TECHNICAL REPORT

Risk of transmission of Ebola virus via donated blood and other substances of human origin in the EU

6 October 2014

Background

The epidemic of Ebola virus disease (EVD) in West Africa in 2014 has increased the risk of Ebola virus transmission via donated blood and blood components, cells, tissues and organs (substances of human origin - SoHO). There are no specific EU regulations or recommendations for the safety of SoHO donated by patients who have recovered from EVD; people exposed to Ebola virus; or people who have visited or reside in EVD-affected areas.

Ebola virus transmissions through donated blood, tissues or organs have not been described. Asymptomatic replicative infections with Ebola virus have been described [1,2]. Travellers from Ebola-affected countries* are deferred for donation because malaria-risk countries overlap with the current Ebola-risk countries in Africa [3]. However, there is a need for specific guidelines to maintain the safety of SoHO donation by people who have been exposed to Ebola virus. There is a possibility that the current outbreaks in West Africa and the Democratic Republic of Congo will spread to areas where there is no malaria risk.

Risk assessment

The risk of Ebola virus transmission through SoHO is related to the presence of Ebola virus in the donor's blood, tissues and organs. The presence and concentration of virus in organs, tissues, blood and other bodily fluids changes during the course of the infection. The virus concentration peaks when the patient is most sick, and viruses can be detected and isolated from breast milk and semen weeks after recovery [4]. There are limited data available on when patients become viraemic and infectious during the incubation period. The assumption is that the rate of virus replication and excretion into bodily fluids is not high enough in the pre-symptomatic phase to result in person-to-person transmission through day-to-day contacts in the community. However, there are no data on when viraemia starts during the incubation period. During the symptomatic phase of EVD, the virus is present in high concentrations in all bodily fluids, tissues and organs [5]. When the disease is fatal, the dead body remains highly contagious. After recovery from the acute phase, a patient may continue to excrete live and infective viruses for long periods [4].

*Countries/areas affected by EVD: the current EVD outbreak is being closely monitored by the European Centre for Disease Prevention and Control (ECDC) which publishes regular epidemiological updates. The list of currently affected countries can be found on the ECDC website at: http://www.ecdc.europa.eu/en/healthtopics/ebola_marburg_fevers/EVDcasedefinition/Pages/Ebola-affected-areas.aspx

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There are currently insufficient data on which to base deferral period recommendations for recovered EVD patients; contacts of EVD cases and people who have visited the EVD-affected countries but do not have a documented exposure. EVD has an acute onset of prominent symptoms that is believed to be temporally related to the viraemia. This makes it unlikely that patients in the viraemic phase would be accepted for donation of SoHO, because it would be obvious that they were ill.

Recommendations for the safety of SoHO donations

Travellers or residents returning from EVD-affected areas

It is expected that a deferral of donation for two incubation periods will provide a reasonable margin of safety for asymptomatic donors returning from EVD-affected areas. The longest incubation period for EVD has been estimated at 21 days. However, a recent study has proposed to extend the longest possible incubation period to 25 days [6]. Thus, asymptomatic travellers or residents returning from EVD-affected areas should be temporarily deferred from donation of SoHO for two months after leaving an area affected by EVD.

It should be noted that all Ebola outbreaks to date have occurred in malaria-endemic areas in Africa and that, according to EU Directive 2004/33/EC of 22 March 2004 [3], asymptomatic blood donors returning from malaria risk areas are deferred for blood donation for at least four months. However, the donor deferral for malarial risk is not required when the donation is used exclusively for plasma for fractionation. So, the asymptomatic travellers or residents returning from EVD affected area should defer donation of plasma for fractionation until two months after return.

According to EU directives, malaria testing of potential donors of tissues and cells returning from malaria-endemic areas is mandatory only under certain circumstances, but for organ donation malaria testing is not mandatory [7,8]. Therefore, asymptomatic travellers or residents returning from an Ebola affected area should be deferred from donation of cells, tissues and organs for two months after return. This period can be reduced to one month in the case of urgent need for organ transplantation, provided that the potential donor tests negative for Ebola virus by nucleic acid amplification testing (NAT).

Individuals monitored after exposure to Ebola virus

Individuals who are being monitored due to history of contact with an EVD patient or other exposure to Ebola virus [9] should be excluded from donating SoHO for two months from the beginning of the monitoring period.

Individuals infected with Ebola virus

Individuals with evidence of Ebola virus infection should be excluded from donating substances of human origin, both as living or deceased donors.

Individuals recovered from EVD

Convalescence from EVD is long and often associated with sequelae such as myelitis, recurrent hepatitis, psychosis, or uveitis. Data on the post-recovery viraemic period are limited. Shedding of Ebola virus has been reported in breast milk and semen after the virus has been cleared from blood [4]. Viable virus has been isolated from semen up to seven weeks after recovery, and spermatogenic transmission of Marburg virus has been documented [10]. There is a paucity of data on Ebola virus in human egg cells. The risk of Ebola transmission should be considered in connection with reproductive cell donations, both for ‘partner’ and ‘other than partner’ donations.

However, the evidence that Ebola virus may persist for some time in the human body after recovery from EVD is insufficient to define a specific deferral period for donors who have recovered from EVD. The current guidance stipulates deferral for 12 months following recovery from a viral haemorrhagic fever [11] and this recommendation also applies to donors who have recovered from EVD. In addition, living or deceased donors of SoHO should have tested negative for Ebola virus by NAT.

Donation of convalescent blood for post-exposure treatment

The above recommendations do not apply to donations of convalescent whole blood (CWB) and plasma (CP) from EVD survivors for the preparation of convalescent plasma for post-exposure treatment. WHO has recently issued guidance on such donations for empirical treatments [12]. WHO currently recommends that only those EVD patients who have been discharged in accordance with WHO criteria (i.e. clinically asymptomatic one month after discharge and tested negative twice for *Zaire ebolavirus* by NAT) should be eligible for such donations.

Importation of SoHO to the EU

SoHO should not be imported from EVD epidemic or endemic countries due to the increased risk of infection with Ebola virus.

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