



Working Party on Transfusion Transmitted Infectious Diseases

Seattle, 15th October 2005

Minutes

The meeting of the ISBT Working Party on Transfusion Transmitted Infectious Diseases was held at the Sheraton Hotel in Seattle during the annual AABB congress.

The meeting began with an address of welcome by Silvano Wendel.

2. Scientific reports:

2.1. Report on the WHO Meeting on TSE

Silvano Wendel

Silvano Wendel reported on the WHO meeting on TSE in Geneva, September 14-16 2005, which he attended as representative of the ISBT WP-TTID.

The Working Party prepared a CD containing all presentations held at this meeting. Copies of this CD are available for all members and can be ordered from the secretariat, provided that its content is available for private use only and is not presented and/or duplicated and/or distributed otherwise.

Following the report of the WHO meeting, it was agreed on establishing a new subgroup of the Working Party. The subgroup on TSE will focus on the discussion of risk analysis and its potential assumptions for the field of transfusion medicine. One problem of the development of new test systems is the fact that no human samples are available for testing.

Members of the subgroup on TSE are:

- Chyang T. Fang - *Chair*
- Mike Busch
- Joe Cervia (Pall)
- Andrew Heaton (Chiron)
- Cees van der Poel
- John Saldanha (Roche)
- Gerald Schochetman (Abbott)
- Qiu Yan

The subgroup is going to develop a draft paper for the meeting next year.

2.2. Anti-HBc and Re-entry of Donors

Cees van der Poel

Cees van der Poel held a presentation on his proposal for an Anti-HBc subgroup. The main reason for setting up a subgroup on Anti-HBc is that in some European countries like Germany and the Netherlands Anti-HBc testing will be introduced in the near future. The slides of his presentation can be ordered from the secretariat by any interested member.

The major issues proposed are as follows: The subgroup should discuss a re-entry protocol for all those donors tested repeatedly reactive on Anti-HBc. Re-entry should be possible if HBV NAT (sensitivity below 30 IU/ml) is negative and Anti-HBs Titer is above 100 IU/l. A surveillance program is necessary in order to monitor such donors prospective. Currently there is no case documenting a transfusion transmitted HBV infection from a donor with neutralizing antibodies above 100 IU/ml. In addition risk factors must be excluded otherwise donors need to be permanently deferred.

The subgroup should start for a Phase IV post marketing study on surveillance potentially including other countries that are already testing for Anti-HBc. The look-back procedures should be proposed by the subgroup and coordinated by the Working Party TTID on all Anti-HBc positive single donation NAT positive HBsAg negative donors. If there are proven infectious donations in the past, repository samples should be retested with respect to their HBV profile.

The first step is to share information (Excel file), secondly a sample repository should be build up and the data should be entered into a central database. ^ see proposal by Kurt Roth

There should be an annual report to members and authorities and alert reports to members when an Anti-HBs positive >100IU/ml infectious donation is documented.

A second arm is proposed where look-back should be performed on all Anti-HBc positive sero-converting donors. This includes donors who are Anti-HBc positive at donation and were Anti-HBc negative at previous donations. Samples from previous donations on the repository should be rechecked by HBV single donation NAT.

For details see the slides of the presentation.

Members of the subgroup on Anti-HBc and re-entry of donors are:

- Jean Pierre Allain - *Chair*

- Mike Busch
- Chyang T. Fang
- Nico Lelie (Chiron)
- Cess van der Poel
- Henk Reesink
- Michael Schmidt
- Susan Straemer
- Silvano Wendel

2.3. Questionnaire on NAT and Blood Safety Measures

Kurt Roth

The subgroup on surveys should internally discuss definitions and aims of the questionnaire (e.g.: prevalence, incidence, confirmed positives etc.). The presented form of a potential questionnaire was generally accepted by the Working Party members. The costs for the questionnaire were estimated at 10,000€.

2.4. Workshop on Bacteria – Proposal for Meeting in Capetown

Thomas Montag

Statements are suggested to be prepared and published first in *Vox Sanguinis*. The Paul Ehrlich Institute developed bacteria standards that could be submitted to any participant of the Working Party. These standards offer the opportunity to design more spiking studies with low inoculums (10 CFU/bag), which might prove to be more realistic under real life conditions.

The subgroup on bacteria plans to hold a workshop on bacteria in order to demonstrate current available screening methods to the audience at the next ISBT congress. Several companies are going to support this workshop.

2.5. Subgroup on Parasites – Action Plan

Silvano Wendel

Gerald Schochetman (Abbott) will support the subgroup on parasites. The main issues from this subgroup are:

1. Define the main parasites with a potential role of transmission by blood transfusions.

2. Define the extension of countries affected by these parasites, with regional epidemiological data, when possible.

3. Study the available strategies used to prevent transfusion transmission
 - a. Questionnaires
 - b. Antibody tests
 - c. Antigen tests
 - d. Confirmatory tests
 - e. Pathogen reduction methods
4. Produce a global map with the main strategies adopted by each country

Members:

- Silvano Wendel
- Anthony Hardiman
- Anthon Heyns
- Eugene Zhiburt
- Emma Castro

Two potential new members will be invited, once they become associated to ISBT. Additionally, a member from a country with a high incidence of diseases of parasites like malaria etc. (e. g.: Nigeria) should support the subgroup on parasites as well

3. Agenda for South Africa

The official meeting of the Working Party will take place on September 1st 2006 (one day before the ISBT world congress 2006 starts). Reports of the subgroups are awaited and will be presented at this meeting. The subgroups might therefore hold individual meetings the evening before to discuss open questions.

