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INFECTED BLOOD INQUIRY

EXHIBIT WITN3939037

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63

AUSTRALIAN RED CROSS SOCIETY

REPORT OF MEETING OF WORKING PARTY ON FACTORS VIII AND IX CONCENTRATES HELD AT CSL ON 29 JUNE 1984

PRESENT:	Dr P Schiff	CSL (Chairman)
	Dr H Ekert	Royal Children's Hospital
	Dr J Koutts	Westmead Medical Centre, Sydney
	Dr J P Morris	Victorian Division BTS
	Dr K A Rickard	Royal Prince Alfred Hospital, Sydney
	Dr M F Willis	BT Director ARCS NHQ
In Attendance:	Mrs C M Bridgart	ARCS NHQ (Recorder)

1. REPORT OF PREVIOUS MEETING

The Report of the previous meeting held at CSL on Friday 27 May 1983 was approved as a true and correct record of proceedings.

2. BUSINESS ARISING

2.1 Activated Factor IX Concentrate

Dr Schiff explained that since the previous meeting pressure of work at CSL and assignment to other projects of a higher priority has resulted in no further progress on development of an activated Factor IX Concentrate. Dr Rickard voiced concern at the delay. Two further patients with Factor VIII inhibitors presenting for treatment at Royal Prince Alfred Hospital for life-threatening bleeding episodes over the previous 12 months had had to be treated with Autoplex, his previous experience with Prothombinex not having been satisfactory. Dr Rickard's cases were unlike the severe bone and joint bleeding referred to in a paper as being successfully treated with Factor IX concentrates. The same was true of cases successfully treated with Prothrombinex by Dr Ekert. Changes some five years ago to Prothrombinex raised the possibility that the present product differed from that formerly used unsuccessfully by Dr Rickard. He said he might be prepared to evaluate the efficacy of the current Prothrombinex in the case of non life-threatening episodes.

Heparin-free Prothrombinex was discussed. Some had been made for the W.A. Division and New Zealand but group members believed this sort of product should be viewed with extreme caution. Neither Dr Rickard nor Dr Ekert would be prepared to use a Heparin-free Prothrombinex, without first reviewing the existing clinical data. Dr Schiff will attempt to obtain same.

It was suggested that an in vitro comparative study of Autoplex and Prothrombinex be set up, and Dr Koutts believed that the Westmead Medical Centre might be in a position to assist in a testing programme. As CSL products posed no commercial threat to overseas manufacturers, Dr Schiff agreed there was merit in the suggestion that Hyland be asked for data on Autoplex with a view to producing a similar product locally. He undertook to advise the Group of the result of enquiries.

2.2 Current levels of VIII:C production

Dr Schiff reported that during the first eleven months of 1983/8 61,705 litres of plasma had been received for A.H.F. productio compared with 47,929 litres for the whole of 1982/83 and tha concentrate production figures for the same periods were 10.55 million units and 8.453 million units respectively. As his productio figures did not include data for the BTS or for June 1984 he undertoo to circulate full figures to Group members when these becam available. It was not likely that they could be included with th report of the meeting. Although CSL figures included input of FF from NSW from January 1984, Dr Schiff believed that there had stil been a substantial increase over the preceding 12 months perio Unfortunately, there had been larger than usual losses throug contamination, mainly with hepatitis B surface antigen, one of which through a clerical error, resulted in a hepatitis B positive donatio being added to the pool. These losses would cut the total quantit available by about one million units. All screening was done b micro-RPHA or RIA which made the other cases of contamination mor difficult to understand and this was a most worrying development Members were disturbed both because of the loss of Factor VIII fo treatment and also because at an estimated cost to CSL and to th BTS of about 35 cents per unit this was economically unacceptabl The Working Party was advised that because of its claimed hig sensitivity the S.A. and W.A. Divisions were contemplating changin from RIA to an ELISA test.

Dr Ekert understood there to be about 460 haemophiliacs in Victoria o which some 272 received regular treatment. These patients wer treated mainly at the Royal Children's and Alfred Hospitals. Th Victorian BTS was issuing whatever was requested by the clinicians, a an average annual usage of about 1.2 units per head of population. I Rickard said that a paper he had presented to the 1983 ASBT meetin gave an accurate picture of conditions in NSW and asked that a copy b attached to the report of the present meeting as an appendix. A attempt would be made to provide similar statistics for Victoria. Th point was made that probably because treatment from early childhood i one State was the norm, the serious cases presenting to RP/ apparently did not develop in Victoria. It was suggested that th number of elective surgery cases in each State might be an indicatio of this fact.

Unfortunately it was possible that the excellent situation in Victor could change with the retirement of Dr Sawers of the Alfred Hospita should that institution not appoint a haematologist interested i haemophilia. The importance of co-operation between clinician treating haemophilia to achieve optimum FVIII usage was stresse Although the twice presented recommendation on specialist treatmen centres had not been taken up at national level by the NBTC, it bel left to Divisional Directors to liaise with their health authoriti on the most effective use of FVIII, the Working Party considered th a further approach should be made, mainly stressing economic ground It was decided that a recommendation should again go forward to t NBTC, at the same time pointing out the virtues of the UK model haemophilia treatment. Although changes within two, five or ten yea which might be brought about by genetic engineering techniques need to be taken into consideration in the longer term, the prese situation required early action in the interests of economy and f maximum efficiency in the management of patients and utilisation resources.

