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

Held on Tuesday 3rd June 2003
at
Training Room, SNBTS Protein Fractionation Centre,
Ellen's Glen Road, Edinburgh.

PRESENT:	Dr E M Armstrong(Chair)	Dr C Tait	Mr A Macmillan Douglas
	Dr J Anderson	Dr H G Watson	Miss S J Pelly (Minutes)
	Dr P Cachia	Dr A Keel	Dr R J Perry
	Dr E Chalmers	Dr P Clark	Dr C V Prowse
	Prof C A Ludlam	Dr P Foster	

APOLOGIES:	Prof GDO Lowe	Mrs S Falconer	Dr R Green
	Dr AE Thomas	Ms D Evans	Dr H Hambley
	Dr W Murray	Prof IM Franklin	Dr W M McClelland
	Prof ID Walker	Dr P Forsyth	Dr S Rawlinson
	Dr M Mark	Dr G Galea	Dr M Turner
	Mr R Stock		

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 (14th June 2002)

These were accepted as an accurate record.

3. MATTERS ARISING

These were covered on the agenda.

4. COAGULATION FACTOR WORKING PARTY (SCOTLAND AND NORTHERN IRELAND) 15th ANNUAL REPORT

4.1. 15th Annual Report

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

Professor Ludlam reported that the arrangements for supply of recombinant products were working well, however, a small residual demand for plasma derived product was envisaged.

A second virus inactivation step has been added to the SNBTS prothrombin complex concentrate but a four-factor concentrate is the treatment of choice for reversal of oral anticoagulation. SNBTS anticipate this product will be ready for clinical trial early in 2004.

The Haemophilia Directors are interested in the trial of fibrinogen in acquired deficiency and wish to be informed of the results.

4.2. Appendix on Product Usage

Miss Pelly commented briefly on her paper on product usage.

Dr Armstrong enquired about the reported usage 0.5 million IU of commercial high purity plasma derived factor IX. Professor Ludlam explained that he had one patient who proved to be allergic to the recombinant product and the SNBTS product HIPFIX had not been available at the time. Dr Keel pointed out that additional NHS funding is required if the SNBTS product is not used.

4.3. Update on SNBTS Product Range

Dr Perry's report was tabled at the meeting.

5. NATIONAL HAEMOPHILIA ACTIVITIES

5.1. UKHCDO and Local Database

UKHCDO database

There had been considerable discussion last year on the issues surrounding confidentiality and data protection. This has been addressed to the satisfaction of the Data Protection Registrar by the production of leaflets which have been supplied to patients and made freely available in clinics. Patients are now well informed and have the opportunity to raise any issues they have concerning the database. Additional information is now being included, for example, on types of prosthesis used.

Dr Keel asked if any patients had asked for their data to be removed from the database and was informed that they had not. Dr Armstrong enquired what the database had been used for and Professor Ludlam told him that it was now possible to look with greater accuracy at usage of product by severity, inhibitor formation and also at the epidemiology with respect to HIV, HCV etc. It also shows whether there is equity of access to the different types of product.

A summary report is produced each year on the number of haemophiliacs, severity of condition and the amount of concentrates used.

Local databases

These are currently being reviewed to ensure that the data in Scotland is collected and will feed into the UK database. Dr Armstrong raised the point that the idea is to have a national approach to clinical datasets in Scotland with a core set of fields and agreed nomenclature and he hoped that the local databases would ultimately conform to this. Professor Ludlam said he would be delighted to look into this and agreed to contact Dr Marion Bain at ISD to discuss the proposal.

5.2. *Analysis of Scottish and NI data*

Professor Ludlam highlighted that a three-month project with an MSc student is about to start. It is proposed to look back over Scottish usage statistics for approximately 20 years including prophylaxis and immune tolerance. The data will be used to assist with planning and negotiations with the purchasers.

