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Select Committee of Experts on the
Responsibility of blood transfusion centres,
especially in connection with transfusion transmitted diseases (SP-R-RT)

1st meeting

Strasbourg, 28-30 September 1993

MEETING REPORT

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I. Opening of the meeting

The Secretariat welcomed the participants and the observers (Appendix I).

The Secretariat informed the participants that this Committee of experts has been set up following the recommendations of the SP-HM (Committee of Experts on Blood Transfusion and Immunohaematology) which has delegated a part of its technical work.

The task of this group is to propose a work programme which will be submitted to the European Health Committee (CDSP). Therefore the several items of the agenda should be examined in a way to point out the particular aspects which need further investigation.

In the light of this work programme the CDSP will then decide on the follow up which should be carried out.

II. Election of the Chairperson

Dr Gunson was elected chairperson. He opened the meeting and thanked experts for their participation at this meeting.

III. Adoption of the draft agenda and examination of the terms of reference

The draft agenda and the terms of reference (Appendices II and III) were adopted. The participation of the legal Directorate of the Council of Europe was requested especially for items IV, V and VI.

IV. Examination of the definition of blood and blood products as therapeutic substances from the legal point of view

Under this headline, the Committee of Experts has taken into account the EC Council Directive no. 89/381 concerning medicinal products derived from human blood or human plasma and no. 85/374 concerning the liability for defective products.

According to national legislation, blood products[1] are considered either a service and/or pharmaceutical products. This leads to different systems of liability for those institutions manufacturing or delivering these blood products.

If blood products are considered as services, then fault or negligence would have to be proved whereas if they are considered as products then product liability will apply in case of damage caused to the recipient by contaminated blood products. In the exceptional circumstance of HIV infection, it seems that the above considerations do not appear to have determined decisions on compensation or other financial payments to infected patients.

[1] Blood products are meant to include all therapeutic substances derived from blood: whole blood, blood components and plasma derivatives. Rec. No. R (88) 4.

V. Legal responsibility as concerns blood products

The concept of legal responsibility shows disparities between member states due to differences in their legal traditions. However, it was noted that for components which can not be virally inactivated, the risk of contamination due to the "window period" can not be completely avoided, although the procedures of viral markers screening have been performed in accordance with the state of the art.

This might lead to consideration of a special concept of liability due to the therapeutic risk.

VI. Criteria for compensation in relation to damage to the recipient

For compensation paid to persons contaminated by the HIV virus following a transfusion, the report of the Committee on the Environment, Public Health and Consumer Protection on "Self-sufficiency in and Safety of Blood and its Derivatives in the European Community" presented by Mrs. Adriana Ceci to the European Parliament (25 February 1993, A3-0075/93) shows considerable disparity among the member states. This is partly due to the different approaches of health and social security systems.

Recommendations for Items IV, V, VI

1. It was considered that guidelines on the definitions, the legal responsibility concerning blood and blood products and the criteria for compensation in relation to damage to recipients, would be advantageous to a number of member states of the Council of Europe.

It is therefore recommended that a Working Party is established to prepare strict guidelines. Note should be taken of the European Convention on Product Liability with regard to Personal Injury and Death (Strasbourg 1977) and 85/374/EEC. The guidelines should embrace existing infections and be applicable to future, as yet unknown, infections.

The Working Party should comprise legal experts, working in the field of transfusion medicine, an expert in transfusion medicine and a representative of the Legal Directorate of the Council of Europe.

VII. Criteria for deciding whether to introduce a new screening procedure for the prevention of blood transmitted diseases

1. This should be considered under three headings :

1.1 Assessment of the medical status of the donor with or without selective testing of donations

1.2 Routine testing of all donations

1.3 Selective testing of donations

2. The following should be considered before the introduction of a new screening test :

2.1 Epidemiology - the prevalence of the disease in the population as a whole and, in particular, in the donor population

2.2 Clinical aspects - the morbidity and mortality of the disease transmitted by blood and/or plasma products

- the immune status of the population
- the existence of the carrier state

2.3 The status of the test in terms of:

- rapidity
- reliability
- reproducibility
- sensitivity
- specificity
- availability of appropriate confirmatory tests

2.4 The effect on the well-being of the donor when informed of an incurable disease or when only incomplete information can only be provided about the consequences of the test results for the donor.

2.5 Whether tests may be recommended as an indemnity against possible legal action by the recipient of the transfused blood.

2.6 Certain tests defined as mandatory by regulatory authorities, governments or non-governmental organisations deputed by governments to make these decisions.

2.7 The state of the art in donor testing should be validated and costed prior to routine use.

2.8 Cost-benefit analysis, which should include the number of positives, loss of donors, the effects of donor counselling, must be performed prior to the introduction of a test and evaluated against the priorities of health care provision as a whole.

2.9 The impact of decisions taken for the testing of blood on organ and tissue transplantation.

3. Conclusions

3.1 Although the criteria used in deciding to introduce a test on scientific grounds are well established, harmonisation is needed to enable free movement of blood and blood products.

3.2 Two areas where further investigation is merited by experts intimately involved in the recruitment of donors are :

i. Medical assessment of the suitability of donors, information provided for the education of donors which should include deferral;

ii. Pre-donation testing.

VIII. The use of unscreened batches of plasma

1. The compulsory use of batches of plasma screened with various microbiological tests may be decided by regulatory authorities and a date limit given for the embargo on batches not screened for all the mandatory infections markers.

2. Various guidelines are in operation for the notification of fractionators by the provider of the plasma when considerations may be given to the withdrawal of the batches, eg. the microbiological tests have not been carried out in an appropriate manner, or late reporting of an infectious disease in one or more donor.

