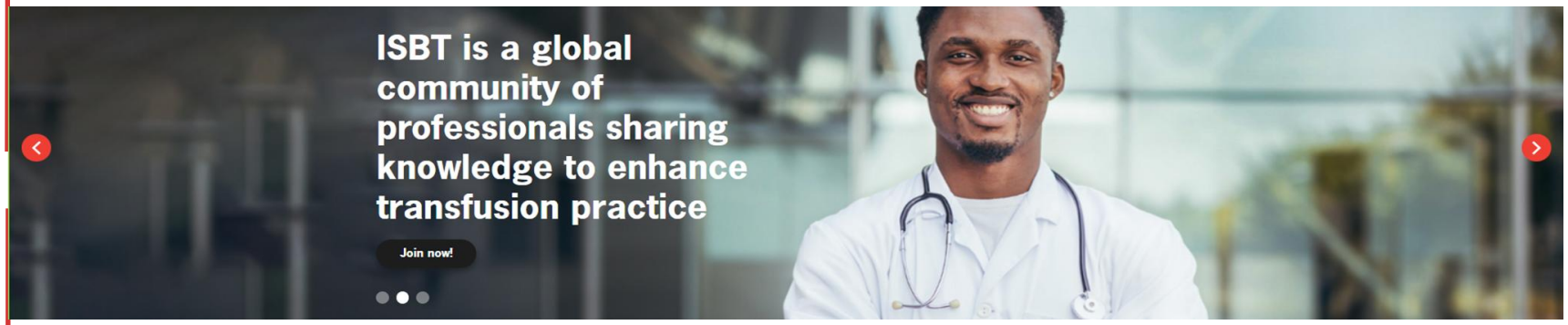
Life after SUPPLY, preparedness in an unpredictable world - panel discussion intro.

IPFA – 2026

Jenny White, Executive Director, ISBT



A world of safe, sufficient and evidence-based blood therapies

Activities related to plasma

- Non-State Actor in official relations with WHO with a triennial workplan supporting WHO Action Framework for universal access to safe, sufficient and quality assured blood products
- Promoting the ISBT code of Ethics protecting patients & donors
- Supporting the WHO Achilles project to increase access to PDMPs in LMIC
- Leading the International Coalition for Safe Plasma Proteins (ICSPP) via ISBT Working Party for Global Blood Safety (GBS)

2000 members in 120 countries

28 Affiliate societies/blood services

16 scientific working parties

SUPPLY - Crisis Scenarios Assessed

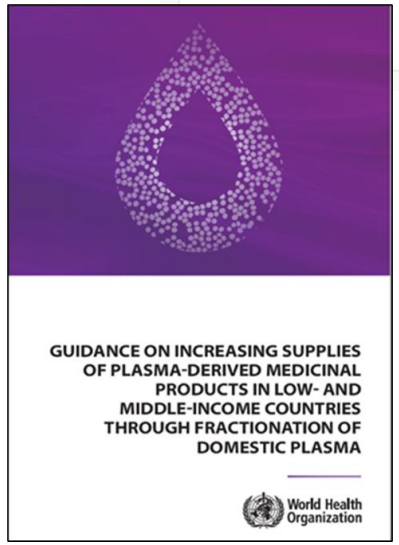
- Pandemic
- War / Armed conflict
- Climate change
- Trade war

For LMIC – also the situation support from WHO and philanthropic programmes being reduced

Preparedness includes getting started in some LMICs

- Weak or no regulatory oversight for blood (or PDMPs)
- Under-developed health and blood systems
- Recovered plasma wasted - unable to meet quality +/- volume requirements of fractionators
- Low donor:population ratio - ? exacerbated if paid for plasma
- Disconnect in country - sale of plasma and purchase of PDMPs
- Limited capacity to collect source plasma
- Fractionation facilities too expensive to implement
- Difficulties exporting across borders
- Reliant on imports, or PDMPs simply not available

- Huge latent therapeutic demand! – low diagnostic capacity to identify need, monitor patients or to advocate for PDMPs



ISBT

MoU with WHO signed by ISBT on behalf of ICSPP with WHO in August 2022 supporting the WHO Achilles project to increase access to PDMPs in LMIC for patients with bleeding disorders, primary and acquired immunodeficiency

IPFA-ISBT workshop Cape Town 2023 (24 countries)

1. The need to acquire support from government authorities for a national plasma policy, recognizing the difficulties posed by unstable political and bureaucratic environments.
2. The value of embedding plasma and PDMPs within a patient blood management (PBM) paradigm to promote optimal clinical use of PDMPs.
3. Training of blood/plasma collection personnel in the relevant principles of Good Manufacturing Practice (GMP), coupled with regulatory oversight of plasma product production in the engaged jurisdictions.
4. Appreciation that limited access to contract fractionation may necessitate a stepwise approach, which may include small-scale preparation of versions of essential plasma proteins as an intermediate phase towards the manufacture of industrial-scale PDMPs from domestic plasma.

