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MINUTES

OF THE

ANNUAL MEETING OF THE SCOTLAND AND NORTHERN IRELAND HAEMOPHILIA DIRECTORS, SNBTS DIRECTORS AND SCOTTISH EXECUTIVE HEALTH DEPARTMENT

Held on Friday 14th June 2002
at
Training Room, SNBTS Protein Fractionation Centre,
Ellen's Glen Road, Edinburgh.

PRESENT:	Dr E M Armstrong(Chair)	Dr C Tait	Prof I M Franklin
	Dr J Anderson	Dr A E Thomas	Mr A Macmillan Douglas
	Dr P Cachia	Dr I D Walker	Dr P Clark
	Prof G D O Lowe	Dr H G Watson	Dr P Foster
	Prof C A Ludlam	Dr A Keel	Dr C V Prowse
	Dr L Horn	Dr J Gillon	Miss S J Pelly (Minutes)

APOLOGIES:	Dr E Chalmers	Mr P Taylor	Dr W M McClelland
	Dr W Murray	Dr P Forsyth	Dr S Rawlinson
	Mr R Stock	Dr R Green	Dr M Turner
	Mrs S Falconer	Dr H Hambley	Dr R J Perry
	Ms D Evans		

1. INTRODUCTION

Dr Armstrong, Chief Medical Officer, Scottish Executive opened the meeting and thanked the group for the invitation to attend and chair the meeting.

Apologies were noted from those listed above.

2. MINUTES OF THE PREVIOUS MEETING (13th June 2001)

These refer to the 12th Annual Report of the Coagulation Factor Working Party which should read 13th. With this correction the minutes were accepted as an accurate record.

3. MATTERS ARISING

These were covered on the agenda.

4. COAGULATION FACTOR WORKING PARTY (SCOTLAND AND NORTHERN IRELAND) 14th ANNUAL REPORT

4.1. 14th Annual Report

Professor Ludlam's report had been circulated and he spoke briefly on the topics covered.

Ms Deidre Evans from the National Supplies Division (NSD) had been invited to join the Coagulation Factor Working Party (CFWP) this year t promote links between NSD and the CFWP. She was unable to attend this meeting but was represented by Dr Jack Gillon. Professor Ludlam was open to discussion on the proposals for future changes to the CFWP arrangements.

Professor Ludlam expressed the gratitude of the Haemophilia Directors to SNBTS for supplying product during the shortage of recombinant factor VIII.

Dr Armstrong asked why the use of factor VIII had increased over the past few years and Professor Lowe informed him that although some new haemophiliacs had been diagnosed, the increase was primarily due to the increase in prophylaxis. The benefits of prophylaxis had been uncertain to start with but were now well recognised.

4.2. Appendix on Product Usage

Miss Pelly commented briefly on her paper on product usage. The use of Liberate had risen over the past year primarily due to the shortage of recombinant product.

4.3. Update on SNBTS Product Range

Dr Foster spoke to Dr Perry's report which was tabled at the meeting. He confirmed that the contracts for plasma supply for manufacture of plasma products were currently being reviewed and renewed. Although the situation has become more complex following the takeover of some of the major plasma suppliers by commercial manufacturers, causing a price increase, he was confident SNBTS would continue to obtain sufficient for their requirements.

5. NATIONAL HAEMOPHILIA ACTIVITIES

5.1. UKCDO Database

This database of patient with haemophilia and allied disorders has been in existence for approximately thirty years but has recently come under scrutiny because of the Data Protection Act. The production of anonymised summaries of the data exempts the database from involvement in obtaining patient consent in England and Wales but the legal system is different in Scotland. Professor Ludlam had written to Dr Keel asking if the same system could be operated in Scotland. Dr Keel felt that, in principle, it could but that the issue of patient information was crucial and it should be made clear that they may opt out of the system if they wish to do so. Dr Armstrong emphasised that, in line with the NHS Scotland policy regarding openness of information, all recognised means of communication must be used to fully inform patients about the database and its implications.

