ISBT Working Party
Transfusion-Transmitted Infectious Diseases (WP-TTID)
Chair: Silvano Wendel, Brazil

Subgroup on Bacteria
Chair: Thomas Montag, Germany
Co-Chair: Erica Wood, Australia

Annual Report 2011
Lisbon, June 19th
1. Establishment of WHO Repository Transfusion-Relevant Bacterial Reference Strains (TRBRS) and request of WHO Expert Committee Biological Standardisation (ECBS) for enlargement of Repository.

2. Preparatory work for enlargement of WHO Repository TRBRS and demonstration of draft study design

3. Presentation by Zainab Mukhtar, Pakistan Transfusion-transmitted bacterial infection and developing world.

4. Contribution of ISBT WP-TTID Subgroup on Bacteria to ISBT WP Haemovigilance.


6. Establishment of an Expert Group on “Assessment of rapid point of care methods and recommendations for their use”

7. Taking over the experience of Subgroup on Virology regarding “International survey on NAT Testing”

8. Extraordinary meeting of Subgroup on Bacteria on occasion of AABB
Background:

International Validation Study on
Transfusion-Relevant Bacterial Strain Repository
(start with 4 bacterial species/strains)
Study Participants

1. **Dirk de Korte**  
   Annika Pettersson  
   Sanquin Amsterdam, NL

2. **Christian Gabriel**  
   Blutzentrale Linz, Austria

3. **Carl McDonald**  
   National Blood Service London, UK

4. **Piotr Radziwon**  
   Centre Transfusion Medicine Bialystok, Poland

5. **Thomas Müller**  
   German Red Cross Springe, Germany

6. **Michael Schmidt**  
   German Red Cross Frankfurt/Main, Germany

7. **Tshilidzi Muthivhi**  
   South African National Blood Service, South Africa

8. **Dana Devine**  
   Sandra Ramirez-Arcos  
   Canadian Blood Services, Canada

9. **Roslyn A. Yomtovian**  
   Michael R. Jacobs  
   School of Medicine, Cleveland, USA

10. **David G. Heath**  
    Walter Reed Army Medical Center, USA

11. **Ray Goodrich**  
    CaridianBCT Lakewood, USA

12. **Julieta Rojo**  
    Centro Nacional Transfusion Sanguenia, Mexico

13. **Cheuk-Kwong Lee**  
    Hong Kong Red Cross, China

14. **Thomas Montag**  
    Melanie Störmer  
    Carl McDonald  
    Erica M. Wood  
    Paul-Ehrlich-Institut, Germany
What are Transfusion-Relevant Bacteria Reference Strains?

1. Blood Bacteria References are able to grow in PCs up to high counts (what is not automatically given in case of reference strains like ATCC strains).

2. Strains grow up in PCs independent on donor properties (tested for relevant multiplication in PCs from at least 100 different donors). *

3. Manufactured by a special procedure, the reference strains are deep frozen, ready to use, stable, and shippable.

4. They are defined in count and consist mainly of living cells (as a rule > 95% living cells).

5. The standards allow “real life” spiking of blood components, i.e. artificial contamination with ~ 10 CFU per bag corresponding to 0.03 CFU per millilitre. *

6. Thus, Blood Bacteria References are a feasible tool for objective validation and assessment of methods for both screening and pathogen reduction in blood components. *
Why do we need Transfusion-Relevant Bacteria Reference Strains?

Those bacterial strains are not killed by donor’s innate immunity like complement, natural antibodies or phagocytosis, i.e. they are able to proliferate in any PC enabling an objective validation (exception: specific antibodies towards the given strain).

Low spiking (0.03 to 0.3 CFU/ml) followed by proliferation allows the bacteria an adaptation to the complex matrix PC, i.e. they express quite different properties in comparison to bacterial cells of the same strain if grown in microbiological culture medium.

