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COVID-19 PANDEMIC AND BLOOD AVAILABILITY IN LOW- AND MIDDLE- INCOME COUNTRIES: WHAT HAPPENED?

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ABSTRACT

Background: Of the 118.5 million blood donations collected globally in 2023, 40% of these were collected in high-income countries, home to only 16% of the global population. An increase of 10.7 million blood donations from voluntary unpaid donors, excluding paid and family and acquainted donors, has been reported from 2008 to 2018. In total, 79 countries collected over 90% of their blood supply from voluntary unpaid blood donors. However, 54 countries collected more than 50% of their blood supply from paid or family/acquainted donors.

Observation – When the COVID-19 pandemic conquered the world, the blood shortage in the less developed world unfortunately decreased. Based on samples of 1000 adult people, the pre-COVID-19 blood donation rate of 31.5 donations in high-income countries, 16.4 donations in upper-middle-income countries, 6.6 donations in lower-middle-income countries and 5.0 donations in low-income countries changed dramatically.

Response – The Asian Association of Transfusion Medicine (AATM) investigated early 2020 the blood supply situation (challenges and approaches) in 25 member states (Low-and Medium Income Countries (LMICs). The Global Transfusion Forum of the Association to Advance Blood and Biotherapies (AABB) did a survey with 31 blood collection institutions in 26 LMICs focused on characterization of the challenges experienced during the global pandemic and the adaptations and resilience, published in 2022

WHO responded immediately to the outbreak, supporting organization and governance of the blood supply.

Conclusion – Due the to the adequate action of WHO in Geneva, and the alertness of AATM, and the GTF of AABB reacting on the outbreak of the COVID-19 the pandemic turned out to be a 'blessing in disguise' for the future of the global blood supply illustrating prominently the existing challenges and weaknesses, and providing tools to accelerate COVID-19 risk mitigation and blood supply progress.

Key words: COVID-19 Pandemic, Blood Supply, Disaster and Emergency preparedness and Response.

INTRODUCTION

The 2019 COVID-19 pandemic caused a serious global disruption of the blood supply responded by WHO[1] and other international and local organizations. However, before the pandemic in the Low- and Middle- Income Country (LMIC) part of the world, home to 84% of the global population, the blood supply still faced a protracting shortage[2].

The Asian Association of Transfusion Medicine (AATM) responded late 2019 with a survey focused on disaster preparedness among their member states (n=25) with a response rate of 92% and published in 2020[3] and a Aide Mémoire type recommendation[4], and guidelines on disaster and emergency preparedness for Asia focused on how to approach the blood supply system during the pandemic and other disasters and emergencies[5,6].

In 2020 the Global Transfusion Forum of the Association to Advance Blood and Biotherapies (AABB) launched a survey among blood collection institutions in LMICs (n=111, response rate 27.9%, representing 26 LMICs) to characterize the challenges experienced during the pandemic and the resilience and adaptations of the responding institutions, which was published in 2022[7].

Evidently, other international and local organizations followed with more publications[8,9] and focused on the collection of COVID-19 convalescent plasma[10,11].

METHODS USED

AATM and AABB used a cross-sectional survey sent by e-mail to respectively 25 and 26 LMICs. AATM survey was sent to the AATM country representatives, and covered largely Asia, Western Pacific and Eastern Mediterranean WHO Regions, where the AABB survey covered largely the Americas (PAHO) and African WHO Regions. Their survey was e-mailed to 111 selected LMIC transfusion practitioners. Statistics: AATM used basic metrics, while AABB used mixed analysis methods including the basic metric statistics. Results of both surveys were published[3,7].

RESULTS: SITUATION, CHALLENGES AND RELATED OBJECTIVES

When prescribed and practiced appropriately, blood transfusion may contribute to saving lives and improving health, but today still many patients requiring supportive transfusion do not have timely access to safe blood or blood components.