5.3. *Haemophilia Alliance*

The Haemophilia Alliance is an umbrella organisation of stakeholders including the UKHCDO, nurses, physiotherapists etc and patients. They have published a document which sets out what is believed to be a reasonable level of service provision. Dr Armstrong asked whether there was an argument for getting this endorsed by NHS QUIS. Dr Cachia felt that the standard of care in Scotland compared favourably with that specified in the document. Dr Watson pointed out that the definition of Comprehensive Care Centres used in the document might be problematic for some Scottish centres. Professor Ludlam felt that there is a need for the development of management protocols for patients between Comprehensive Care Centres and Haemophilia Centres. All haemophilia patients should have access to comprehensive care.

5.4. *UKCDO Audit*

This audit programme has been ongoing for 13 years and the experience is that the same problems are identified repeatedly over issues which cannot be or have not been resolved. Professor Ludlam explained that these issues tend to be mainly local and are either financial or, for example, problems with parking.

An Audit Working Party has been set up to design an audit tool for Haemophilia Centres as opposed to Comprehensive Care Centres. All Comprehensive Care Centres will have been audited by Spring 2004 and all centres in Scotland by June 2004.

Dr Foster asked about the progress of the questionnaire for patients/parents on their experiences associated with changing from plasma derived to recombinant products. Professor Ludlam agreed to provide the results once they were available.

6. vCJD INCIDENTS PANEL

6.1. Update

The Panel's recommendations were circulated to the four Chief Medical Officers in Autumn 2002 and were considered at a meeting in February 2003. The recommendations had been accepted with the exception of the proposal for a two-tier database of named patients in which one level would be informed they were on it and the others would not. It was agreed at the February meeting to put together a letter of response including all the recommendations except this one, and recommending a full public consultation to be led by the Department of Health.

Mr Macmillan Douglas felt that the issue of notification had been dealt with succinctly in Professor Ludlam's report and the SNBTS perspective had been that the co-operation between SNBTS, the Haemophilia Directors and the Scottish Executive had been excellent. The delay in issuing the report had been a difficult issue that had left us open to media criticism.

The latest draft of the recommendations is due for review and agreement at a meeting on 12th June 2003 and suggests adoption of a stricter risk basis based on cumulative treatment of recipients. The updated draft is more prescriptive and states that patients will be told if they have received an implicated batch of product. Scottish Haemophilia Directors were not aware of this development, although UKHCDO is represented on the Panel.

Dr Cachia pointed out that although the letter sent out by the Haemophilia Directors had been carefully worded not to state whether patients had received implicated batches, all Dundee patients assumed they had. However, the reaction of patients to the letter had varied enormously across the country. Patient opinions also vary widely on how future issues should be handled. There is also the issue of record keeping and the possibility that it may not be possible to determine if patients have received implicated batches.

Professor Ludlam tabled a draft proposal for responding to future notifications of implicated batches prepared by Professor Lowe.

6.2. Future Notification Strategy

Once the recommendations have been finalised by the Panel, SNBTS will produce, in consultation with all involved parties, a Standard Operating Procedure (SOP) for future notifications to allow adoption of a standard approach in Scotland.

7. HEPATITIS

7.1. Scotland and NI project

A group of virologists, haematologists and others interested in hepatology has been formed to gather and pool available information on the treatment of haemophiliacs with Hepatitis C.

7.2. *'Compensation' payments*

American lawyers are attempting to obtain information in support of litigation and patients have been asking for their records. However, records going back that far have proved very patchy and Dr Keel asked for confirmation that patient case notes still exist and have not been destroyed. Dr Watson informed her that some notes appear to be missing but they have not been deliberately destroyed.

7.3. *Treatment*

This was covered under 7.1 above.

8. INFORMATION FOR PATIENTS ON RISK FACTORS ASSOCIATED WITH TRANSFUSION

SNBTS has a policy of transparency in advising patients that transfusion is safe but not zero risk. They are working closely with colleagues in hospitals to provide improved documentation on the risks for both clinicians and patients. This information has been shared with NHSQIS.