Form 2
CLEARANCE

2.3 Hepatitis Safe VIII and IX Concentrates

Dr Schiff said CSL was currently evaluating a heat treatment method obtained from the Scottish BTS with a 30 - 40% loss of activity. However, heat treatment of final product claiming losses of only 10 - 15% is being considered and information sought from the manufacturer - Hyland. It was hoped that the situation could be clarified by the beginning of 1985. However, this would still result in less F.VIII being available for ultimate use than at present and more starting plasma would be required to meet the projected VIII:C demand. Although insufficient data was available at present on this aspect it was hoped that research would show that the heat treatment would also affect the non-A, non-B hepatitis viruses which accounted for about two-thirds of the cases of hepatitis in F.VIII concentrate recipients. The retrovirus claimed to be associated with AIDS might also be affected by the heat treatment. Both Dr Ekert and Dr Rickard agreed they had no problem with liver disease, hence they would prefer to have sufficient concentrate for all cases rather than be short of concentrate because of heat treatment. The Working Party was reminded that it had been established to advise the NBTC and if it was considered further thought should be given to the implications of implementing such a process this should be conveyed to that Committee. The BTS Executive Sub-committee had, in fact, urged at its February 1984 meeting that no decision be taken hurriedly by CSL on a matter which would have such far reaching consequences, and that State and Federal Governments should be made aware of the implications should such a decision finally be made.

2.4 AIDS effects on the blood supply

There have been reports of isolation of a retrovirus as a possible causative agent of AIDS and that production of diagnostic reagents is likely in the near future. CSL hoped to obtain some samples of the research material so that an attempt could be made to develop a screening test for AIDS. CSL was making every effort to keep in touch with developments worldwide to obtain early information on possible solutions to the problem, particularly the screening of blood donations and plasma products.

The Victorian BTS reported about a 4% drop in donors during the height of the AIDS scare and it was understood that the NSW service had also suffered a drop in donor numbers. So far no local haemophiliac had contracted AIDS nor had any blood products been implicated in Australia. Thirteen cases of AIDS had been identified in Australia or were under investigation.

2.5 Use of hepatitis B vaccine for haemophiliacs

About 12 months earlier the NH&MRC had issued recommendations on the use of the vaccine and a special working party set up to advise the Federal Minister of Health on priorities for administration of hepatitis B vaccine and responsibility for payment had met a number of times. It had been stated that the vaccine carried no risk of transmitting AIDS as the virus is inactivated by the manufacturing process. It was understood that haemophiliacs without hepatitis B markers would be eligible to receive the vaccine which should be given [illegible] to the patient.

3. ANY OTHER BUSINESS

3.1 Factor VIII Concentrate made at CSL by the CPG method

Dr Rickard reported good response to treatment and excellent in vivo recovery of activity with the F.VIII concentrate made at CSL by the CPG method. The product had now been used several times in case of major surgery and he believed it to be comparable to the material formerly produced in Sydney. The lower yield currently being achieved by CSL was thought to be due to the larger scale of the operation. It was anticipated that with further experience yields would improve. The possibility of a further visit by Dr Margolis to CSL for consultation was being explored.

3.2 Supply of Factor VIII Concentrate (CPG)

Dr Rickard asked whether there was any way in which the scheduling of supplies to NSW could be arranged on a more regular basis. Dr Schiff said he would seek advice on production schedules which might throw light on this matter. He advised that Dr G Woodfield, Director of the Auckland BTS is processing some FFP by the CPG method.

3.3 DDAVP

Drs Ekert and Rickard advised that DDAVP was now available for treatment of haemophiliacs.

3.4 Recombinent DNA and Factor VIII Production

Dr Ekert urged that every effort be made to keep up to date with information on the stage reached in research on recombinent DNA and FVIII production. He believed that the necessary clincial trials here should be carried out through a national body rather than in a single institution. Dr Schiff advised that CSL was already in contact with commercial companies who were active in this field. Dr Ekert mentioned that a Danish medical scientist, presently working at the Royal Children's Hospital, has considerable experience in this area.

3.5 Next Meeting

It was decided not to set any date for the next meeting of the Working Party but it was suggested that between meetings of the Group a summary of any relevant discussions at other meetings should be summarised and circulated to members.

RECOMMENDATION

TREATMENT IN SPECIALIST HAEMOPHILIA CENTRES

The Working Party noted the NBTC's view that it was inappropriate for Re Cross to make official statements on this matter, and that health i primarily a State concern. Nevertheless it feels strongly that the matte of well integrated and co-ordinated management of haemophiliacs has bot clinical and economic implications, and that it should be drawn to th attention of Commonwealth and State health authorities. Factor VIII i this country is an expensive and relatively rare resource, and its use mus be managed as efficiently as possible.

Despite increased efforts in recent years, Australia is still supplying less than 1.5 units of FVIII:C per inhabitant. While supplies in most States appear adequate this is not so in NSW where there is a long waiting list of patients for elective surgery. Current efforts being made to introduce virucidal treatment of VIII preparations, to reduce the risk of hepatities B, will lead to a loss of VIII:C available for therapy. This will further raise costs and reduce the total amount of material available.

The effect of both factors on the health care system is a matter for concern. The inappropriate use of Factor VIII must be minimized, and this can be achieved by treating patients in specialist haemophilia centres. Where this is not feasible it is suggested that the primary care physician consult with the relevant specialist before therapy is prescribed.

THE WORKING PARTY RECOMMENDS that Specialist Haemophilia Centres be established in all States, and that in States where more than one centre looks after such patients, a co-ordinating committee be set up to allocate AHF stocks, particularly when large amounts are required, e.g. surgery, management of inhibitors. This practice works well in the UK, is in line with the World Federation of Haemophilia's policy, and is not seen as an infringement of the rights of either the patient or his doctor.

Attach:

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