The blood donation rate per 1000 adult people is 31.5 in high-income countries, 16.4 in upper-middle-income countries, 6.6 donations in lower-middle-income countries and only 5.0 donations in low-income countries. During the pandemic the Middle- and Low-Income Country rates changed dramatically during the pandemic. In the immediate pre-pandemic episode, of the annual global blood donations 40% were collected in high-income countries, home to only 16% of the global population which means that 60% was collected in that part of the world home to 84% of the global population. An increase of 10.7 million blood donations from voluntary unpaid donors, excluding paid, family and acquainted (replacement) donors, has been reported from 2008 to 2018[2]. Data show that in total about 80 countries collected over 90% of their blood supply from voluntary unpaid blood donors. However, 54 countries collected over 50% of their blood supply from paid or family/acquainted (replacement) donors, a serious infection risk (HBV, HCV, HIV and Syphilis) being equal to first time and untested voluntary non-remunerated donors (VNRD).

Providing safe and adequate blood and blood components from regular and non-remunerated donors – male and female – should be an integral part of every country's national health care policy, legislation and operational infrastructure.

WHO recommends a health care policy[12] that all activities related to blood collection, testing, processing, storage and distribution to licensed health care facilities be coordinated at the national level through effective organization, governance and integrated blood supply networks. The national blood system should be governed by a

national blood policy and legislative framework to promote uniform implementation of standards and consistency in the quality and safety of blood and blood products/components[13].

In 2018[2], 73 %, or 125 out of 171 countries, had a national blood policy. Overall, 66% or 113 out of 171 countries had a specific legal framework covering the organization and governance of the blood system, and the safety and quality of blood transfusion, including:

- 79% of high-income countries (HIC);
- 63% of middle-income countries (MIC); and only
- 39% of low-income countries (LIC).

Additionally, the capacity to provide patients with the different blood components they require, like red cells, platelets, plasma and cryoprecipitate is still limited in low-income countries: 38% of the blood collected in LICs was separated into components, 75% in lower-middle-ICs, 96% in upper-middle-ICs, and 96% in HICs reflecting a gap in the rationalization of supportive treatment in clinical transfusion medicine (TM).

WHO responded to the pandemic outbreak supporting in particular the LMICs with an '*Action Framework to advance universal access to safe, effective and quality-assured blood products 2020-2023*'[14] which lists the main challenges experienced and still present, and provides a series of six strategic objectives each with a number of high-level outcomes to be expected.

DISCUSSION

Challenges –

Since 1998, WHO has collected and analyzed data on blood and blood products safety and availability from Member States through the online WHO Global Database on Blood Safety (GDBS)[15], providing evidence-based data for action to improve blood transfusion services globally. The present 2021 document[2] cites an interim analysis of the more recent 2015 GDBS. Although the WHO GDBS has a number of acknowledged limitations, the 2015 survey benefited from a response rate of close to 90% and provides guidance and high-level insights to global efforts to ensure access to safe blood components also during disasters like the COVID-19 pandemic and humanitarian emergencies (armed conflicts), identifying a series of current challenges:

1. <u>deficiencies in national policy, governance and financing</u>;
   barriers to a well-functioning national blood system include lack of political commitment and awareness of the essential role of a national blood system in the larger health system and failure to appreciate the societal cost of blood insufficiency versus the cost of providing an adequate and safe blood supply;

2. <u>insufficient supply of safe, effective and quality-assured blood products for transfusion</u>;
   barriers to adequate blood collection include ineffective donor motivation strategies with low rates of voluntary non-remunerated donation; cultural resistance or lack of education affecting willingness to donate; family or replacement and paid collection instead of regular community-based donation to maintain an available inventory; absence of support for voluntary non-remunerated donation with repeat donation as the basis of a sustainable system; absence of a nationally coordinated blood service; logistical complexity of blood collection in non-urban areas (particularly in LMICs); lack of government commitment to a nationally coordinated blood service that optimizes resources and minimizes destructive competition amongst multiple service providers;