Plasma products are not covered, as there is statutory information which SNBTS, as the manufacturer, must supply with the products. SNBTS agreed to explore with the Medicines and Healthcare products Regulatory Agency (MHRA) the possibility of supplying additional information regarding the risks associated with plasma products, in a more patient friendly form.

9. RECOMBINANT VIIa USAGE

9.1. *Patient Groups*

This product has been used successfully to treat inhibitors in haemophiliacs. However it is also being used to treat major haemorrhage in non-haemophiliacs and this has potential major financial and clinical implications. The product is not licensed for this indication. The Haemophilia Directors have put together a protocol, included with the agenda papers, on the extended use of rVIIa, which has been sent to Trust Medical Directors for guidance.

Dr Keel was informed that data on patients receiving rVIIa was being collected by the manufacturer, Novo-Nordisk, in response to her question.

9.2. *Funding*

All commercial clotting factors are now funded with the exception of rVIIa, which is not funded, even for treatment of haemophiliacs. This does not affect all NHS Boards as they do not all have patients requiring treatment with rVIIa. Boards are currently reconsidering risk sharing for haemophilia care.

10. PROTHROMBIN COMPLEX CONCENTRATE (PCC)

10.1. *S/D DEFIX*

Dr Clark reported that the clinical study of this product in warfarin reversal was ongoing. Although recruitment was low some useful lessons had been learned from the study.

10.2. *Four Factor PCC*

Dr Foster reported that the development of the four-factor concentrate was on track for clinical trial early in 2004.

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

11.1. Availability of MBT:FFP

A contract is now in place, for Scotland and Northern Ireland, to import plasma from the USA for patients born after 1st December 1995. Two deliveries have been received to date and the first batch has been processed. A letter will be circulated with definitive dates on when the product will be available for use but the current estimate is July 2003. This letter will include information on levels of coagulation factors in the product. The Health Department has issued a letter to Trust Chief Executives indicating which patients should receive this product (i.e. children born after 31 December 1995).

The SNBTS timescale is similar to that of the National Blood Service (NBS) who aim to have their imported plasma product available by the end of 2003.

Dr Tait enquired whether UK MBT:FFP would be available for treating adults and he was informed that SNBTS is not funded to supply product for this group of patients.

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

This was covered under 11.1 above.

12. LIBERATE®HT

Miss Pelly reported that the clinical trials of Liberate®HT in Poland are complete and the Product Licence application will be submitted within the next couple of weeks.

13. HIPFIX

This double virus inactivated product is not currently being used in Scotland but it completes the SNBTS portfolio of products for external contracts.

14. FIBRINOGEN

The study in congenitally deficient patients is ongoing but only one patient has been treated to date. The pilot study in patients with acquired hypofibrinogenaemia has recently started at Edinburgh Royal Infirmary but, to date, no patients have been recruited.

15. FIBRIN SEALANT

The study in liver surgery in Birmingham is nearly complete. A Product Licence submission is planned for late 2003.

Thrombin is currently being used fairly widely in the treatment of pseudoaneurysms on a Named Patient Basis and SNBTS are continuing to investigate the possibility of conducting a trial to licence it for this indication.

16. THROMBOTIC THROMBOCYTOPENIC PURPURA (TTP) SURVEY and ENSURE (SCIEH)

The Scottish audit of treatment of TTP has proved very successful. It has emerged that SCIEH has an interest in cases of the disease from an infective origin and following discussions with them their survey has now been broadened to include non-infective causes. Dr Prowse asked whether the questionnaire included product used for treatment and Professor Ludlam said he thought it did.

17. ADVERSE EVENTS

No adverse events had been reported during the past year.

The SHOT system deals with reporting of adverse events and 'near misses' associated with components and a well-defined pharmacovigilance system exists for plasma products. It was agreed that internal Trust mechanisms could be reviewed to improve reporting.

18. AOCB

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

19. DATE OF NEXT MEETING

To be arranged.