WHO ACTION FRAMEWORK AND GUIDANCE ON MAINTAINING BLOOD SUPPLY DURING COVID-19 PANDEMIC

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OUTLINE

• Introduction
• WHO Action framework for blood products 2020-2023
• WHO Guidance on Maintaining blood supply during pandemic of COVID-19
• Collection of COVID-19 Convalescent Plasma (CCP)
Introduction

• WHA 63.12 urges Member States to ensure availability, safety and quality of blood products

• GDBS 2015 point to a number of inadequacies related to the supply and safety of blood

• Blood services play an important role during emergency situations, but blood supply in this situation always experiences problems

• Emergency situation includes natural disaster, conflict situation and infectious disease outbreaks

• Emergency preparedness in blood services must be done, not only to guarantee the availability of blood but also its safety and quality
Reason of development of the Action Framework

- To respond an inadequacy of blood supply and safety, WHO has issued not only WHA resolutions but also guidance documents on blood.

- Countries that implement these resolutions and guidance (mostly developed countries) are making progress in providing safe blood and blood products.

  - BUT...

- Progress in establishing and strengthening national blood systems has been slow in many countries.

- Need to push for implementation of WHO guidance at country level - particularly in low and middle income countries (LMICs).
Action framework for blood products 2020-2023

- **Action framework** has been launched on 27 February 2020
- **Strategic direction** to global efforts to address present barriers to safe blood
- Responds to **WHA 63.12** on Availability, safety and quality of blood products
- Aligns with **13th WHO GPW** and Strategic Plan for WHO Regulatory Support Activities for Health Products 2019-2023
- **Implementation** of resolutions, goals & strategies
- To be used for **partnership and fundraising**

**Mission**
- Promote Health - Keep the World Safe - Serve the Vulnerable

**Strategic Priorities**
- **Health Coverage:** 1 billion more people with health coverage
- **Health Emergencies:** 1 billion more people made safer
- **Health Priorities:** 1 billion lives improved

https://www.who.int/health-topics/blood-transfusion-safety/#tab=tab_1
CHALLENGES IN BLOOD SERVICES

- Inadequacy in policy, regulations, governance & financing
- Insufficient supply of blood products
- Deficiencies in safety, effectiveness and quality
- Lack of availability of PDMPs
- Poor access to blood during emergency
- Sub-optimal clinical practices
- Limited use of component
  - Low vol & quality of plasma

- No blood preparedness during emergency situation
- Patient Blood Management not in place

- 60-70% MS with blood policy, legislation, oversight system
- 66 population MS with donation rate <10/1000
- 80% of donated blood was tested in LMICs

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- Low vol & quality of plasma

- Poor access to blood during emergency

- Sub-optimal clinical practices

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PROPOSED ACTIONS: SIX STRATEGIC OBJECTIVES

- Appropriately structured, well-coordinated and sustainably resourced national blood system
- Appropriate national framework of regulatory controls
- Functioning and efficiently managed blood services
- Effective implementation of patient blood management
- Effective surveillance, haemovigilance and pharmacovigilance
- Partnerships, collaboration and information exchange
ACTIVITIES 2020-2023

DEVELOPMENT OF GUIDELINES

1. Guidance on centralization of blood testing & processing
2. White Paper on PDMPs
3. Guideline on preparedness of an adequate and safe blood supply during emergency situations
4. Revise guidelines on clinical use of blood
5. Guidance on Patient Blood Management
6. Guidance on Costing of blood services

TECHNICAL ASSISTANCE

• On Regulatory and/or Technical aspect of blood services:
  1. Workshop/Webinar
  2. Training
  3. Site visit
  4. Site assistance

• WHO Interim Guidance first published on 20 March 2020
  o Adapted from WHO Guidance for National Blood Services on Protecting the Blood Supply During Infectious Disease Outbreaks https://www.who.int/publications-detail/protecting-the-blood-supply-during-infectious-disease-outbreaks-guidance-for-national-blood-services and risk assessments on COVID-19 from regional networks and institutions
  o Response to regional requests to increase flexibility and to add details
  o Addition of recommendations on collection of convalescent plasma
  o Inputs received from subject experts of many international organizations

Content of the Interim Guidance

• General Considerations
• Mitigating the potential risk of transfusion-transmitted SARS-CoV-2
• Mitigating the risk of staff and donor exposure
• Mitigating the impact of reduced donor availability
• Managing the demand for blood products
• Ensuring supplies of critical materials and equipment
• Communication
• Collection of convalescent plasma
General Considerations (I)

Transfusion transmission of SARS-CoV-2 has not been reported, but theoretically is possible warranting reasonable precautions.

Reduced blood donation and collection → impact blood supplies.

Appropriate actions to mitigate harms require data-driven risk assessments of the local epidemic (country/region) in the context of the public health system.