3. <u>deficiencies in blood product safety, effectiveness and quality</u>;
   barriers to quality-assured infectious diseases, blood grouping and compatibility testing of blood donations include insufficient regulatory and professional oversight; absent or poorly

implemented legislative and regulatory frameworks; unreliable supply management of reagents and assays (for example, test kits for donation screening and blood grouping reagents); weak or absent controls of reagents and assays, and related laboratory practices; poor ease of use of available laboratory systems relative to skill levels (education); weak or absent quality management systems in blood collection and preparation of blood products; lack of hemovigilance monitoring to identify safety issues and drive improvements; but also barriers to ensuring that blood is collected from low-risk donors which include costs of donor motivation; insufficient public education and outreach to promote awareness and to overcome fears and cultural biases; inadequate pre-donation screening and risk assessment of donors; absence of epidemiological monitoring for transfusion-transmissible infections in the general population and in the blood donor population, hindering public health efforts to identify and motivate low-risk donors.

4. insufficient availability of PDMPs;
   barriers to the provision of quality and safe plasma for fractionation include limited use of component preparation to generate recovered plasma; failure to meet internationally recognized standards for blood collection and blood component preparation necessary to ensure quality of recovered plasma acceptable to a contract fractionator; poor cold chain and supply chain logistics; high cost and complexity of apheresis to generate plasma; absence of regulatory oversight precluding assurance that appropriate standards are met;

5. suboptimal clinical practices in transfusion of blood components;
   barriers to appropriate clinical use of blood include limited training and knowledge in transfusion medicine (education); lack of awareness and education on patient blood management (PBM); absence of national evidence-based guidelines for transfusion; absence of effective transfusion committees in hospitals (HTC); poor practices in blood component preparation, storage and handling, including maintenance of the cold chain;

6. insufficient access to blood during emergency situation;
   globally, the number of people affected by disaster and emergency situations, and blood service disruptions, including infectious disease outbreaks like the COVID-19 pandemic, is increasing. During a disaster and an emergency, the need for blood transfusions can increase significantly. Therefore, safe and quality blood components to rationally treat those affected are of lifesaving importance. However, ensuring a safe blood supply often proves to be challenging, as:
   The emergency or disaster may have damaged the available civil and health care infrastructure which in many LMICs is commonly weak and brittle; disrupting mobility, transportation and service provision; the population may stay away from donating blood, due to either fear, gossip or (COVID-19) illness; the means of communication may not be reliable or be disrupted; the overall health care system may have become overburdened.

The Action Framework[14] lists a number of responsive and stimulating strategic objectives with high-level outcomes for countries in need, largely the LMICs. These are responsively and intentionally linked to the above mentioned challenges in the attempt to provide a road map for further development, sustainability and strengthening of blood supply systems. .

Strategic objectives –
The strategic objectives have a log frame that supposedly will guide the development, strengthening and implementation of action, context-specific to address the needs of regions and countries such as the Eastern Mediterranean

Region, the Southeast Asian Region and the Sub Sahara African Region, and countries in the Latin-American part of the Americas Region (PAHO).

The six strategic objectives with their high-level outcomes are:

Strategic objective 1. - An appropriately structured, well-coordinated and sustainably resourced national blood system.

To achieve strategic objective 1, the following high-level outcomes have been identified –

1.1 The national blood system is appropriately structured, well-coordinated and integrated into the national health system.

1.2 The national blood system is adequately and sustainably costed, financed and budgeted.

1.3 National policies and decisions involving blood products are made through good policy process and risk-based decision making.

1.4 There is an adequate and safe blood supply during emergency situations such as infectious disease outbreaks like the COVID-19 pandemic, natural disasters and humanitarian emergencies.

Strategic objective 2. - An appropriate national framework of regulatory controls, national standards and quality assessment programs.

To achieve strategic objective 2, the following high-level outcomes have been identified –

2.1 The national blood regulatory system is in place and functions at an externally assessed maturity level of 3 or 4 under the Global Benchmarking Tool (GBT) Plus Blood.