5.2. *Haemophilia Alliance*

Professor Ludlam informed the meeting of the publication of the Haemophilia Alliance's detailing a service specification for provision of haemophilia care. He hoped this would be regarded favourably by commissioners and purchasers.

5.3. *UKCDO UK Therapeutics Working Party*

Professor Ludlam had been asked to Chair this Working Party to revise the 1996 Guidelines. The final draft is ready to be sent out for widespread consultation over the summer, with a view to submitting it to the UKCDO Annual General Meeting in September for approval.

5.4. *Audit of Haemophilia Centres*

Professor Lowe has received the last reports on the UK wide comprehensive care centres which include Edinburgh, Glasgow and Belfast. The results will be presented at the UKCDO AGM in September. Trusts may use these results to improve their provision of haemophilia care. The Haemophilia Alliance document will provide the basis for future audits.

A separate audit of all centres in Scotland and Northern Ireland, including non-comprehensive care centres has been carried out. All audits are confidential but each Trust and NSD will receive a report of the findings. The Chair of the UKCDO can take any immediate action deemed necessary as a result of the UK audits. In the case of the Scottish/Northern Ireland centres any action would be taken by Professors Lowe and Ludlam.

As agreed with NSD a two-page questionnaire has been compiled for sending to patients/parents asking for their experiences on changing from plasma derived to recombinant products. Now everyone is back on recombinant product this will be sent out with a view to completing the survey by September.

6. INFORMATION FOR PATIENTS ON CLOTTING FACTOR CONCENTRATES

Mr Macmillan Douglas advised the meeting that although SNBTS products are safe by most standards they are not risk free and SNBTS try to be open about that risk. Patient and prescriber information is currently being piloted for red cell and platelet products but for plasma products it is against the regulations for SNBTS to provide any information other than that approved by the Medicines Control Agency.

Professor Lowe observed that the requirement for additional patient information arose when some patients had to receive Liberate because of the shortage of recombinant. Now all patients are back on recombinant product it is no longer necessary. Dr Armstrong suggested that the Haemophilia Alliance could be approached to write more comprehensive information for patients on all products.

7. vCJD NOTIFICATION STRATEGY

The Incidents Panel is still awaiting further advice from the Committee on Safety of Medicines (CSM), the Spongiform Encephalopathy Advisory Committee (SEAC) and the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT).

Professor Franklin observed that although no decisions have yet been made on notification strategy, everything possible has been done as far as Public Health is concerned.

Professor Ludlam summarised the current situation. All patients in Scotland had been written to following the incident in England and a further letter had been prepared after SNBTS had notified the Haemophilia Directors of incidents involving Scottish products. The Incidents Panel has not issued any advice to date and so far the letter has not been sent. As an increasing number of people are aware of the incidents and it is only a matter of time before patients ask or it gets into the media. The Haemophilia Directors have prepared a press statement on behalf of the Trusts to be used in this situation as a precaution.

Dr Anderson reported particular problems in Belfast with one patient who had been in receipt of the implicated batches needing haemodialysis within the next six to eight weeks and another who had received the BPL batch requiring tonsillectomy. The advice from the Incidents Panel had not been the same as that given to the ENT surgeons.

Dr Armstrong agreed to raise the issue at the meeting of the Chief Medical Officers and put the questions to the Incidents Panel. He felt that an appropriate panel should be convened in Northern Ireland to discuss the haemodialysis issue. Professor Ludlam would highlight the Haemophilia Directors' concerns in a memo to Dr Armstrong and include copies of the letters for patients. He would also send a copy of the results of the UKCDO surveillance survey on tonsils to Dr Ironside.

