SaBTO

Advisory Committee on the Safety of Blood, Tissues and Organs

Ebola Virus Disease and Substances of Human Origin

Executive Summary

The epidemic of Ebola Virus Disease in West Africa, from which the first cases were notified in March 2014, has increased the potential risk of Ebola virus transmission via donated blood and blood components, cells, tissues and organs (substances of human origin - SoHO), in all geographical locations, including, due to population movements, non-endemic, unaffected areas such as Europe.

There has been, as yet, no documented description of Ebola virus infections being transmitted via transfusions or through donated tissues or organs.

Based on current knowledge on Ebola, other viral haemorrhagic fevers and published advice from ECDC, SaBTO has produced the following recommendations for the safety of blood, tissue, cell and organ donors.

The overall risk of Ebola to the UK population remains low. However the following guidelines should be consulted when considering potential donors of SoHO.

Recommendations

Scenario	Suitability for blood, cell, tissue or live organ donation	Suitability as a deceased organ donor	Note
Asymptomatic travellers or residents returning from EVD-affected areas, with no known contact with EBoV-infected persons	Deferral from blood, gamete, tissue and living organ donation for two months after leaving an area affected by EVD.	Decline for deceased donor organ transplantation if donor has visited an affected area within the preceding two months unless in exceptional circumstances (see notes).	For organ donation from deceased donors, there is a risk that organs will transmit the virus so a full risk assessment should be made, with expert clinical microbiologist's advice and organs used only in exceptional circumstances. In such cases, the surgeon responsible should document the discussions and decision and ensure the patient gives appropriately informed consent. The risk of transmission is less if the interval is more than one month and the potential donor is tested negative for EBoV by nucleic acid amplification testing (NAT). Undetectable virus in blood does not exclude risk of transmission through cells tissues and organs due to potential virus compartmentalisation.
Individuals being monitored after exposure to EBoV	Exclusion from blood, tissue, gamete and living organ donation for two months from the last day of exposure.	Decline for deceased donor organ transplantation if donor been exposed to EboV within the preceding two months unless in exceptional circumstances (see notes).	In exceptional cases, potential deceased organ donors can be considered if negative for EBoV by NAT (see notes above)

Individuals being investigated for possible EVD	Excluded from any live or deceased donation of SoHO	Decline for deceased donor organ donation and transplantation.	
Individuals infected with EboV	Excluded from any live or deceased donation of SoHO	Decline for deceased donor organ donation and transplantation	
Individuals recovered from EBoV infection	Deferral of living donation for 12 months from onset of illness or from detection of EBoV infection. In addition such living or deceased donors of SoHO should test negative for EBoV by NAT.	Decline for deceased donor organ transplantation if less than 12 months since detection of EboV infection unless in exceptional circumstances (see notes).	In exceptional cases, potential deceased organ donors can be considered if more than two months has passed since recovery AND if negative for EBoV by NAT. **Exception**: Convalescent plasma and whole blood donations follow current WHO criteria (i.e. clinically asymptomatic one month after discharge and twice tested negative for Zaire EBoV by NAT).
Importation of SoHO from endemic or epidemic EVD areas	No importation due to high risk		

Background
The Ebola virus (EBoV) causes an acute, serious illness which is often fatal if untreated. Ebola virus disease (EVD) first appeared in 1976 in two simultaneous outbreaks in Africa[1].

The current outbreak in West Africa (first cases notified in March 2014) is the largest and most complex Ebola outbreak since the virus was first discovered. There have been more cases and deaths in this outbreak than all others combined. It has spread between countries, starting in Guinea then reaching Sierra Leone, Liberia, Nigeria and Senegal. A separate, unrelated Ebola outbreak has begun in Boende, Equateur, an isolated part of the Democratic Republic of Congo [2].

