

Programme of the Workshop
Stepwise Access to Safe Plasma Proteins in Resource-Constrained Countries:
Local Production & Pathways to Fractionation

Online Workshop organized by the Working Party for Global Blood Safety (GBS) of ISBT

Day 1. Tuesday September 21, 2021 (13:00 – 16:00 CEST)

13:00-13:10 Introduction of the Workshop:
Introduction and housekeeping issues (Martin Smid, The Netherlands - Chair ISBT WP GBS)
Welcome from ISBT (Erica Wood, Australia - President ISBT)

Unmet Needs for Plasma Derived Medicinal Products (PDMP) in Low- and Middle- Income Countries

Moderators: Jean-Claude Faber (Luxembourg – ISBT WP GBS) and Cesar Garrido (Venezuela - WFH)

13:10-13:30 Coagulation factors (FVIII, VWF, FIX, PCC, fibrinogen, others)

(Saliou Diop, Senegal - WFH)

13:30-13:50 Immunoglobulins (polyvalent) (Johan Prevot, Belgium - IPOPI)

13:50-14:05 Discussion/Q&A

Options for fractionation of domestic plasma

Moderators: Thierry Burnouf (Taiwan - ISBT WP GBS) and Junping Yu (Geneva - WHO)

14:05-14:25 Wastage of plasma in LMIC (Yuyun Maryuningsih, Geneva - WHO)

14:25-14:45 Key steps to improve quality of plasma for further processing (Vee Armstrong, Australia)

14:45-15:05 Plasma fractionation technologies: benefits and limitations; technical issues (Jan Bult, The Netherlands - PPTA)

15:05-15:25 Oversight of contract plasma fractionation (Françoise Rossi, France - IPFA)

15:25-15:45 Country experiences: Thailand (Narin Kijkriengkraikul, Thailand - Thai Red Cross Society), Argentina (Andrea Corina Zucchi, Argentina - UNC)

15:45-16:00 Discussion/Q&A

Day 2. Wednesday September 22, 2021 (13:00 – 16:00 CEST)

Options to improve access to safe plasma protein products in LMIC

Moderators: Jean-Claude Faber (Luxembourg - ISBT WP GBS) and Jay Epstein (USA - ISBT WP GBS)

- 13:00-13:20 Recruitment and retention of safe Donors (Giuliano Grazzini, Italy - FIODS)
- 13:20-13:40 Quarantine of plasma as a means to reduce the risk of transfusion-transmitted infection: logistics and feasibility (Pierre Tiberghien, France - EFS)
- 13:40-15:20 Technologies for pathogen reduction (PR) of single-donor or mini-pools of plasma, cryoprecipitate, and immunoglobulins: experience from suppliers and users:
- Strategies to move safe plasma products into low resource areas: overview and experience with Riboflavin/UV (Jeffrey McCullough, USA)
 - Psoralen/UVA (Hans Vermeij, Brazil - Cerus)
 - Methylene blue/light (Stefan Reichenberg, Germany - Macopharma)
 - Pathogen reduction of COVID-19 convalescent plasma (Salwa Hindawi, Saudi Arabia - King Abdulaziz University)
 - Mini-pool solvent/detergent of plasma, cryoprecipitate & caprylic acid fractionation of immunoglobulins (VIPS) (Magdy El-Ekiaby, Egypt - Shabrawishi Hospital)
- 15:20-15:40 Viral safety of plasma derived components (Johannes Bluemel, Germany - PEI)
- 15:40-16:00 Discussion/Q&A

Day 3. Thursday September 23, 2021 (13:00 – 16:00 CEST)

Scale-up for domestic processing of plasma: technology options, equipment and oversight

Moderators: Micha Nuebling (Germany - WHO/PEI) and Thierry Burnouf (Taiwan - ISBT WP GBS)

- 13:00-13:15 Potential contribution of single-use technologies for processing domestic plasma components (Prity Bengani-Lutz, USA - Sartorius)
- 13:15-13:30 Domestic scalable plasma processing: technological approaches and solutions for LMIC (Josephine Cheng, Taiwan; Jian-Fei Shou, China - Merck Millipore)
- 13:30-13:45 Potential contribution of nanofiltration to the virus safety of domestic plasma components (Tomoko Hongo-Hirasaki, Japan - Asahi Kasei Medical)
- 13:45-14:00 SARS-CoV-2 immunoglobulins in India as an example for domestic production of immunoglobulins: Safety, efficacy and quality attributes (Suma Ray, India - Intas Pharmaceuticals)
- 14:00-14:20 Plasma fractionation of animal-derived immunoglobulins in LMIC: lessons to be learned for human plasma IgG production (Mariángela Vargas, Costa Rica - Instituto Clodomiro Picado)
- 14:20-14:40 Regulatory considerations for authorization of plasma processing devices: example of an EU CE marking (Mohamed Ghonim, Switzerland - QSE Consulting)
- 14:40-15:00 Discussion/Q&A
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The Way Forward

Moderators: Martin Smid (The Netherlands - ISBT WP GBS) and Jay Epstein (USA - ISBT WP GBS)

- 15:00-15:20 Models for technology transfer and technical assistance (Leni von Bonsdorff, Finland - IPFA)
- 15:20-16:00 Panel discussion: Lessons learned and next steps (Yuyun Maryuningsih, WHO; Giuliano Grazzini, FIODS; Cesar Garrido and Salou Diop, WFH; Johan Prevot, IPOPI; Johannes Bluemel, PEI; Leni von Bonsdorff, IPFA; Jan Bult, PPTA)
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Closure of the Workshop