The Bacteria References are dedicated to validation and assessment of both Pathogen Reduction Methods and Screening Methods.
<table>
<thead>
<tr>
<th>Event</th>
<th>Details</th>
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<tbody>
<tr>
<td>ISBT Meeting 2006</td>
<td>ISBT WP-TTID discusses a Prevalidation Study on Blood Bacteria References and decides to organise a Validation Study</td>
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<tr>
<td>Cape Town, South Africa</td>
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<td>WHO CC Meeting 2007</td>
<td>Proposal to organise a Validation Study on Blood Bacteria References</td>
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<tr>
<td>Bethesda MD, USA</td>
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<td>ISBT Meeting 2008</td>
<td>Kick-off Meeting of Validation Study, ISBT WP-TTID, Subgroup on Bacteria</td>
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<tr>
<td>Macao, China</td>
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<td>AABB Annual Meeting 2008</td>
<td>Extraordinary meeting Bacteria Group: Final decision on study design</td>
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<td>Montreal, Canada</td>
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<td>WHO CC Meeting 2009</td>
<td>Recommendation of WHO CC Meeting to submit Validation Study to WHO ECBS</td>
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<tr>
<td>Langen, Germany</td>
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<td>June 30th, 2009</td>
<td>Submission of report on Validation Study on Blood Bacteria References to WHO ECBS</td>
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<tr>
<td>WHO ECBS 2009</td>
<td>Validation Study endorsed as a project, discussion of enlargement of panel</td>
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<tr>
<td>Geneva, Switzerland</td>
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<td>Annual Meeting Bacteria Group, Berlin, 2010</td>
<td>Discussion of panel enlargement</td>
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<td>AABB Annual Meeting 2010</td>
<td>Extraordinary meeting Bacteria Group: Final discussion of panel enlargement</td>
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<tr>
<td>Baltimore, USA</td>
<td></td>
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<tr>
<td>WHO ECBS 2010</td>
<td>1. WHO Repository Transfusion-Relevant Bacteria Reference Strains adopted</td>
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<tr>
<td>Geneva, Switzerland</td>
<td>2. Enlargement endorsed as a project (study design has to be approved by WHO ECBS)</td>
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<td>June 30th 2010</td>
<td></td>
</tr>
<tr>
<td>Annual Meeting Bacteria Group, Berlin, 2010</td>
<td>Approval of “Instructions for Users” by WHO ECBS via circulation</td>
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<tr>
<td>WHO CC Meeting 2011</td>
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<tr>
<td>London/Herfordshire, UK</td>
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<tr>
<td>WHO CC Meeting 2011</td>
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ESTABLISHMENT OF THE FIRST INTERNATIONAL REPOSITORY FOR TRANSFUSION RELEVANT BACTERIA STRAINS -
ISBT Working Party Transfusion-Transmitted Infectious Diseases (WP-TTID),
Subgroup on Bacteria

Short running head: International repository for transfusion relevant bacteria strains

Melanie Störmer¹*, Antonio Arroyo², Julia Brachert¹, Hector Carrero³, Dana Devine⁴, Jay S. Epstein⁵, Christian Gabriel⁶, Cohava Gelber⁷, Ray Goodrich⁸, Kay-Martin Hanschmann¹, David G. Heath³, Michael R. Jacobs⁹, Shawn Keil⁸, Dirk de Korte¹⁰, Bernd Lambrecht¹¹, Cheuk-Kwong Lee¹², Jan Marcelis¹⁰, Susanne Marschner⁸, Carl McDonald¹³*, Siobhan McGuane¹³, Marian McKee⁶, Thomas Mueller¹¹, Tshilidzi Muthivi¹⁴, Annika Pettersson¹⁵, Piotr Radziwon¹⁶, Sandra Ramirez-Arcos⁴, Henk W. Reesink¹⁷, Julieta Rojo², Ineke Rood¹⁰, Michael Schmidt¹⁸, Christian K. Schneider¹, Erhard Seifried¹⁸, Ute Sicker¹, Silvano Wendel¹⁹, Erica M. Wood²⁰*, Roslyn A. Yomtovian²¹ and Thomas Montag¹*
1. Establishment of WHO Repository Transfusion-Relevant Bacterial Reference Strains (TRBRS) and request of WHO Expert Committee Biological Standardisation (ECBS) for enlargement of Repository.