ICSPP

World Apheresis Association

international plasma and fractionation association

FIDS

PPTA Plasma Protein Therapeutics Association

Examples of building resilience in LMIC

Regional not for profit fractionator

E.g., S Africa - National Bioproducts Institute (NBI) - Plasma from Africa for Africans

- Toll fractionation for Namibia supplying 100% PDMPs
- Under assessment – Rwanda, Uganda, Ethiopia, Zambia, Tanzania, and Senegal

Stepwise appraoch to production of PDMPs

ICSPP Projects in Ethiopia and Senegal

Plasma viewed as an asset by counties with developing blood systems (pros & cons)

- Can drive quality improvements and development of regulatory systems and provide funds for blood services, but need a structure to have PDMPs returned

Public Private partnerships - toll manufacturing and technology transfer, followed by domestic manufacturing

- Egypt (Grifols) in early phase – technology transfer to come
- Indonesia (SK Plasma)

Some generalisations globally

Global Imbalance and Over-reliance on the US dependance on imports creates exposure to market fluctuations and shortages

High Infrastructure Costs: Establishing, operating, and maintaining plasma collection centres and fractionation facilities - few fractionators in market, long timelines

Increasing Demand: , IVIG use is rising rapidly due to new applications, inappropriate use, and increased diagnosis

Donor Safety vs. Demand: Increasing donation frequency to meet demand risks donor health, reduce yield and paid donation can impact VNRBD sustainable systems

Logistical and Regulatory Barriers: Regulation variable, necessary but restrictions on moving plasma and PDMPs products across borders

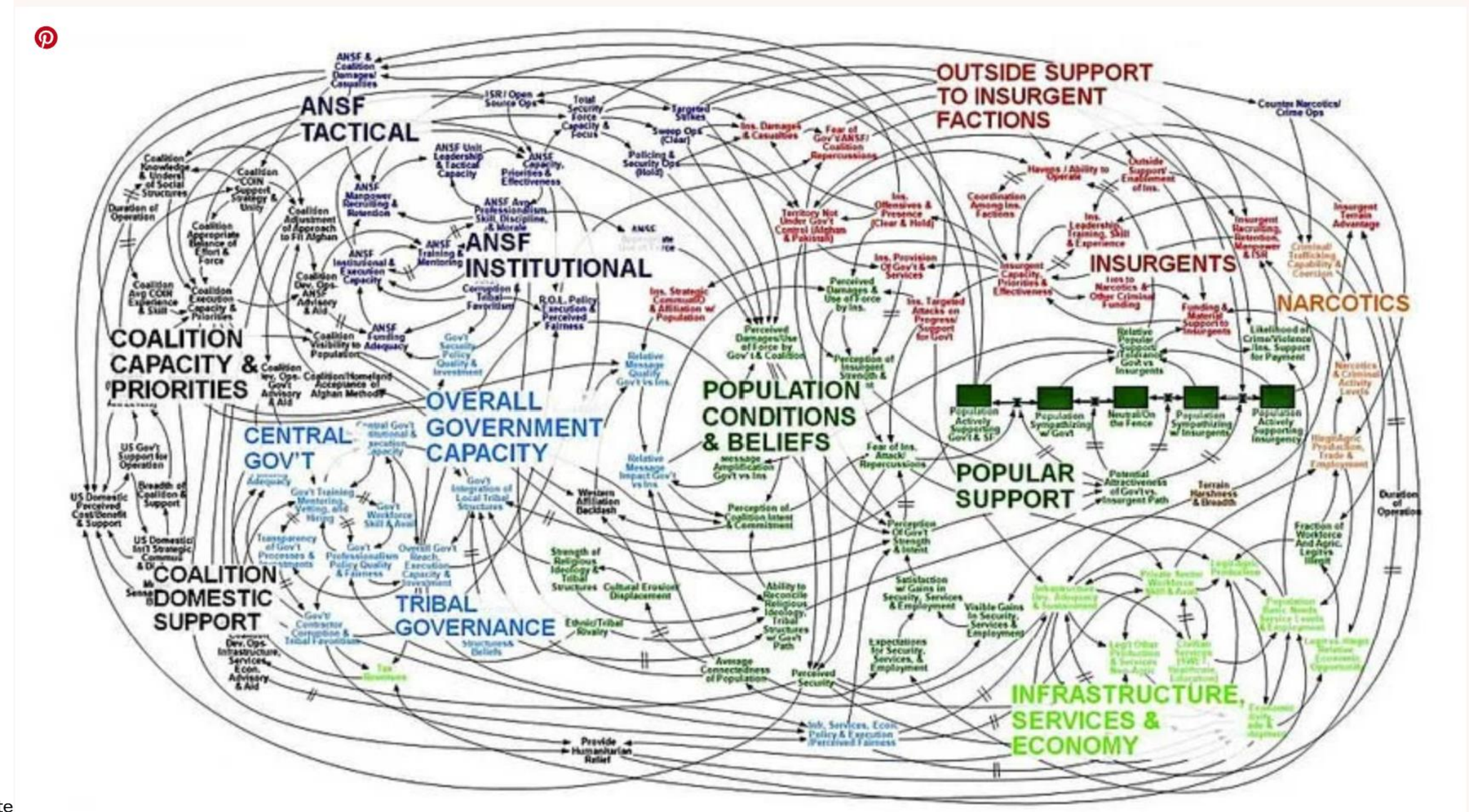
Asia, W Pacific, LATAM, Africa: increasing PDMP production but still not meeting local demand