8. PROTHROMBIN COMPLEX CONCENTRATE (PCC)

8.1. *S/D DEFIX*

Dr Clark reported that the clinical study of this product in warfarin reversal was ongoing but no patients had been recruited to date. The question of whether a three or four-factor prothrombin complex should be used in this indication was raised. Dr Armstrong asked whether the use of DEFIX for warfarin reversal reflected on the clinical usage of warfarin.

Professor Lowe informed him that, each year, 1% of Scottish patients on warfarin therapy experience complications that require reversal. There is a wide variation in treatment for warfarin reversal and it is an area where audit is needed. It can be difficult to regulate anticoagulation with patients being over anticoagulated up to 20% of the time. The mortality of patients in this category is 1 in 400.

8.2. *Four Factor PCC*

Professor Ludlam notified the meeting that there had been three publications in the last year on the efficacy of four-factor concentrates in this indication. The Scottish Intercollegiate Guidelines Network (SIGN) and the British Committee for Standards in Haematology (BCSH) Guidelines recommend a four-factor concentrate. Dr Watson said that although there is a good logical rationale for using a four-factor concentrate there is no hard evidence that it is better than a three-factor one.

Professor Franklin reminded the meeting that DEFIX is the only product licensed for this indication in the UK and Dr Clark pointed out that the Guidelines specifically mention using DEFIX with factor VII if available.

NSD feel it is inappropriate for a four-factor concentrate to be part of the contract so the Haemophilia Directors must now advise their Trusts to buy a four-factor prothrombin complex concentrate to treat patients requiring reversal of anticoagulation.

Professor Ludlam emphasised the importance of SNBTS bringing forward production of a four-factor concentrate as far as possible as evidence was building that a four-factor concentrate is better than a three-factor one.

Dr Foster assured the meeting that SNBTS is aware of the urgency attached to this development and is progressing it as quickly as possible.

9. METHYLENE BLUE TREATED FRESH FROZEN PLASMA (MBT:FFP)

9.1. Availability of MBT:FFP

Dr Prowse reported that for the UK donor product the position is the same as last year and between 4000 and 5000 units can be made available for specific groups of patients.

9.2. Importation of Non-UK Fresh Frozen Plasma (FFP)

SNBTS are investigating sources of non-UK fresh frozen plasma to treat patients born since December 1995. It is intended to leucodeplete and methylene blue treat this plasma and the process is currently under validation. It is likely that this plasma will be available in early 2003. Professor Ludlam enquired whether this meant there would be two types of methylene blue treated plasma available and this was confirmed. He further enquired as to whether there was any intention to move over entirely to imported plasma and Mr Macmillan Douglas explained that the December 1995 date is based on when the UK food chain was deemed 'safe'.

10. LIBERATE®HT

Miss Pelly reported that the clinical trials of Liberate®HT in Poland are on schedule to be completed by the end of 2002. A Product Licence application will then be submitted. The Haemophilia Directors agreed to notify SNBTS if there was likely to be any change in the requirements for product in Scotland.

11. HIPFIX

This product is now licensed.

12. FIBRINOGEN

The study in congenitally deficient patients is ongoing but only one patient has been treated to date. A pilot study in patients with acquired hypofibrinogenaemia has been approved by the Trial Monitoring Committee and will now be submitted for Ethics Committee approval in Lothian.

13. FIBRIN SEALANT

The study in liver surgery in Birmingham has started and is scheduled for completion by the end of 2002. The protocol for a study in Dundee assessing biliary leakage is still under discussion.

14. THROMBOTIC THROMBOCYTOPENIC PURPURA (TTP) SURVEY

An audit of treatment of TTP in Scotland has been initiated. Approximately three quarters of the data from the study comparing cryosupernatant with fresh frozen plasma as the exchange material for treatment of TTP has been collected.

15. ADVERSE EVENTS

Only one adverse event had been reported in the past year, on the Liberate®HT Surveillance Study. It was not product related.

16. AOCB

Professor Ludlam thanked Dr Armstrong for attending and chairing the meeting.

17. DATE OF NEXT MEETING

To be arranged.