2. Preparatory work for enlargement of WHO Repository TRBRS and demonstration of draft study design

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4. Contribution of ISBT WP-TTID Subgroup on Bacteria to ISBT WP Haemovigilance.


6. Establishment of an Expert Group on “Assessment of rapid point of care methods and recommendations for their use”

7. Taking over the experience of Subgroup on Virology regarding “International survey on NAT Testing”

8. Extraordinary meeting of Subgroup on Bacteria on occasion of AABB
Proposal: Study Design

PART 1
Pre-characterisation

Starting as soon as possible

Results up to May 2012

→ Selection of 6 candidates
→ Circulation of Study Design
   Enlargement

Submission of Study Design to ECBS (30.06.2012)

PART 2 Enlargement Study

Winter 2012
Submission of results on 30.06.2013
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Bacterial Contamination of Blood Products and the developing world

Dr. Zainab Mukhtar
Technical Expert
Safe Blood Project
GIZ Health Program
Ministry of Health
Pakistan
ISBT Working Party on 
Transfusion-Transmitted Infectious Diseases

Subgroup on Bacteria
ANNUAL REPORT
Sunday, 19th June 2011, Lisbon

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ISBT Working Parties on Haemovigilance and Transfusion-Transmitted Infections

Transfusion-transmitted bacterial infections (TTBI):
Proposed standard definitions for classification of clinical cases in haemovigilance systems
ISBT Working Party on Transfusion-Transmitted Infectious Diseases

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ISBT-AABB Working Party on Cellular Products

- established on occasion of ISBT Berlin 2010

- chairs:
  Paolo Rebulla (Italy)
  John McMannis (USA)

- Melanie Stoermer and Thomas Montag were foundation members

- first activity: publication of reviews on topics relevant in cellular therapy
Contribution of ISBT WP-TTID Subgroup on Bacteria to ISBT-AABB Working Cellular Therapy

Microbial Safety of Hematopoietic Progenitor Cells

Thomas Montag¹, Erica M. Wood², Utta Schurig¹, Ingo Spreitzer¹, Carl P. McDonald³, Christian K. Schneider¹,⁴, and Melanie Stömer¹

¹ Paul Ehrlich Institute, Federal Institute for Vaccines and Biomedicines, Langen, Germany
² Monash University, Melbourne, Australia
³ NHS Blood and Transplant, London, United Kingdom
⁴ Twincore Centre for Experimental and Clinical Infection Research, Hannover, Germany

pre-final draft has been sent to Paolo Rebulla
1. Establishment of WHO Repository Transfusion-Relevant Bacterial Reference Strains (TRBRS) and request of WHO Expert Committee Biological Standardisation (ECBS) for enlargement of Repository.

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Two different strategies for platelet bacteria screening

Early sampling for culture methods

Late sampling for rapid methods
-> as late as possible
-> bed side like

Proposed in “Transfusion Today”, March 2006, by ISBT Working Party Transfusion-Transmitted Infectious Diseases, Subgroup on Bacteria

Conclusion:
There is a need to evaluate rapid methods for bacteria detection

Outcome of Annual Meeting 2011 of ISBT WP-TTID Subgroup on Bacteria

Establishment of an expert group of ISBT WP-TTID Subgroup on Bacteria having the topic:

“Assessment of rapid point of care methods and recommendations for their use”
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Adapting experience from ISBT WP-TTID
Subgroup on Virology

Activity of Subgroup on Virology:

“International Survey on NAT testing of blood donations: expanding implementation and yield from 1999 to 2009”

Plan of Subgroup on Bacteria

• Assess whether algorithm and software of NAT survey could be used for international survey on microbial safety of blood components

• planned topic of Subgroup on Bacteria but postponed because of International Validation Study on Blood Bacteria

References

• consider request for financial support from WP-TTID
ISBT Working Party on Transfusion-Transmitted Infectious Diseases

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Thank you !