SUPPLY - Crisis Scenarios Assessed

- Pandemic
- War / Armed conflict
- Climate change
- Trade war

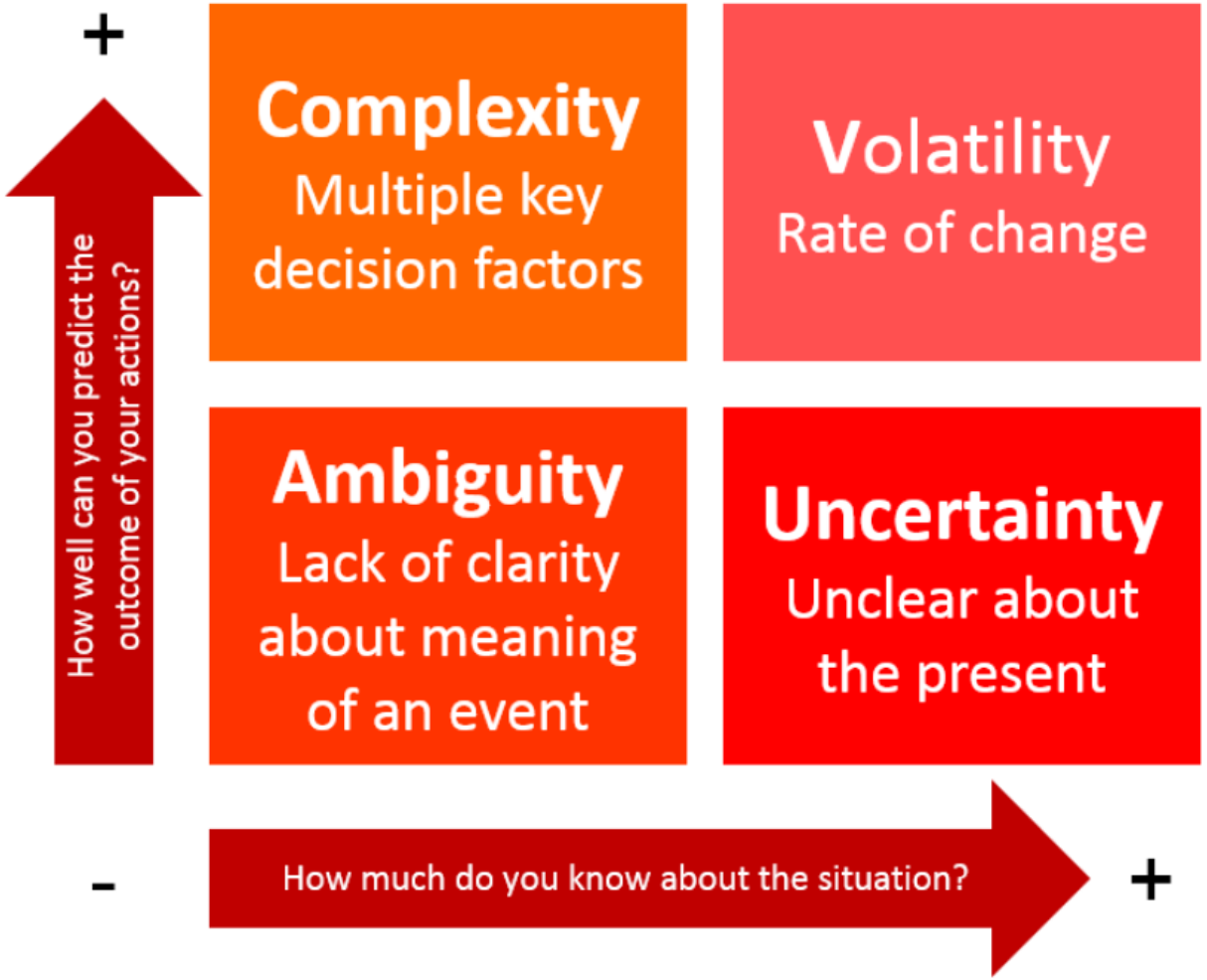
Crises may overlap and **amplify impacts** on plasma supply

The world today …. simple right!



Inte
of Blood Transfusion

A VUCA world!


+
How well can you predict the outcome of your actions?
Complexity
Multiple key decision factors
Volatility
Rate of change
Ambiguity
Lack of clarity about meaning of an event
Uncertainty
Unclear about the present
-
How much do you know about the situation?
+

SUPPLY – conclusions on resilience for Europe

Plasma is a public health asset

Resilience must be built before crises occur

Crises are inevitable and interconnected

Strategic autonomy requires:

- Activate national SoHO emergency plans
- Implement PDMP prioritisation protocols
- Intensify communication with:
  - EMA, manufacturers, patients, donors
- Adapt donor recruitment strategies
- Ensure flexible crisis funding
- Maintain donor and patient protection

Political commitment

Long-term planning

Coordinated EU and national action