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WHO Blood Regulators Network (BRN)

Donor selection in case of pandemic situations *

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Donor selection in case of pandemic situations

In case of a pandemic situation, such as influenza pandemic, the major question to regulatory authorities is whether donor selection criteria should be eased to avoid blood shortage owing to lack of donors - and possibly of blood establishment personnel - in good health.

General aspects:

First, any country should make sure that blood transfusion services are alerted appropriately and included in national pandemic plans, including information systems.

Second, it would be desirable to try to develop a scenario which estimates the degree of affection of donors and blood establishment personnel, possibilities to attenuate the situation, and the critical need of transfusion. Obviously, an appropriate management of transfusion requirements has to be arranged in terms of an optimal and restricted use of blood components.

Third, it should be further explored, whether and to which extent any relaxation of criteria would really help to maintain 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)

BRN position:

The following items need to be addressed in view of pandemic period phase 6 according to the WHO, taking into account national standards of quality and safety for the collection, testing, and processing of blood and blood components¹:

- 1) Information to be provided to prospective donors of blood or blood components** should not be changed. However, any blood establishment should use current discussions on provisions to be foreseen in a pandemic situation as a stimulus to revise the information material provided to the donors as to its comprehensibility and to donor acceptance in order to save time and to shorten the stay during blood donations. Special information on hygiene measures may be added; this information should be in line with information given by health authorities to the public. Donor vaccination should be recommended. All information has to conform to national requirements.

¹ For example, for the European Community, general donor management, selection, testing is laid down in Directive 2004/33/EC

2) Information to be obtained from donors by blood establishments at every donation are part of donor identification and selection and therefore should not be changed.

3) Donor eligibility criteria

The standard procedures in blood establishments are usually well implemented, familiar to the trained employees by daily routine and running more or less smoothly. Basically, any changes in the standard procedures bear the danger of making mistakes, while it is doubtful whether they would really improve the situation. Moreover, it may be difficult for the blood establishment personnel to understand that hitherto strictly observed standards would be discounted. Therefore, any deviations from donor selection criteria should be clearly communicated to the blood establishment staff as a measure in exceptional circumstances.

- a) Generally, any changes to donor screening should be regarded as a last possibility and should only be allowed in situations of extreme necessity; the triggers for implementing change should be individually fixed within each country.
- b) Without extreme necessity, no changes should be permitted in donor screening for infectious parameters, i.e. test panels and test procedures. All serological assays have to be performed using unchanged procedures. This principle should also apply to routinely performed NAT-testing as any interruption of normal routine may create deviations in actual safety and also for the time after. For example, the preparation of back up samples for test repeats in look-back-procedures is often combined with sample preparation for NAT-testing. In such cases, cancelling of NAT-tests may influence accurate back up sample preparation.
- c) Without extreme necessity, no changes should be permitted with respect to permanent or temporary donor deferral criteria issued to avoid serious danger for donors' health and to avoid transmission of infectious diseases by transfusion.
- d) It is conceivable, **under the responsibility of a qualified healthcare professional and in appreciation of the effective risk situation**, to apply less restrictive criteria for individual donations as follows:
 - i) raised upper age limit for donors, preferably for regular donors
 - ii) lowered Haemoglobin level for females and males
 - iii) shortening of donation intervals for platelet apheresis, provided that parameters like haemoglobin, platelet count, protein content, IgG content in donor blood and plasma are within ranges harmless to donor health.
- e) Deadlines for reporting (other than notifications of severe adverse reactions) which fall within the pandemic period may be temporary suspended by the responsible authorities.

4) Quality and safety requirements for blood components

Even during a pandemic situation, an appropriate level of in-process-controls has

to be maintained to guarantee regular production. However, these controls may be performed in a way not to waste blood components, e.g. by sterile sample drawing using sterile connecting devices. For quality requirements (e.g. the lower limits of volume, haemoglobin, platelet content) a deviation may be allowed, which should be well defined in advance. However, it has to be proven that the product quality is well maintained despite these deviations (e.g. lowering the withdrawal volume may lead to a critical citrate concentration).

- a) Depending on the availability of personnel, cancelling of autologous donations could be considered, as this kind of donation has a lower degree of standardization and therefore may be too time consuming and error-prone in case of staff shortage.

5) Particularities in case of pandemic influenza

- a) The time interval for donor re-entry after cessation of symptoms should be defined according to the state of knowledge; blood establishments should be advised accordingly by the responsible national authority.
- b) Donors should be asked for intensive contact with flu patients (sick-nursing) within the last 7 days and may be accepted for donation by the responsible qualified healthcare professional depending on safety measures taken during contact. They should be requested to inform the donation centre in case of signs of flu following donation.
- c) To minimize contagion between donors, donation dates should be arranged in a way to avoid gathering. Masks can be provided, and hand disinfection should be advised to donors (see also Point 1).