LW 12/1/95

MINUTES OF THE WORKING GROUP FOR THE REPORTING OF SERIOUS HAZARDS FOLLOWING TRANSFUSION

The first meeting of the group was held at Watford NBA Headquarters on the 21st December 1994.

Present:
Dr E Love
Dr T Napier
Dr D Norfolk
Dr A Robinson
Dr P Skacel
Dr A Todd
Professsor A Waters
Dr L Williamson

Apologies: Professor J Cash

ACTION

1. Appointment of Chair and Secretary

Chair - Dr L Williamson
Secretary - Dr E Love

2. Composition and remit of Group

2.1 Dr Robinson outlined possible reporting arrangements for the group which she had discussed with Dr Wagstaff but not yet with Professor Cash. The group should be independent of the National Blood Authority and should report to the Standing Advisory Committee to the "Red Book" guidelines.

Whether the group should be a sub-committee of the Transfusion Transmitted Infections SAC or separate had not been decided but further discussion favoured a separate group.

2.2 Remit of the Group

1. To produce recommendations for the reporting of serious complications. This will require a definition of what is a serious complication and will involve the design of a system for reporting.

2. To educate in the field of hazards of transfusion in order that reporting should be as comprehensive as possible. There was some discussion as to how this could take place but a BMJ editorial or publicity via the Royal Colleges could precede the "launch" of the reporting sytem.

Professor Waters notified the group of a pilot study which he is to undertake on the audit of documentation of transfusion and adverse reactions. This study is the outcome of a College of Physicians Research Unit workshop on the audit of transfusion practice which took place earlier.

ACTION

Whilst audit of transfusion practice is essential the remit of the Serious Hazards of Transfusion (SHT) group, should focus on the incidence of complications whilst Professor Water's audit continues in parallel and will provide valuable information.

The group concluded that a number of mechanisms will be required to disseminate awareness of the hazards of transfusion and the necessity to report them.

2.2.3 Composition of the Group

A micro biology representative would be valuable and it was suggested that Philip Mortimer should be invited. Dr Williamson will write to Dr Mortimer. LW

Northern Ireland is currently not represented on the group and Dr Williamson will write to Maurice McClelland for his views on representation. LW

Other representatives may be invited when the tasks of the group have been more clearly defined.

3. Practice in Other Countries

Dr Robinson is attempting to obtain details of the FDA reporting system used in the USA. The current FDA style reporting system is considered cumbersome and Dr Kay Sazama is redesigning a more "user friendly" system. AR

It was not known whether the French Haemovigilance System has been launched but this will be a very extensive mandatory reporting arrangement with indefinite storage of patients samples, compulsory follow up of patients at six months post transfusion and detailed documentation. Dr Robinson is to speak to the new French Medical Director. AR

Dr Robinson will also make enquiries about the existence of reporting systems in other countries such as Finland and the Netherlands. AR

There followed discussion as to whether the UK system should be voluntary or mandatory and the mechanism by which reporting can be made mandatory. This would require a DoH executive letter. It was concluded that the approach should be to commence with a voluntary system, which would be analysed after a suitable interval and could be recommended as mandatory if indicated.

4. Other Confidential Reporting Systems in UK

Other confidential enquiry systems such as those for maternal and surgical deaths could provide useful information and there may be a need to establish links with such systems. Dr Williamson will make further enquiries. LW

ACTION

There was brief discussion on the "yellow card" system for reporting of adverse reactions to drugs. This encourages the reporting of any event which might possibly be related to the use of a particular drug and as a result of this analysis may be able to establish links between adverse events and the use of the drug. The SHT system would probably not follow these lines.

5. Consideration of Specific Topics

The components which would be involved in the SHT reporting system were clarified as those from local Transfusion Centres ie:

- All red cells
- Platelets
- Fresh frozen plasma
- Cryo precipitate
- Buffy coats
- Granulocytes

Products of fractionation processes are thought to be covered by the "yellow card" system and this assumption is to be checked AR

Working groups exist for tissue banking, cord and peripheral blood stem cells, and it was not known to what extent these were considering hazards. These additional topics were felt to be too wide for the remit of the SHT group, but it was considered essential to inform the respective Chairman of the other groups of the existence and remit of the SHT group. Dr Williamson will contact David Pegg and Derwood Pamphilon. LW

5.1 ABO Incompatibility and "Near Misses"

It was recommended that all incidents of "blood into wrong patient" should be reported. Incidents without morbidity and those involving death and morbidity should be included. All such events indicate a serious systems failure of some sort.

"Near misses" are frequent and picked up before the event of transfusion. Whilst hospitals should keep a record of such incidents for discussion at Hospital Transfusion Committees, it is not practical for the SHT reporting system to support these.

5.2 Other Haemolytic and Non Haemolytic Reactions

The reporting of delayed haemolytic reactions should be encouraged. These may be potentially serious and Dr Todd cited a recent fatal example. The extent of such reactions is not really known and Professor Waters explained that he did not expect his audit study to reveal information on the incidence and frequency of reactions in general. However, it will reveal the extent of documentation and of the reporting of adverse reactions.

Cont/d..

ACTION

In order to assist the reporting process a robust definition of events is required and guidance will be needed on the minimum data to be recorded on the ward that will trigger a report.

