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WHO Blood Regulators Network (BRN)

Interim Position Paper on blood regulatory response to the evolving outbreak of the 2019 novel coronavirus SARS-CoV-2*

*This document contains the collective views of members of the Blood Regulators Network (BRN), an international group of blood regulatory authorities, and does not necessarily represent the decisions or the stated policy of the World Health Organization or of the participating regulatory authorities.

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1. Background

Following the first reports of cases of acute respiratory syndrome in the Chinese Wuhan municipality, Hubei province, at the end of December 2019, Chinese authorities have identified a novel coronavirus now named "SARS-CoV-2" (severe acute respiratory syndrome coronavirus 2) as the main causative agent of the "coronavirus 2019 disease" (COVID-19). The outbreak has rapidly evolved, affecting other parts of China. SARS-CoV-2 infections have also been detected in several countries in Asia, as well as in Australia, Europe, North America and Africa. Further global spread is likely. Although many infections appear to be asymptomatic or mild, there are infection courses with disease symptoms of differing levels of severity, with an overall fatal outcome in around 2% of infections in Hubei province, elsewhere possibly less (frequency dependent on case definition and case detection efficiency). (1)

The potential for transmission of SARS-CoV-2 through substances of human origin is not known at present. Potential viraemia during the asymptomatic or subclinical phase of infection, during the disease incubation period, the symptomatic phase of disease, or after symptom resolution is currently unknown and thus, remains an issue in relation to the safety of blood transfusion. However, respiratory viruses, in general, are not known to be transmitted by blood transfusion, and there have been no reported cases of transfusion-transmitted coronavirus so far.

Updated information can be found under the following links:

WHO: https://www.who.int/emergencies/diseases/novel-coronavirus-2019
ECDC: https://www.ecdc.europa.eu/en/novel-coronavirus-china
CDC: https://www.cdc.gov/coronavirus/2019-nCoV/summary.html
GOC: https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection.html

The WHO Blood Regulators Network (BRN) and its national or international agencies for epidemiological surveillance, such as CDC, ECDC and other federal and international institutes, are closely monitoring the evolving outbreak of SARS-CoV-2 and are regularly exchanging new developments and regulatory responses with WHO BRN member countries.

The intention of this interim position paper is to share current WHO BRN thoughts and to support regulatory decisions as a response to the evolving outbreak of SARS-CoV-2. The WHO BRN will continue to monitor the situation and issue updated information as it becomes available.

2. General aspects of blood safety in SARS-CoV-2 pandemic situation

The national blood regulatory agency should ensure that the epidemiological situation regarding COVID-19 is carefully monitored in the country and updated epidemiological information on COVID-19, e.g. from national reporting systems of communicable diseases, is captured and used as an element for assessing the safety of blood donations.

It is recommended that the national blood regulatory agency makes sure that blood transfusion services are alerted appropriately and are included in national pandemic plans. Obviously, in epidemic situations appropriate management of transfusion requirements must be arranged in terms of optimal use of safe blood components.

It is important that also in the early stage of the epidemic, blood safety measures are proportionate and do not risk the ability to maintain a sufficient blood supply with overly precautionary restrictions. The measures taken need to reflect the current outbreak situation in a particular region or country, and the estimation of appropriate safety measures will be different in countries with a rapidly evolving outbreak locally/regionally and in countries that so far have no or only a limited number of infection cases.

3. Donor selection in non-endemic countries

Donor selection is an essential element of blood safety. The principles for donor selection, as laid down in the WHO BRN Position Paper on Donor selection in case of pandemic situations (2007) remain applicable to the current outbreak of SARS-CoV-2 (2). Thus, with the current knowledge on SARS-CoV-2 potential, the permanent or temporary donor deferral criteria already issued to avoid transmission of infectious diseases by transfusion appear sufficient to balance the safety of blood against sufficient availability of blood components.

As a precaution, blood establishments may consider whether to provide donor education, encourage self-deferral, and manage post-donation information about subclinical or COVID-19 associated symptoms. Donation procedures may need to be organized so as to minimize contagion between donors while still assuring a proper flow of work. Facemasks may be provided, and donors should be advised of hand disinfection, following the local or national recommendations on pandemic preparedness measures.

Provision of information material to donors prior to attending to donate blood would facilitate timely “self-deferral” and also contribute to reduce contacts at the blood establishment with potentially infected donors. This measure is recommended depending on the local epidemiological situation.

It is recommended that the blood services raise their awareness of the SARS-CoV-2 outbreak, especially in relation to the travel history of donors or their potential contacts with known infected or “at risk” (e.g. quarantined) individuals, and to assure appropriate post-donation information from donors. Blood donors should be encouraged to report the subsequent development of any flu-like symptoms or a diagnosis of SARS-

CoV-2 infection as soon as possible to the blood establishment.

