

**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

**ISBT Working Party on
Transfusion-Transmitted Infectious Diseases**

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

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 - 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.**
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 - 6. Establishment of an Expert Group on "Assessment of rapid point of care methods and recommendations for their use"**
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 - 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

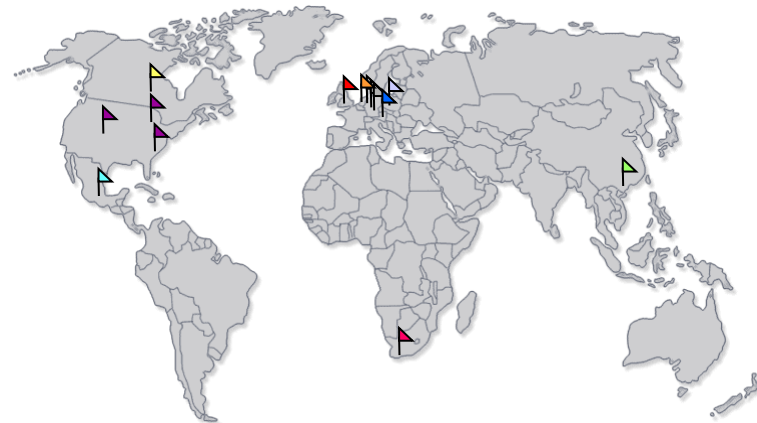
School of Medicine, Cleveland, USA

- 10. David G. Heath**

Walter Reed Army Medical Center, USA

Study Direction:

Thomas Montag
Melanie Störmer
Carl McDonald
Erica M. Wood



- 11. Ray Goodrich**

CaridianBCT Lakewood, USA

- 12. Julieta Rojo**

Centro Nacional Transfusion Sanguinea, Mexico

- 13. Cheuk-Kwong Lee**

Hong Kong Red Cross, China

- 14. Thomas Montag**
Melanie Störmer

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.

History of WHO Repository Transfusion- Relevant Bacteria Reference Strains

ISBT Meeting 2006
Cape Town, South Africa

ISBT WP-TTID discusses a Prevalidation Study on Blood Bacteria References and decides to organise a Validation Study

WHO CC Meeting 2007
Bethesda MD, USA

Proposal to organise a Validation Study on Blood Bacteria References

ISBT Meeting 2008
Macao, China

Kick-off Meeting of Validation Study, ISBT WP-TTID, Subgroup on Bacteria

AABB Annual Meeting 2008
Montreal, Canada

Extraordinary meeting Bacteria Group: Final decision on study design

WHO CC Meeting 2009
Langen, Germany

Recommendation of WHO CC Meeting to submit Validation Study to WHO ECBS

June 30th, 2009

Submission of report on Validation Study on Blood Bacteria References to WHO ECBS

WHO ECBS 2009
Geneva, Switzerland

Validation Study endorsed as a project, discussion of enlargement of panel

June 30th 2010

Submission of report on Validation Study on Blood Bacteria References to WHO ECBS

Annual Meeting Bacteria Group, Berlin, 2010

Discussion of panel enlargement

AABB Annual Meeting 2010
Baltimore, USA

Extraordinary meeting Bacteria Group: Final discussion of panel enlargement

WHO ECBS 2010
Geneva, Switzerland

- 1. WHO Repository Transfusion-Relevant Bacteria Reference Strains adopted**
- 2. Enlargement endorsed as a project (study design has to be approved by WHO ECBS)**

WHO CC Meeting 2011
London/Herfordshire, UK

Approval of "Instructions for Users" by WHO ECBS via circulation

last formal step

Publication accepted by Vox Sanguinis


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 Störmer^{1*}, 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 McDonald^{13*}, Siobhan McGuane¹³, Marian McKee⁶, Thomas Mueller¹¹, Tshilidzi Muthivhi¹⁴, 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. Wood^{20*}, Roslyn A. Yomtovian²¹ and Thomas Montag^{1*}

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Proposal: Study Design

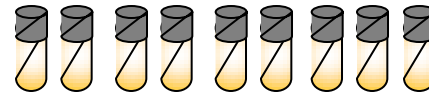
PART 1 Pre- characterisation

Starting as soon
as possible

Results up to May 2012

- Selection of 6 candidates
- Circulation of Study Design
Enlargement

9 Candidates
will be sent to the participating laboratories



Growth in PC
(n=5)

Selection of 6 Candidates for
Enlargement of Repository

----- Submission of Study Design to ECBS (30.06.2012) -----

PART 2 Enlargement Study


Winter 2012

Submission of results on 30.06.2013

Growth in PCs
(n=?)

