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

# Recruitment and retention of safe blood and plasma donors

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I declare that I have NO affiliations with or involvement in any organization or entity with any financial interest, or non-financial interest in the subject matter or materials discussed in this presentation.

#### Agenda

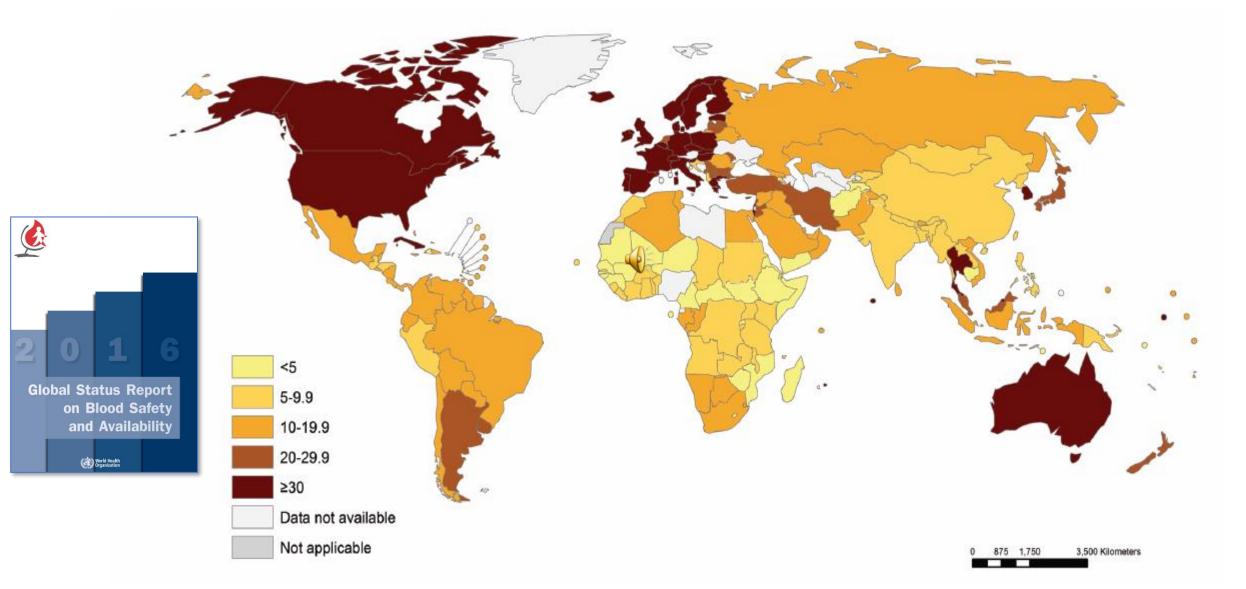
- Overview on the current status of blood and plasma availability worldwide according to WHO data
- Guiding principles for recruitment and retention of blood and plasma donors in LMIC
- Culturally sensitive promotion of blood and plasma donation and social marketing
- The role of Blood Donor Organizations and Associations
- Sensitization and education of donors on the specific value of plasma and its products
- Protection of donors' health and rights
- Final comments / Take-home messages

#### Aims of the topics

- To provide a general overview on blood donation and blood and plasma availability in LMIC.
- To provide general guidance on:
  - implementation and consolidation of culturally sensitive promotion of donation
  - applying the principles of social marketing as a strategy for donor recruitment and retention
  - sensitization and education of donors on the specific value of plasma and its products

World Health Organization

#### Figure 3. Whole blood donations per 1000 population, 2013





### WHO Global Database on Blood Safety – 2018 Update (1/4) 171 reporting countries

• As of <u>2018</u>, about <u>118.4 million</u> blood donations are collected worldwide. <u>40% of these are collected in high-income countries</u> (HIC), home to 16 % of the world's population.

MEDIAN WHOLE BLOOD DONATON RATE/1000 pop	
High-income countries (HIC)	31.5
Upper-middle-income countries (UMIC)	15.9
Low-middle-income countries (LMIC)	6.8
Low-income countries (LIC)	5

• 62 countries report collecting fewer than 10 donations/1000 pop. All of these are LMIC.



### WHO Global Database on Blood Safety – 2018 Update (2/4) 171 reporting countries

- In 56 countries, more than 50% of the blood supply is still dependent on family/replacement and paid blood donors (47 LMIC).
- 79 countries collect more than 90% of their blood supply from voluntary unpaid blood donations.
- An increase of 7.8 million blood donations from voluntary unpaid donors from 2013 to 2018 has been reported by 156 countries.