3. Factors which need to be considered in the withdrawal of plasma derivatives are :

   i. the safety of the final product

   ii. the avoidance of wastage and the possible creation of shortage if the batch is destroyed

   iii. public perception that the use of the products is potentially dangerous.

4. There may be instances when certain products from an unscreened pool may be used eg. albumin and IM immunoglobulin. Such decisions should not be taken without validation of the fractionation process.

Conclusions

1. It is important that there is close co-operation between the plasma providers and the fractionators. Usually there is a contractual obligation to provide plasma according to agreed specifications.

2. The plasma provider is obliged to inform the fractionator when plasma does not meet agreed specifications particularly when a later seroconversion has occurred.

3. The fractionator should decide whether to proceed, halt production or withdraw the batches.

The Group of experts recommends :

1. That further work is carried out on the general guidelines for acceptance of plasma.

2. The relationship between plasma providers and fractionators require clarification particularly with respect to the liability of each party to contract fractionation.

IX. The duties of medical services involved in the provision and need of blood in keeping proper records

1. This involves maintaining documentation from the acceptance of the donor to the transfusion of the patient with a blood product and also post-transfusion surveillance.

2. It was considered that practices varied widely in different countries and that deficiencies occurred in this area.

3. It is important to be able to trace blood products transfused to the patient back to the donor not only for medical reasons ie. the deferal of the donor to prevent the recurrence of the event but also, possibly for legal reasons involving compensation (the donor will not be held personally liable for accidental transmission of diseases (Ref. Recommendation (88) 4).

4. Post-transfusion surveillance is a cooperative effort between clinicians and manufacturers of blood products and reporting systems should involve regulatory authorities.

Conclusions

1. It was considered inappropriate for practical and financial reasons to investigate the documentary procedures which are currently operating in CE member States.

2. It is important to provide guidance which can be made flexible enough so that the member States could comply.

Recommendation

A working group should consider preparation of guidelines on the documentation and records regarding the collection, preparation and use of blood and blood products.

X. Measures for the prevention of contamination of staff of blood transfusion centres

This topic was considered under the following heading :

1. Training. The importance of training the supervisors who train other staff was stressed.

2. Removal of hazards. Steps should be taken to make premises and procedures as safe as possible. However staff should be made aware that every blood sample handled could potentially transmit infection.

3. Immunisation. This may be appropriate for certain infectious diseases eg. hepatitis B. Those staff members at particular risk of contracting infection during the course of their work should be encouraged to undergo appropriate vaccination.

4. Microbiological testing of staff prior to employment. These procedures have limited value and for certain infectious disease markers eg. anti-HIV cannot be recommended.

Recommendation

Guidelines, similar to the procedures already implemented in hospitals, would be useful and the present group considers that there was sufficient competence within the group to draft these guidelines.

XI. Miscellaneous

The Committee of experts raised also the following matters :

- Optimal use of blood products :
  a group of specialists on the clinical use of blood products is considering this question;

- Autologous transfusion :
  the SP-R-GS is in charge of this matter but it is noted that it involves the responsibility of the hospital or the blood transfusion centre which performs it;

- Migration of population :
  this question has to be considered in the view of assuring safety and adequacy of the blood supply while avoiding discrimination. This could be studied by the group suggested for item VII 3.2

Appendix I

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Appendix II

Agenda

I Opening of the meeting

II Election of the Chairman

III Adoption of the draft agenda and examination of the terms of reference

IV Examination of the definition of blood and blood products as therapeutic substances from the legal point of view

V Legal responsibility as concerns blood products.

VI Criteria for compensation in relation to damage to the recipient.

VII Criteria for deciding whether to introduce a new screening procedure

VIII The use of unscreened batches.

IX The duties of medical services involved in the provision and used of blood in keeping proper records.

X Measures for the prevention of contamination for the staff of blood transfusion centres.

XI Drawing up of a work programme in the light of the above review

Appendix III

SPECIFIC TERMS OF REFERENCE

1. Name of Committee: Select Committee of Experts on the responsibility of blood transfusion centres, especially in connection with transfusion transmitted diseases (SP-R-RT)

2. Type of Committee: Select Committee of Experts

3. Source of Terms of Reference: European Health Committee (CDSP) and Committee of Experts on Blood Transfusion and Immunohaematology (SP-HM) *)

4. Terms of Reference:

   a) Examine the definition of blood and blood products as therapeutic substances (gift of merchandise?) from the legal point of view.

   b) Review the situation in member states on the following matters:

      i) Legal responsibility as concerns blood products.
      ii) Criteria for compensation in relation to damage to the recipient.
      iii) Criteria for deciding whether to introduce a new screening test.
      iv) The use of unscreened batches.
      v) The duties of doctors and hospitals in keeping proper records.
      vi) Measures for the prevention of contamination for the staff of blood transfusion centres.

   c) Proposed work programme.

5. Membership of the select committee of experts:

   a) The Council of Europe's budget will cover travelling expenses and subsistence expenses of one expert from each of the following states: Finland (legal expert), France (legal expert), United Kingdom (transfusion expert), Switzerland (transfusion expert), and of one United Kingdom member of the SP-HM.

   b) The Commission of the European Communities may send a representative without the right to vote or defrayal of expenses, to meetings of the Select Committee.

   c) The following organisations may send a representative without the right to vote or defrayal of expenses, to meetings of the Select Committee : WHO, FDA.

6. Working structures and methods: The Select Committee of Experts will report to the CDSP after its first meeting and propose a programme of work.

   Number of meetings in 1993: 1. Duration of the Meetings: 2 1/2 days.

7. Duration: These Terms of Reference expire on 31 December 1993.

*) Terms of reference approved by the European Health Committee according to item 4 (v) of the SP-HM terms of reference.