Jane Many thanks. I've suggested a few minor changes. Should we set a date now for next year?

faxed 16/8.

263

MINUTES

OF THE

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

Held on Monday 14th June 2004
at
Board Room 1, Royal Infirmary, Edinburgh

PRESENT:	Dr E M Armstrong(Chair)	Dr A Keel	Mr KP Thompson
	Dr P Cachia	Dr A Bryson	Dr M Turner
	Dr L Horn	Dr P Foster	Dr C V Prowse
	Prof GDO Lowe	Dr KG Reid	Miss S J Pelly (Minutes)
	Prof C A Ludlam		

APOLOGIES:	Dr J Anderson	Prof ID Walker	Prof IM Franklin
	Dr E Chalmers	Dr H G Watson	Dr R Green
	Dr AE Thomas	Ms D Evans	Dr H Hambley
	Dr W Murray	Mr R Stock	Dr W M McClelland
	Dr C Tait	Dr M McCarthy	Mr P Taylor

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 (3rd June 2003)

These were accepted as an accurate record.

3. MATTERS ARISING

dnsense specific in relation to national/data sets for haemophilia

5.1 Prof Ludlam reported that he had written to Dr Bain but the proposal was a little in advance of what ISD could cope with at present.

5.2 The report on usage data is complete and available. It will be used as part of the basis of an application for future funding.

5.4 Prof Lowe reported that all Comprehensive Care Centres had been audited by the end of 2003 and copies of the findings had been sent to management in

the relevant Trusts. Other Haemophilia Centres had been audited according to a modified protocol.
The results of the patient questionnaire on changing from plasma derived to recombinant products had been circulated.

8 Prof Lowe asked whether SNBTS had pursued the provision of additional information for patients on the risks associated with plasma products with the Medicines and Healthcare products Regulatory Agency (MHRA). SNBTS are looking into the possibility of generic information relating to plasma products in conjunction with NHSQIS and are awaiting feedback.
Prof Lowe would like enhanced information in a patient friendly format for patients with acquired haemophilia. Mr Thompson enquired why patients with acquired haemophilia were treated with plasma derived product rather than recombinant. Prof Ludlam explained that such patients were usually elderly and required large amounts of product. As the risk from known viruses is small it is reasonable to treat these patients with plasma derived product.

4. COAGULATION FACTOR WORKING PARTY (SCOTLAND AND NORTHERN IRELAND) 16th ANNUAL REPORT

4.1. 15th Annual Report

Professor Ludlam's report had been circulated and he spoke briefly on the topics covered. The membership of the group had remained much the same but he welcomed Mr Thompson who had replaced Mr Macmillan Douglas as National Director of SNBTS.

He welcomed the development of a four-factor Prothrombin Complex Concentrate and hoped the clinical trial would be starting in the near future.

He highlighted the items on vCJD and implicated plasma donations and recombinant factor VIIa, but these were both covered on the agenda.

4.2. Appendix on Product Usage

Miss Pelly commented briefly on her paper on product usage and highlighted that the figures for previous years had now been adjusted following the finding last year that issues to Yorkhill had been included in the Glasgow Royal usage.

Dr Keel commented that factor VIII usage is now at 5.71IU per inhabitant and asked how this compares with the EU and USA. Prof Ludlam confirmed that this figure is comparable to other European countries and cited France as an example. Prof Lowe notified the meeting that it was intended to submit a proposal to the Chief Scientist's Office within the next six months for funding for a research assistant to look at the factors affecting usage.

4.3. Update on SNBTS Product Range

Dr Reid spoke to her paper. The product licence application for Liberate®HT had been submitted in July 2003 but the MHRA have only just started the assessment.

A CTX has been granted for the four-factor concentrate and the protocol is in the process of finalisation.

The study of fibrinogen in congenitally deficient patients is ongoing but SNBTS planned to discuss the possibility of a biochemical endpoint for a study in patients with acquired deficiency with the MHRA at a meeting later in the month.

5. vCJD INCIDENTS PANEL

5.1. Update

Dr Keel confirmed that SEHD were working closely with SCIEH and SNBTS to develop a coherent notification strategy.

