



International Society
of Blood Transfusion



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

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

The program will feature presentations by experts from international organizations and associations (WHO, WFH, IPOPI, IPFA, PPTA) and suppliers of pathogen reduction technologies & plasma processing devices and equipment

Save the dates: September 21-23, 2021 (daily 3-hour online sessions)

Programme and registration form will become available at: www.isbt-web.org

Scope and Purpose: *The workshop will identify pragmatic technical options for stepwise access to safe plasma protein therapies in resource-constrained countries to support implementation of recent WHO guidance on “Increasing Supplies of Plasma-derived Medicinal Products in Low- and Middle-income Countries through Fractionation of Domestic Plasma” and “Centralization of Blood Donation Testing and Processing.”*

WHO Guidances:

<https://www.who.int/publications/i/item/9789240021815>

<https://www.who.int/publications/i/item/9789240020825>

Topics Covered:

- Unmet clinical needs in safe plasma protein therapies for treatment of bleeding disorders and immunodeficiencies
- Robust quality and safety criteria of plasma for fractionation and plasma-derived products, including coagulation factors and immunoglobulins
- Stepwise measures to avoid wasting recovered plasma and to increase availability of plasma for plasma protein manufacture
- Considerations to implement a contract/toll plasma fractionation program and to address technical and financial issues
- Cost considerations in plasma collection and fractionation
- Interim alternatives to fractionation through local production by blood establishments of safe therapeutic plasma proteins: quarantine/retested plasma; pathogen-reduced plasma, cryo-poor plasma, and cryoprecipitate; pathogen-reduced mini-pool plasma products (cryoprecipitate, IgG, and other products)
- Single-use processing for local plasma protein purification and virus inactivation
- Technical solutions from the suppliers of single-use devices for local processing and virus inactivation of plasma, cryoprecipitate, cryoprecipitate-poor plasma and immunoglobulins
- Role of suppliers in training of personnel and local implementation of technologies
- Regulatory considerations for validation of small/medium scale plasma processing

Discussions:

Time will be allocated for exchanges among participants