The virus family Filoviridae includes 3 genera: Cuevavirus, Marburgvirus, and Ebolavirus. There are 5 species that have been identified: Zaire, Bundibugyo, Sudan, Reston and Taï Forest. The first 3, Bundibugyo ebolavirus, Zaire ebolavirus, and Sudan ebolavirus have been associated with large outbreaks in Africa. The virus causing the 2014 West African outbreak belongs to the Zaire ebolavirus species[1].

The epidemic of EVD in West Africa has increased the potential risk of Ebola virus transmission via donated blood and blood components, cells, tissues and organs (substances of human origin - SoHO), in all geographical locations, including due to population movements, non-endemic, unaffected areas such as Europe.

The overall risk of Ebola infection to the UK population remains very low.

Transmission
The natural reservoir for EBoV is thought to be fruit bats of the Family *Pteropodidae*. Ebola is introduced into the human population through consumption for food, or other direct physical contact with the blood, secretions, organs or other bodily fluids of infected animals.

EBoV then spreads through human-to-human transmission via direct contact with the blood, secretions, organs or other bodily fluids of infected people, and with surfaces and materials contaminated with these fluids. EBoV does not transmit through casual contact and is not an airborne infection.

In the health care setting, health-care workers have been infected while treating patients with suspected or confirmed EVD. This can occur through close contact with patients when infection control precautions are not strictly practiced [2].

The incubation period varies from 2 to 21 days. The presence and concentration of the virus in organs, tissues, blood and other bodily fluids changes over the course of the infection. The virus concentration peaks in the blood when the patient is most sick. The data on when patients become viraemic and infectious during the incubation period are limited. It is believed that virus replication is not sufficiently high in the pre-symptomatic phase to lead to a person-to-person transmission via normal contact in the community. There are no data on when viraemia starts during the incubation period. During the acute symptomatic phase of EVD, the virus is present in high concentrations in all bodily fluids, tissues and organs [1].

After recovery from the illness, a patient may continue to excrete, including in semen, live and infective viruses for up to 90 days [1, 3, 4, 5].

When the disease is fatal, the dead body remains highly contagious.

There is no proven treatment available for EVD. A range of prototype treatments including blood products, immune therapies and drug therapies are currently being evaluated. No licensed vaccines are available though two potential vaccines are undergoing evaluation [2].

In the UK, testing for EboV is undertaken by Public Health England at the Rare and Imported Pathogens Laboratory (RIPL) Porton Down, Wiltshire.

The advisory committee on Dangerous Pathogens (ACDP) has published specialist guidance on the management (including infection control) of patients with viral haemorrhagic fever (VHF). The guidance is available at https://www.gov.uk/government/publications/viral-haemorrhagic-fever-algorithm-and-guidance-on-management-of-patients

Ebola Virus and safety of substances of human origin

As regards to the EBoV-infected but asymptomatic potential donors of Substances of Human Origin (SoHO), there are no substantial data on when viraemia starts, when it ends and more importantly, for how long there is a risk of transmission through the use of such substances.

There has been, as yet, no documented description of Ebola virus infections being transmitted via transfusions or through donated tissues or organs.

In the UK, travellers from Ebola-affected countries are deferred from donation of blood, tissues and cells because malaria risk countries overlap with the current Ebola risk countries [6]. However, it is possible that the virus could spread to non-malaria endemic areas and travel or residency risk for malaria does not preclude living nor deceased organ donation. Therefore there is a need for specific guidelines addressing the safety of organ donation in the UK in relation to the ongoing Ebola epidemic in West Africa [7].

It is accepted that clinical symptoms correlate with levels of EBoV in the blood and as regards to the usual routes of transmission, person-to–person spread is most likely during the symptomatic phase, with the highest risk when the person is most ill. These individuals would not normally be considered for donation of SoHO. The risk remains for those who, having left an EVD-affected area, are still asymptomatic, but carry a risk of transmission through donation of SoHO regardless of the virus being detected in blood or not. There is insufficient data at the moment to precisely inform those risks.

Based on current knowledge on Ebola, other viral haemorrhagic fevers and published advice from ECDC [4], SaBTO has produced these recommendations for the safety of blood, tissue, cell and organ donors.

References

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