Professor Ludlam felt that a major issue was how to classify which patients should be placed in the notifiable group. If only patients who have received implicated batches are notified then it is almost inevitable that more batches will be implicated in the future, which will result in additional patients being notified and so on. He was keen for all recipients of British plasma products to be notified as he considers this to be less threatening to those patients who fall into this group. Prof Lowe supported this 'umbrella' approach to treat all patients as high risk as it addresses two additional issues; individual patients desire to know whether they have received an implicated batch and the problem that the data on which patients have received implicated batches may not be complete. Dr Keel sympathised with this view but pointed out it would be preferable to develop a consistent policy and it was clear that the clinicians treating immunodeficient patients were not in favour of this approach. In addition, the issues of calculation of infective dose and traceability are very difficult for some of the other plasma products.

The judgement on approach currently lies with the CJD Incidents Panel and an announcement was anticipated in the first week in July. Dr Keel enquired whether the 'umbrella' approach had been agreed with Haemophilia Directors south of the Border. Prof Ludlam informed her that it had and they would like all patients who had been treated for a hereditary bleeding disorder with a British plasma product since 1980 included. Dr Keel asked if this has been communicated in writing to the Health Protection Agency and Prof Ludlam agreed to contact Dr Hill to suggest this.

The Medical Research Council has funded a UKHCDO study to gather information on patients who have received implicated batches of plasma products. The Department of Health is to take forward a public consultation on the set up of a database of patients who fall into the risk categories.

5.2. Future Notification Strategy for New vCJD Implicated Donations

The protocol agreed by the Coagulation Factor Working Party for adoption in the event of future notifications had been circulated with the agenda papers. Prof Lowe wished it to be recorded formally that this had been discussed at the Annual Meeting. Dr Armstrong commented that it made no mention of SCIEH or the Scottish Health Protection Organisation. Dr Reid responded by observing that the situation was evolving rapidly at present and the protocol would be reviewed once guidance from the Incidents Panel had been published.

press Dr Turner commented that in the past a significant proportion of the communication associated with such notifications had been managed by SNBTS and asked whether the Haemophilia Directors wished this to be the case in future. The Haemophilia Directors confirmed that they did.

6. DATA TRANSFER/RECORDS - CONFIDENTIALITY

Correspondence between Prof Ludlam, Dr Muir and Dr Swainson was circulated. A copy of the information leaflet for haemophilia patients regarding the database had been included with the agenda papers. Prof Ludlam confirmed that, in the main, patients seemed happy with this.

7. HEPATITIS C

7.1. 'Ex gratia' payment scheme

A letter from the SEHD on establishment of the Skipton Fund and the scheme for compensation was tabled at the meeting. Prof Lowe intends to write to all his Hepatitis C positive patients informing them of the scheme.

8. RECOMBINANT VIIa USAGE

8.1. Haemophilia Use

This product is used to treat patient with inhibitors but is not funded through the contract with NSD. Dr Bryson commented that when last asked, the majority of Health Boards did not wish it to be included but this view may change in future.

Dr Armstrong enquired whether inhibitors were a factor in the continuing upward trend in factor VIII usage. The Haemophilia Directors felt this was ~~more~~ likely to be due to a small number of patients requiring high doses to cover ~~orthopaedic surgery~~. Immune tolerance and orthopaedic surgery.

Dr Foster asked if the incidence of inhibitors is recorded on the database and whether this information could be analysed to determine the reason for inhibitor development. Prof Lowe explained that inhibitors are recorded but factors affecting their development, such as a higher risk in some ethnic groups, are not. He pointed out that tolerisation as a treatment for inhibitors had only been introduced in the last five years and this could have affected usage.

8.2. Non-Haemophilia Usage/Audit

Recombinant VIIa ~~is the product of choice~~ may be used for emergency use in severely bleeding patients. Usage at present throughout Scottish hospitals is small but could go up significantly. This could result in considerable expense for Health Boards which is the reason for the questionnaire and audit.

9. FACTOR VIII AND IX USAGE

The present system for data collection is working well with figures available on a monthly basis to SNBTS and NSD. The usage of both factors VIII and IX is within

the predicted limits but the usage of factor VIII is still increasing and the Haemophilia Directors wish to investigate the reasons behind this.

10. PROTHROMBIN COMPLEX CONCENTRATE (PCC)

10.1. Four Factor PCC

This had been covered in Dr Reid's report.

11. FIBRINOGEN

This had been covered in Dr Reid's report.

12. FIBRIN SEALANT

This had been covered in Dr Reid's report.

13. ADVERSE EVENTS

No adverse events had been reported during the past year.

14. AOCB

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

15. DATE OF NEXT MEETING

To be arranged.