.8 units/kg. Estimated savings in cost would be £27,000/year. Patients had established arthropathy. Duration of study one year, therefore conclusions related to short-term.

In the ensuing discussion the following difficulties in designing a collaborative study were raised:

- an increasing proportion of patients, especially in the younger age group, were on prophylaxis.
- there might be difficulty in obtaining batches of concentrate of specific and appropriate unitage in sufficient volumes for the numbers of patients needed.
- all bottles, of whatever dose, would have to be labelled the same so that patients did not have any clue as to their contents.
- an independent laboratory should be asked to undertake quality control on initial vial unitage and possible deterioration during the period of the trial.
- numbers involved must be sufficient to give good statistical analysis.

It was eventually agreed that a proposal for a collaborative study proceed with the following guidelines:

- two doses (i.e. 250 and 500 i.v. per vial) would be simpler than four (200 and 250 for 'random' bleeds and 400 and 500 for 'bad joint' bleeds) because of numbers of patients.
- if 250 v 500 only adults should be included.
- ethical consideration be sought although it was thought there could be no objection as the optimism dose was unknown and a placebo was not being used.
- attention be directed at the number of bleeds responding to the first treatment, anything else being regarded as a failure.
- patients be matched for age and severity (including prior frequency of haemorrhage).
- 50 patients (52 bleeds a year) would provide approximately 1000 bleeds for each 'arm' of the study. Statistical advice was to be sought (PJ) as to whether this was appropriate for significance.

Finally, PJ was to ask whether the Oxford /St Thomas HT trial had produced any pointers to the effects of differing dosage regimes.

- 3d Long term side effects. CF reported the results of discussions in Glasgow on morbidity monitoring in haemophiliacs. He summarised the possible long term sequelae of concentrate infusions as Beneficial or Adverse: (SEE APPENDIX 1)

After much discussion the following suggestions were made:

- (i) arrangements be made to monitor the blood viscosity and fibrinogen levels of patients on prophylaxis with Factor VIII concentrates.
- (ii) the Glasgow study on the economic aspects of HT be extended to Birmingham & Newcastle. This collaborative study would require the help of a research worker. CF agreed to draw up a specific proposal and suggested protocol for circulation.
- (iii) any scheme for long-term monitoring would be heavily dependent on expertise in immunology.

It was agreed that an immunologist be invited to advise the working party on the subjects of chronic antigenic challenge. CF said that he would suggest a tentative protocol for discussion.

Whatever form the study took arrangements must be made for the deep freeze storage of sera (preferably ← 300) for later analysis.

- 3e NHS Home Therapy Pack PJ reported that he had written to Sir William Maycock about the suggestion for an NHS pack. No reply had been received and Sir William had now retired. There seemed little point in pursuing the matter unless there was a marked improvement in NHS concentrate supply, but PJ would contact the new Director of Elstree for advice.

- 3f Disposal pack for needles MF said that Travenol had produced a prototype single infusion needle disposal pack for comment of the working party.

There was unanimous agreement that the prototype had many faults, and that the simplest way of dealing with the problem of aerosol contamination was to provide a simple, sealable waxed-card or plastic container which, with its used needles, could be placed in the plastic disposal bag recommended previously. PJ was to approach Travenol for further discussion.

- 3g Employment study. Detailed discussion on this study was scheduled for the afternoon.

- 4 PJ Would prepare a report on the Working Party for the Haemophilia Centre Directors November meeting and check its content with CF and JS beforehand.

- 5 A.O.B.

- (a) It was agreed that the returns on HT to the Working Party include factor IX as well as factor VIII.
- (b) CF, JS and MF agreed to make suggestions for new simplified forms for the Directors returns on HT. PJ would distribute examples of the old version.
- (c) The next meeting should be scheduled for February, perhaps in tandem with the Employment group.

Peter Jones October 1978

Long Term Sequellae of Infusion of Concentrates in
Home Therapy and Prophylaxis

BENEFICIAL

Cost: Study of cost/benefit of home therapy.

(a) Reduction of number of bleeds.

Number of admissions.

Number of days in hospital.

Number of outpatient attendances.

Reduction of joint deformity.

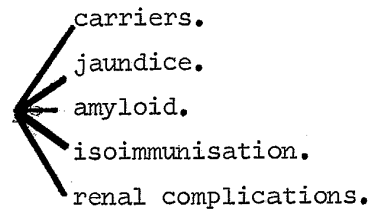
Reduction of mortality.

Cost.

Amount of concentrate used.

Increased attendance at (a) school
(b) work

Psychological factors (?) questionnaire of happiness.

Increase in complications 
carriers.
jaundice.
amyloid.
isoimmunisation.
renal complications.

ADVERSE

Long Term Sequellae of Infusion of Concentrates

LIVER

L.F.T.s (bilirubin, albumin, globulin,
alkaline phosphates, Enzymes (SGOT, SGPT, GT
? B.S.P. retention test.
AuSHAg/Ab

KIDNEY

Proteinuria/Microscopic Haematuria-Addis counts.
Blood urea/creatinine.
Blood pressure.
I.V.P. /Renogram.

SPLEEN

Clinical assessment of splenomegaly.
Straight X-ray abdomen.
Radionuclide scanning.

HAEMOLYSIS

Anti-A/antiB agglutinins.

ISOIMMUNISATION

Red cell antibodies.

FIBRINOGEN LEVELS.

? Associated with accelerated atherosclerosis.

SERUM ANTIBODIES

Gm and Inv screen/Levels of immunoglobulins.

FACTOR VIII/IX Inhibitors.

Sub group already reporting.

THROMBO-embolism

Sub group already reporting.

VEIN PROBLEMS

Inefficient venepunctures by patient.