A national approach should be adopted for coherence and coordination and to ensure public confidence in blood safety & supply.

Blood services should be included in the national outbreak response.

Actions taken should be appropriate for the situation, proportionate to risk, and take into consideration:

1. Extent of COVID-19 Spread
2. Level of community circulation
3. Local epidemiology
4. Risk of transfusion transmission in context of overall burden of disease
5. Quality of health care system
6. Public health response
7. Blood supply sufficiency
8. Operational impacts
9. Cost effectiveness of interventions relative to overall country situation
Mitigating the potential risk of transfusion-transmitted SARS-CoV-2

1. Educate donors on risk factors for self-deferral and actively defer donors for risk factors
2. Current pre-donation criteria excluding symptomatic individuals
3. Ask donors to report post-donation illness consistent with COVID-19
4. During widespread community transmission, donor restrictions may need to be evaluated and reduced
5. A haemovigilance system should be in place

- Testing donors or donations for SARS-CoV-19 RNA is not presently indicated in the absence of documented transfusion transmission
- Although likely effective to inactivate SARS-CoV-2 in plasma and platelets, introduction of pathogen reduction technology (PRT) is not recommended where it is not already in place
- No presumed risk of transmission from plasma derivatives
Mitigating the risk of staff and donor exposure to SARS-CoV-2

• Strategies should be proportionate and evidence-based and follow public health measures
  o Public health measures appropriate to community environments with frequent public contact should be followed (e.g., screening for COVID-19 related symptoms, masks and gloves for staff, social distancing, hand hygiene and regular environmental decontamination)
  o If COVID-19 is confirmed in a blood donor or staff, the management of contacts should be done

• Providing information to donors and public about measures taken contributes to gaining confidence to continue donating blood

• Prevent crowding of donors and staff:
• Ensure safety of the donation process and exclude individuals who should not donate at earliest opportunity
• Staff Education on IPC
Mitigating the impact of reduced availability of blood donors

- Prepare in advance how best to respond to a shortfall in donations
- Ensure a clear and consistent communication strategy
- Monitor donation numbers closely to enable a rapid response to evolving shortages, especially of platelets (due to short shelf-life)
- Cooperate closely with hospitals to monitor inventories and demand
- Address barriers to blood collection
- Consider importing blood components from less affected areas of the country, or other countries as permitted by regulatory authorities
Managing the demand for blood and blood products

• Demand for transfusions may decrease during a widespread epidemic
  - The health care system shifts toward treating COVID-19 patients
  - Elective surgeries and non-urgent clinical interventions are deferred

• Transfusions remain necessary for emergency situations (i.e., trauma, post-partum hemorrhage, severe infant anemia, blood dyscrasias, urgent surgeries requiring blood availability)

• Increased blood stocks may be needed to support COVID-19 patients with sepsis or requiring extracorporeal membrane oxygenation

• Good patient blood management and coordination with transfusing physicians can optimize blood use to minimize demand
Ensure undisrupted supplies of critical materials and equipment

• Many factors may compromise the supply of critical materials and equipment used in blood collection, component preparation and laboratory testing (including shortage of immunohematology reagents and infectious disease screening assays)
  o Border closures, transport/trade restrictions, quarantines
  o Disrupted production

• The blood service must take steps to ensure continuity of supplies
  o Early identification of risks to the supply chain from the pandemic
  o Identification of alternative sources
  o Cooperation among blood establishments to share critical supplies as able
Collection of COVID-19 convalescent plasma

• WHO recognizes COVID-19 convalescent plasma (CCP) as an experimental therapy appropriate for evaluation in clinical studies and as a starting material for the manufacture of experimental hyperimmune globulins.

• Clinical studies of CCP may include randomized controlled trials (RCTs) and structured observational studies similar to active arms of an RCT.

• CCP should be prepared only in blood services that can assure product quality in compliance with recognized international standards.

• Preparation and clinical use of CCP should meet ethical criteria for human experimentation in regard to both donors and product recipients.

• Common criteria for acceptance of donors of CCP should be in place.

• CCP should be collected by plasmapheresis to avoid unnecessary red cell loss and to optimize the plasma volume that can be obtained.

• Outcome therapy should be reported.
For general advice on use of CP see: WHO Blood Regulators Network Position Paper on Use of Convalescent Plasma, Serum or Immune Globulin Concentrates as an Element in Response to an Emerging Virus (2017)

Further information on maintaining blood supplies during the SARS-CoV-2 pandemic and on policy statements and protocols for studies of COVID-19 convalescent plasma can be found at an open access website of the International Society of Blood Transfusion

WHO does not endorse any of the statements or protocols listed at this website; reference to this information is provided exclusively to assist stakeholders with identifying links to the various statements, guidelines and protocols.
THANK YOU