### WHO Global Database on Blood Safety – 2018 Update (3/4) 171 reporting countries

- World Health Assembly resolution WHA63.12 urges Member States to pursue blood <u>and plasma</u> self-sufficiency through efficiently managed and sustainable blood <u>and plasma</u> programs.
- Individual governments should **ensure sufficient and equitable supply of plasma-derived medicinal products (PDMPs)**; driving products: immunoglobulins and coagulation factors.
- Only 55 of 171 reporting countries produce PDMPs through the fractionation of plasma collected in the reporting country.
- Around **25.6 million litres of plasma** from (only) 39 reporting countries were fractionated for the production of PDMPs in 2018 (~47% recovered plasma).



### WHO Global Database on Blood Safety – 2018 Update (4/4) 171 reporting countries

- Nearly 100% of the donations in UMIC are screened following basic quality procedures, as compared to 82% in LMIC.
- The prevalence of transfusion-transmissible infections in blood donations is considerably higher in LMIC than in HIC
- Only **37% of the blood collected in LIC is separated into components, 69% in LMIC**, 95% in UMIC, and 97% in HIC.
- In most LMIC, millions of litres of plasma that could be recovered from whole blood are currently either not separated or are destroyed.
- The volume of recovered plasma wasted in the world that would be potentially available for fractionation is close to 10 million litres.

(https://www.who.int/phi/publications/blood-prods technology transfer.pdf)

Part of this plasma might also be used in larger blood centers for local preparation of safe plasma proteins, using pathogen reduction or virus-inactivation steps when finishing therapeutic products such as FFP and cryoprecipitate.

#### Recruitment and retention of blood and plasma donors in LMIC

- Any donor population should be healthy, stable, reliable and flexible.
- **Blood and plasma donor management** is the first of many steps in the blood transfusion chain. It helps to make the blood supply safer and more sustainable.
- Effective donor management and donation systems should rely on low-risk, regular, voluntary unpaid donors, include donor care and protect donors' health and rights.
- The development and application of national and local strategies for donor recruitment and retention are high priorities.
- The strategies should aim at maintaining a sufficient and safe blood supply, according to the increasing demand for blood components for transfusion due to progressive medical advancements in LMIC and unmet needs, including those for plasma-derived medicinal products PDMPs.

#### Culturally sensitive promotion of blood and plasma donation (1/4)

- Blood and plasma donation rates vary significantly by area, location and community. Different ethnic groups have different donation rates.
- There are strong relationships between donation rates and age, gender, education, social class, occupation and religion.
- Promoting blood and plasma donation requires identifying the relevant **behavioural and psychological characteristics of donors = what motivates some individuals and not others to donate**.
- It involves understanding fundamental aspects of donors' social networks and community, beyond focusing on appeals to altruism.

#### Culturally sensitive promotion of blood and plasma donation (2/4)

- Interventions for donor recruitment and retention need to be socially and culturally focused and designed to overcome any discrimination.
- Blood and plasma donation should be seen as **an inclusive process**, encompassing **not only individual-level factors** but **also the expression of socially determined commitments, including social reciprocity**.
- Donors should become motivated to act in the <u>wider interest of the networks in which these</u> relationships have been formed.

### Culturally sensitive promotion of blood and plasma donation and *social marketing* (3/4)

<u>Social marketing</u> is an approach used to develop activities aimed at <u>changing or maintaining</u> people's behaviour for the benefit of individuals and society as a whole.

Combining ideas from *commercial marketing* and the *social sciences*, social marketing is a proven tool for influencing behaviour in a sustainable and cost-effective way.

- **Up-to-date principles of social marketing** should be applied to recruitment and retention of blood and plasma donors if a secure and safe blood and plasma supply is to be ensured.
- Social marketing in blood donation is <u>not</u> <u>about selling or offering products</u> but about <u>selling a</u> <u>good feeling to donors and to the whole community</u>.

### Culturally sensitive promotion of blood and plasma donation and social marketing (3/4)

- *Marketing* of donor recruitment should be a socially oriented process that not only informs the population about blood and plasma needs but <u>also changes attitudes and public orientation</u> so that more members of the community will become donors.
- The ultimate goal is to create a solid and positive culture of voluntary non-remunerated blood donation as a normal part of a healthy lifestyle.
- It is fundamental for any well performing blood organization to establish a **long-lasting relationship with donors and their social environment**, since this can enhance consistency and flexibility of supply, cost-effectiveness and blood safety.