The risk mitigation strategy with regard to SARS-CoV-2 may also include the following specific measures with regard to donor selection. Several of these measures are already in place in many countries to address known risks due to other infectious agents and are likely to be effective in addressing the current risk related to SARS-CoV-2.
These measures include (and may be adapted as deemed more appropriate):

- introducing deferrals of confirmed COVID-19 cases for 3 months depending on the supply situation, but at least 1 month from the resolution of symptoms and completion of therapy,
- introducing deferrals of close contacts with confirmed COVID-19 cases for 28 days (after the last contact)
- introducing deferrals for travelers returning from SARS-CoV-2 endemic areas or confirming that existing deferrals related to potential exposure to infectious agents (e.g. West Nile Virus, Chikungunya, Dengue, Malaria, etc.) due to travel history of donors are in place; this normally includes a deferral of at least 28 days after returning from such risk areas. This measure is considered to be sufficiently effective also for travelers returning from SARS-CoV-2 endemic areas.
- confirming that defined deferrals of symptomatic donors are applied, e.g. donors who are currently unwell with respiratory symptoms, severe fatigue or fever.

Depending on the current standard donor selection criteria, no new questions may need to be introduced on the donor questionnaire or when interviewing the donors about their travel history. In the current situation, it is recommended to blood regulatory agencies to verify if the existing donor selection criteria already comply with these current international recommendations to address risks of infectious agents.

Blood establishments collecting source plasma intended for subsequent fractionation may consider applying similar precautionary measures, although SARS-CoV-2 is likely to be inactivated by virus inactivation steps during manufacturing of plasma derivatives.
Quarantine of plasma for transfusion and subsequent interviews of the donor for potential symptoms in the interim period(s) may be an additional safety measure.

4. Donor selection in endemic countries

At present no information about the potential transmission of SARS-CoV-2 via blood and blood components is available; potential transmission is estimated unlikely based on knowledge of other types of corona virus. However, in SARS-CoV-2 endemic regions with ongoing transmission, the balance between supplies of life-saving blood components versus safe blood donations must be taken into account. Measures to be taken may differ between outbreak-affected countries, dependent on the specific local situation. The general principals summarized in the WHO interim guidance on “Maintaining a safe and adequate blood supply during Zika virus outbreaks” (WHO/ZIKV/HS/16.1) might be taken into account (3).

It may be further explored whether and to which extent any relaxation of established criteria would become necessary to maintain an adequate blood supply in such an emergency. Any deviation from normal blood establishment procedures, however,

should be limited to pandemic period phase 6 according to the WHO global influenza preparedness plan (WHO/CDS/CSR/GIP/2005.5) (4)

5. Current infectious disease testing

Without extreme necessity, no changes should be permitted in established routine donor screening for infectious diseases. All established assays should be performed using unchanged procedures. This principle should also apply to routinely performed nucleic acid testing (NAT), as any interruption of normal routine may compromise blood product safety.

6. Considerations on testing blood collections for COVID-19

The potential for a viraemic phase of SARS-CoV-2 is currently not known and is likely to be limited to severe disease, analogous to other respiratory infections. With the current knowledge gaps there are too many uncertainties to recommend testing of blood donors for SARS-CoV-2 at present. So far, suitable serological assays for SARS-CoV-2 have not been developed, although the diagnostic community has established NAT protocols for throat swabs. Testing throat swabs of blood donors would interrupt established routine test procedures without a confirmed increase of blood safety.

7. Considerations on collection and use of Convalescent Plasma or Serum

Based on the concept of passive immunization, supported by historical experience, the general possibility exists that application of whole blood, plasma, serum or immune globulin concentrates obtained from convalescent persons might be effective in disease prevention or treatment. For this reason, it is prudent to consider the use of convalescent plasma or serum as a potential treatment measure in response to COVID-19. A decision whether to pursue this option requires a rapid, but thorough, review of the knowledge base for the etiologic agent or related agents and the immune response to them in order to assess the likely benefits and risks of passive immunization in a specific epidemic.

The general principles laid down in the WHO Blood Regulators Network Position Papers on Use of Convalescent Plasma, Serum or Immune Globulin Concentrates as an Element in Response to an Emerging Virus (2017) and on Collection and Use of Convalescent Plasma or Serum as an Element in Middle East Respiratory Syndrome Coronavirus Response (2014) remain applicable also to this outbreak of SARS-CoV-2 (5, 6). It is recommended to explore scientific studies on the feasibility and medical effectiveness for collection and use of convalescent plasma or serum through clinical trials that can be established concurrent with their empirical use. Regulatory agencies should enable progress in this area by establishing appropriate regulatory conditions for the collection of convalescent plasma or serum, the ethical conduct of clinical studies, and the monitoring and reporting of assessable patient outcomes. It should be ensured that only convalescent plasma or serum collections that meet the safety and

quality criteria consistent with established regulatory standards are used.

8. Summary

Based on these considerations, the WHO BRN confirms that the principles in existing guidance of BRN and WHO for assuring blood safety or for using convalescent plasma as a potential treatment option apply also to the recent SARS-CoV-2 outbreak. In the current situation, which is still characterized by fundamental knowledge gaps, the well-established precautionary principles for ensuring blood safety concerning emerging infections should be followed. In endemic regions, an appropriate balance between blood safety measures and sufficiency of the blood supply is key. The WHO BRN will carefully monitor both the current SARS-CoV-2 outbreak and evolution of scientific data, knowledge and understanding of SARS-CoV-2 and continuously update this interim position paper.

9. References

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