2.2 Regulatory mechanisms are in place for comprehensive oversight of blood products, associated substances and medical devices, including IVD devices.

2.3 Quality assessment of blood products, associated substances and medical devices, including IVD devices, is carried out by relevant authorities and national control laboratories.

2.4 Performance of blood products and associated substances and medical devices, including IVD devices, is assured through use of reference biological standards and external quality assessment schemes.

Strategic objective 3. - Functioning and efficiently managed blood services.

To achieve strategic objective 3, the following high-level outcomes have been identified –

3.1 There has been achievement of 100% voluntary, non-remunerated blood donation, protection of blood donor health and safety, and promotion of repeat donation.

3.2 A functioning quality system is in place across the entire blood transfusion chain.

3.3 Blood services are efficiently and cost effectively managed, and donated blood processed according to clinical need with minimal wastage.

3.4 Availability of the volume and quality of plasma for manufacture into PDMPs has been clearly increased.

Strategic objective 4. - Effective implementation of patient blood management to optimize clinical practice of transfusion.

To achieve strategic objective 4, the following high-level outcomes have been identified –

4.1 Good patient blood management (PBM) is practiced, based on national clinical guidelines and practice standards.

4.2 A quality system is in place in hospitals for all pre-transfusion testing and clinical transfusion processes, including hospital blood bank laboratories.

Strategic objective 5. - Effective surveillance, hemovigilance and pharmacovigilance, supported by comprehensive and accurate data collection systems.

To achieve strategic objective 5, the following high-level outcomes have been identified –

5.1 There is a national system for standardized data collection and reporting, and mechanisms to ensure uniform implementation.

5.2 There are systems for traceability, surveillance, hemovigilance and pharmacovigilance at national and organizational levels.

5.3 The WHO GDBS provides comprehensive and accurate data on the global status of blood product availability, safety and quality.

Strategic objective 6. - Partnerships, collaboration and information exchange to achieve key priorities and jointly address challenges and emerging threats at global, regional and national levels.

To achieve strategic objective 6, the following high-level outcomes have been identified –

6.1 Training programs on key functions of the national blood system are in place.

6.2 Capacity to carry out external assessment and accreditation of national blood establishments is available.

6.3 The capacity to evaluate relevant new technologies and other innovations is incorporated into the national blood system to overcome local impediments and to address urgent situations.

6.4 Regulatory capacity is strengthened through collaborative capability-building and harmonization initiatives, including use of reliance.

For each of the first five sets of high-level outcomes WHO created a practical Guidance related to the identified challenges.

Strategic objective 1

High-level outcome: *Structured, well-coordinated, and sustainably resourced national blood system,.*

- Guidance on costs of blood services;
- Guidance on ensuring a safe blood supply during emergency situations.

Strategic objective 2

High-level outcome: *Appropriate national framework of regulatory controls.*

- Guidance on quality assessment of blood products, associated substances, and medical devices, including IVD devices.

Strategic objective 3

High-level outcome: *Functioning and efficiently managed blood services.*

- Guidance on centralization of blood donation testing and processing;
- Guidance on increasing the supply of PDMPs in LMICs through fractionation of domestic plasma.

Strategic objective 4

High-level outcome: *Effective implementation of patient blood management.*

- Education module on updating the clinical use of blood;
- Policy brief for the implementation of patient blood management

Strategic objective 5

High-level outcome: *Effective surveillance; hemovigilance and pharmacovigilance.*

- Tools for stepwise implementation of a hemovigilance system.

Unfortunately, the regional and country progress showed to be disappointingly slow due to the challenges, but also due to the COVID-19 pandemic, which interrupted or sometimes even paralyzed the operational blood supply system with extreme shortages and fear of populations as an outcome.

WHAT HAPPENED?