# Culturally sensitive promotion of blood and plasma donation and social marketing - The role of Blood Donor Organizations (4/4)

• In many countries in the world, millions of blood donors giving millions of blood and plasma donations per year are organized in not-for-profit, nationally recognized blood donor organizations and associations, coordinated at global level by the International Federation of Blood Donor Organizations (FIODS/IFBDO).



• These blood donor organizations and associations, where present, make a significant contribution to their respective national and local blood organizations and health care systems.

# Sensitization and education of blood and plasma donors on the specific value of plasma and its products (1/3)

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Selection of Blood, Blood Components, and Blood Products as Essential Medicines in 105 Low- and Middle-Income Countries



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 In 105 LMIC the median number of WHO listed blood products of human origin included in the of national lists essential medicines was 4 (range 0-10). Immunoglobulins were most frequently included (73%),overall inclusion of plasmaderived products was around 50%, and blood and blood components, which were added to the WHO listing in 2013, were the least selected products **(15%)**.

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### Sensitization and education of blood and plasma donors on the specific value of plasma and its products (2/3)

- Sensitization and education of blood donors on the importance of plasma components for transfusion and of plasma as a raw material for fractionation, as well as on the clinical value of PDMPs, should focus on their crucial therapeutic role, and on the strategic value of plasma as an essential resource for healthcare.
- The continued importance in LMIC of fresh frozen plasma, cryoprecipitate and cryoprecipitate-poor plasma as alternative therapies in the absence of specific lifesaving PDMPs (for example, factor IX, factor VIII and fibrinogen) should be emphasized.
- In LMIC, the **intensity of interventions of social marketing** to promote blood and plasma donation, **should be commensurate with the state of development of the blood system**, taking into account gaps that may exist in GMP compliance of the blood services.

### Sensitization and education of blood and plasma donors on the specific value of plasma and its products (3/3)

- Raising awareness of the value of plasma for fractionation is intrinsically challenging.
- The progression of blood collection from whole blood to whole blood plus plasma (through plasmapheresis) is a fundamental path towards increased production of plasma for fractionation.
- Introducing plasmapheresis requires significant additional investment in terms of specific promotion, social marketing interventions involving donor education and motivation, and a strong focus on donor retention.
- World Blood Donor Day (WBDD) provides a springboard for longer-term donor education programs and blood donation campaigns throughout the year, hence it could serve concurrently to raise awareness in all countries of the importance of plasma as a strategic resource.

#### Protection of donors' health

#### Protection of donors' health:

- is an imperative for ensuring a continued supply of blood, and even more so of plasma for manufacture
- should include **donor vigilance**, to be undertaken as a basic part of a nationally organized haemovigilance system
- should be specifically enhanced if frequent plasmapheresis is implemented.

#### Protection of donors' rights

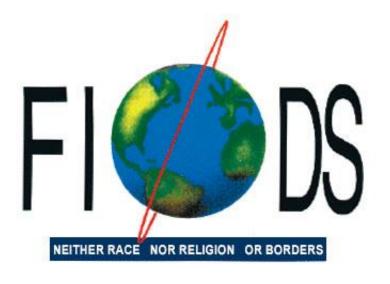
- Protection of donors' rights should be **part of the fundamental ethical principles** underpinning any well established national blood organization.
- The **health**, **safety and well-being of donors** should not be compromised in order to meet the needs of patients and at the same time donors' eligibility to donate should not be unnecessarily restricted.
- The **acceptance criteria** should not be conditioned arbitrarily by gender, race, nationality, religion, sexual orientation or social class, thus excluding any kind of non-evidence-based discrimination.

WHO Blood donor counselling implementation guidelines (2014)

ISBT Code of ethics relating to transfusion medicine (2017)

### Final comments / Take-home messages

- The need for red blood cells separated from whole blood will be steadily increasing in LMIC due to the (hopefully) progressive medical advancements in these countries.
- As a consequence, an increasing volume of plasma potentially usable for fractionation will be generated that will be discarded if no action is taken to improve the current status in these countries.
- Donor management and up-to-date strategies for recruitment and retention of safe blood and plasma donors, based on social marketing, culturally sensitive promotion of donation and the strategic value of blood and plasma, should be extensively implemented in resource-constrained countries.
- Safety and security of the blood supply and voluntary unpaid donation should be priorities, targeting low-risk populations, promoting blood and plasma donation as part of a healthy lifestyle and protecting donors' health and rights.
- Blood Donor Organizations and Associations may play an important role, making a significant contribution to their respective national blood organizations and health care systems.



#### THANKS FOR YOUR ATTENTION!