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The background of the slide features a close-up, slightly blurred image of several blood product containers. One prominent label in the foreground is white with black and red text, including 'ANTICOAGULANT', 'CITRATE', 'PHOSPHATE', 'DEXTROSE', and 'SGL'. Another label below it has 'CPD' in large red letters and '500' in red. A yellow tube is visible, connected to one of the containers. A large, solid red rectangular box is overlaid on the right side of the image, containing the main title in white text.

Bacterial Contamination of Blood Products and the developing world

Dr. Zainab Mukhtar
Technical Expert
Safe Blood Project
GIZ Health Program
Ministry of Health
Pakistan

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Input of Subgroup on Bacteria (Erica Wood and Carl McDonald) to the ISBT WP Haemovigilance (Chair: Pierre Robillard)

**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*

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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, Uta Schurig¹, Ingo Spreitzer¹, Carl P. McDonald³, Christian K. Schneider^{1,4}, and Melanie Stoermer¹

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

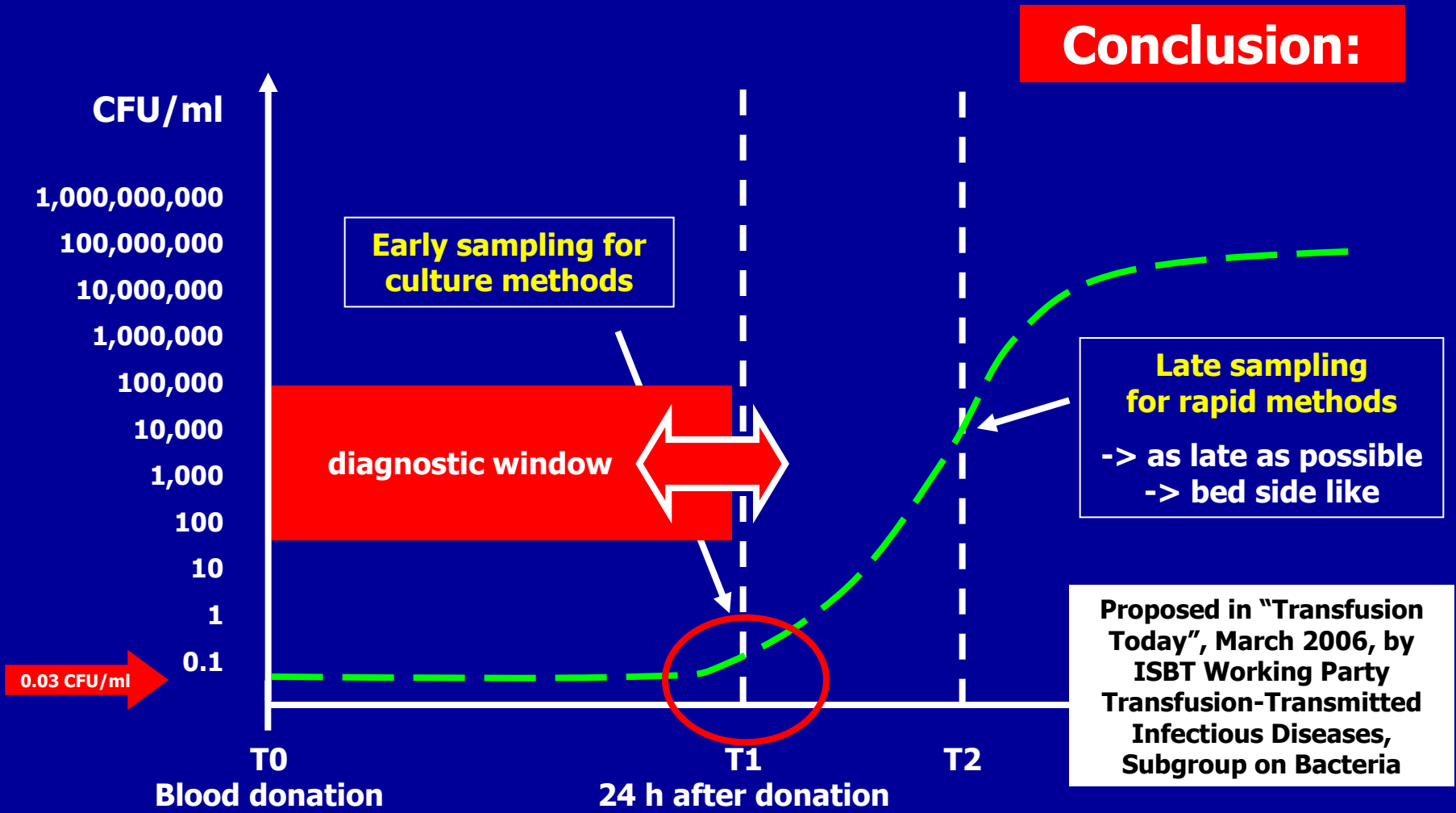
pre-final draft has been sent to Paolo Rebulla

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Two different strategies for platelet bacteria screening



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**

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Thank you !