The two surveys showed the informative results – AATM survey: Response rate: 92%; HDI classification: Low– 1; Medium– 9; High– 9 and Very High– 4 countries; population range: 540,544–1,380,000,000; blood collection/1000 donations: 24–361. Ranges/1000: hospital beds, intensive care/isolation beds and ventilators respectively: 0.5–82; 0.019–18; 0.0007–111. All countries had quarantine facilities. All but three countries had sufficient personal protractive equipment (PPE). All but three countries had blood testing facilities . All but one country listed challenges and responses. Most common challenges and approaches were, respectively, shortages in blood donors and operational supplies (19/22), staff safety (13/22); and mass media education and awareness campaigns (21/22), staff education on safety practices and universal precautions (18/22).

AABB GTF survey: Response rate: 27.9%. Replacement donation (3/27), 67% (16/24) of respondents experienced a considerable decline in

blood availability, ranging from 10-50%. Contributing factors included public fear of COVID-19 (21/24); stay-at-home measures (18/24); logistics (14/24); significantly less blood donation (16/24); cancelled blood drives (16/24). However, adaptations included increased collaboration (17/27), donor eligibility changes (21/31); social media or telephone promotion (22/39).Fifteen respondents reported COVID-19 convalescent plasma (CCP) donations (48.4%) while CCP transfusion only occurred in 6 (19.4%). The primary barrier was engaging recovered patients for donation (7/15).

WHO concluded that the slow pre-COVID-19 pandemic progress of the blood supply in LMICs was further affected and existing challenges increased. Response consisted of a '*Guidance to identify barriers in blood services using the blood system self-assessment (BSS) tool*' consisting of an Introduction, and chapters on the Action framework challenges and strategic objectives, a chapter on the development of the BSS, and a chapter on potential solutions followed by a series of practical annexes[16], The BSS tool was developed in collaboration with the USAID and the Boston Consulting Group (BCG)[17].

Resilience and Recovery

Disaster management is a cycle of recurring events with four interwoven phases: mitigation, preparedness, response and recovery, the last two based on resilience of a population including health professionals.

Frequency, scope and diversity of manifestations of disasters and emergencies and the occurrence in different parts of or spread over the world, like the COVID-19 pandemic, make it is important to be well prepared for diverse crises and their potential impact on the availability and safety of the blood supply. Where there is already a shortage existing the impact may be dramatic.

Disaster and emergency planning for events to happen that could affect the blood supply availability and safety should be carefully considered at local and national levels. The need for blood during disasters is not limited to injured people because transfusion-dependent patients (surgical, obstetric, hematologic, oncologic, pediatric and hemoglobinopathies like sickle cell disease (SCD) and thalassemia, and coagulation disorders like thrombocythemia, hemophilia and von Willebrand Disease) are also likely to be affected due to disruption of the blood supply. Planning for disasters and emergencies to occur should involve a healthcare integrated and coordinated, multidisciplinary approach to define and document the various tasks and responsibilities. The plan should be documented, validated, well communicated and beforehand tested to ensure that it can address critical needs depending on the available resources.

The key health service functions that are best associated with a resilience strategy are governance and stewardship, finance, resource and service delivery associated with alternative and flexible approaches to deliver care as good and personal as possible. The key resource is a well-educated, motivated and well-supported workforce who deserve support and encouragement to anticipate, cope and adapt.

CONCLUSION

Emergencies and disasters like the COVID-19 pandemic may affect and disrupt seriously blood collection (donors), screening, processing, an\d the cold chain part storage and distribution, and in the hospital or healthcare institution the bedside issuing and transfusion in different ways depending also on implemented mitigation measures like a general lock down or local triages in blood establishments and hospitals or health care institutions. AATM and the GTF of the AABB responded to the LMICs with a survey to find out the impact of the pandemic on the blood supply in the LIMCs. WHO responded with supportive guidance to strengthen the blood supply system in LMICs.

Afterall the COVID-19 pandemic has shown to be a 'blessing in disguise'.

CONFLICTS OF INTEREST

The author declares to have no conflicts of interest.

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