There followed discussion of a possible reporting algorithm. Many members of the committee felt that there should not be insistence on reporting adverse reactions via the local Transfusion Centre, unless the Transfusion Centres involvement essential for the resolution of the case. Insistence on mandatory reporting via the Tranfusion Centre could discourage disclosure of information. For example, hospitals may be hesitant to report incidents of "blood into wrong patient" if there is perceived lack of confidentiality, whereas Transfusion Centre involvement will be needed for the follow up of reports of bacterial infection, transfusion transmitted infection, Graft Versus Host disease (GVHD) and Transfusion Related Acute Lung Injury (TRALI). LWA

A possible reporting algorithm was outlined for discussion at a further meeting (Appendix 1).

Some members of the committee agreed to submit their local practice guidelines. ALL DN AW PS

5.3 Bacterial Infections

It was considered essential to establish the current position of Dr Ruthven Mitchells work which was the subject of a confidential DoH paper. It was known that this work also addressed the manner of investigation by microbiology laboratories and the group considered that clear guidelines on the most appropriate investigations would be helpful. Dr Williamson will invite Dr Mitchell to report to the group on the progress of his work and to consider whether the introduction of his reporting system should be delayed. DW

Dr Robinson has been asked to report back to the MSBT at the end of February/early March 1995 to present a coordinated approach to this subject. AR

Dr Napier recalled that several years ago he, John Barbara and Alison Uttley had been asked to consider the reporting of bacterial infections, but he was not sure what further progress had been made. Dr Williamson agreed to request information from John Barbara. DW

5.4 Viral Transmission

There was thought to be probable under-reporting from Hospital Clinicians and lack of awareness by General Practitioners so that some "feed in" to GP practices would be required. Kate Soldan is the newly appointed PHLS/NBA liaison person and her role may overlap with the SHT reporting system. Dr Williamson will discuss this with her. DW

ACTION

There was considerable discussion as to the existence of feed back mechanisms for new cases of post transfusion hepatitis in terms of tracing transfusion history. Awareness amongst Clinicians and General Practitioners may need to be increased perhaps via a CMO letter. Another possible source of information would be via the PHLS but this might breach confidentiality. Dr Williamson will write to Dr Ala, Chairman of the SACTTI for guidance on the reporting of cases and standardisation of investigations.

Dr Williamson will also write to Dr Barbara on the subject of accessing PHLS information.

Transfusion transmitted infections which would be considered for reporting include HIV, HCV, HBV, CMV, Parvo virus, HAV, HTLV and Malaria.

(Appendix 2) describes a possible algorithm for the reporting of transfusion transmitted viral infection (for example hepatitis) for further discussion.

5.5 Transfusion Related Acute Lung Injury (TRALI)

The need for possible investigation of the donor as well as the recipient must be borne in mind.

Professor Waters will investigate the definitions of TRALI with local anaesthetists. AW

5.6 Transfusion Associated GVHD

With the recent recognition of micro-chimerism the definition of GVHD requires further clarification.

Appropriate investigations also need to be defined.

5.7 Other Items

It was agreed that post transfusion purpura should be included for reporting purposes.

6.0 How to Make it Happen

A voluntary reporting system was favoured with direct reporting from hospitals to a central collator for serology problems and via the Transfusion Centre for other hazards, both hospital and Transfusion Centres having responsibility for reporting to the central collator.

ACTION

The possible mechanism for central collation was discussed further and a balance of opinion was in favour of a reporting structure within the College of Physicians or an Intercollegiate group to ensure professional confidence and integrity.

The central collator should not be seen as a "controller". Local collation of reports has some attraction but there could be objections of the basis of confidentiality at a local level. For example where laboratory errors are concerned, hospitals may not wish this information to be known locally. It was suggested that there should be anonymised central collation with follow up at Zonal level as required. The duties of a medical collator were discussed. This/these person(s) would act as adviser and feedback mechanism possibly at a Zonal level with a national address being available for more sensitive issues. Those reporting adverse reactions would be free to direct their enquiries to Transfusion Centres if desired or to a nominated haematologist from the SHT group. Dr Norfolk and Dr Skacel provisionally agreed to act in this capacity. Alternatively, enquiries could be directed to the Chairman of the group. Analysis of anonymised data would be conducted by the group. Obviously, the exact mechanisms for reporting are not clear at this time but in order to further discussions the following action will be taken:-

Dr Williamson will write to Dr Contreras in her capacity as Chairman of the Royal College of Pathologists Tranfusion Sub-committee. LW

Professor Walters will speak to Dr A Hopkins to obtain the view of the College of Physicians. AW

Dr Todd will discuss the views of the Edinburgh College of Physicians with Professor Cash. AT

7. Any Other Business

None

8. Date of Next Meeting(s)

Wednesday 8th February 1995 ? West End Donor Centre
or Tuesday 21st March 1995 ? " " " "

Summary of items for the next meeting.

1. Report back on various action comments.
2. Documentation
3. Mechanisms of collation of reports.
4. Mechanisms for feed back.
5. Pilot studies.

cc. Dr P Mortimer, PHLS CDSC Colindale

EML/4/95 - minwrkgroup