

SCANDIATRANSPLANT GUIDELINES FOR PREVENTION OF TRANSMISSION OF INFECTIOUS DISEASES FROM ORGAN DONORS TO RECIPIENTS.

Basic screening for infections in organ donors (further detailed below)

1: Before organ procurement and/or transplant:

Anti-HIV, HBsAg, anti-HBc, anti-HCV, SARS-CoV-2

2: As soon as possible (not necessarily before organ procurement and/or transplant):

Anti-CMV IgG, anti-EBV, anti-HSV-1/2, anti-Treponema pallidum, anti-Toxoplasmosis, IGRA

RESPONSIBILITIES:

The transplantation coordinator:

- is responsible for adequate tests being requested and performed according to the protocol, and that the results are forwarded to the surgeon in charge of grafting.

The surgeon in charge of grafting:

- is responsible for the acceptance and the use of the organ, and thus for knowing the results of the performed tests. The surgeon should acquire travelling history of the donor.
- is responsible for judging if a test could be postponed until after grafting or a mismatch could be accepted for the specific recipient.

STORING OF SERUM: Adequate material (sera) for testing and storage in the recipient centre must accompany each organ. Recipient centres should store donor and recipient (pre-transplant) serum (10 years).

STORING OF BACTERIAL OR FUNGAL SPECIES: In case of a donor with an infection with a multiresistant bacteria or fungus, bacterial or fungal species should be stored at the local department of clinical microbiology for potential further susceptibility testing.



BASIC SCREENING OF THE DONOR

The following tests should be run before organs are offered. The decision to accept or reject an organ from a donor with a positive test must be taken by the responsible surgeon

Test	Interpretation of positive reaction	Comment 1	Comment 2
HBsAg+*	The liver can be given to HBsAg+ recipients who are HDV-negative*.	HBsAg+ recipients are given entecavir or tenofovir from the time of transplantation.	HBIG prophylaxis has no value.
	The liver can be given to HBsAg-negative recipients in urgent cases.	The recipient must be given entecavir or tenofovir from the time of transplantation.	HBIG prophylaxis has no value.
	Non-liver organs can be given to all recipients in urgent cases.	HBsAg-negative recipients should preferably exhibit anti-HBs. For HBsAg-negative/anti-HBs+ recipient: Either careful monitoring and antiviral treatment at earliest sign of HBV recurrence or prophylaxis with entecavir or tenofovir at time of transplantation. For HBsAg-/anti-HBs-negative recipient: Both HBIG and entecavir or tenofovir should be given.	Prophylactic antiviral treatment recommended when HBV DNA level in donor is high.
Anti-HBc+*	The liver can be given to all recipients who are HDV-negative*	The recipient must be given entecavir or tenofovir from the time of transplantation.	HBIG prophylaxis is recommended only when recipient is HBsAg+.
	Non-liver organs can be given to all recipients.	If the donor is anti-HBs- negative, recipients without HBV markers should receive a single dose of HBIG prior to revascularization and short-term entecavir or tenofovir treatment may be considered	
Anti-HBs+	If anti-HBc+: see above.		
	If anti-HBc-negative all organs can be used.	No prophylactic treatment is indicated.	Anti-HBs reactivity is most probably due to previous immunization of the donor.

Test	Interpretation of positive reaction	Comment 1	Comment 2
Anti-HCV+	All organs can be used. Priority should be given to recipients who are HCV RNA+.	Antiviral treatment against HCV should be initiated soon after transplantation if the result of HCV-RNA of the donor is positive.	
Anti-HIV+	Organs cannot be used, with the exception of urgent organ need in HIV+ recipients.		

** Organs should only be used if co-infection with HDV is very unlikely or excluded by anti-HDV or HDV-RNA*

It is recommended that recipients give an informed consent to the use of organs from donors with signs of viral hepatitis

Samples taken before donation, analyzed as soon as possible (not necessarily before organ procurement and/or transplant)

Test	Interpretation of positive reaction	Comment 1
Anti-EBV IgG+	Increased risk for EBV complications in D+/R-.	Organs can be accepted regardless of the anti-EBV IgG status of the donor. Particularly important for pediatric recipients. All seronegatives at risk of post-transplant lymphoproliferative disease (PTLD). Suitable monitoring should be adopted in D+/R- recipients.
Anti-CMV IgG and IgM	Increased risk for infection and severe complications in D+/R-.	Organs can be accepted regardless of the anti-CMV IgG status of the donor. Suitable prophylaxis or virological monitoring with pre-emptive treatment should be adopted in recipients, particularly in D+/R-).
Syphilis antibody+	Indication for treatment and/or special follow-up.	Organs can be accepted regardless of test result.
Toxoplasma IgG+	In case of a IgG+ donor, prophylaxis should be given to heart recipients that are Toxoplasma IgG- (high risk of infection). Prophylaxis should be considered for other organ recipients that are Toxoplasma IgG-.	Organs can be accepted regardless of donor and recipient serostatus Trimethoprim-sulfamethoxazole is effective against Toxoplasma. Seroprevalence in adults: 10-15%.
IGRA test+ (only taken in donors with risk for latent tuberculosis)	If no history of ongoing tuberculosis in the donor, a positive test indicates latent infection or previously treated infection.	Organs can be accepted regardless of IGRA result. Medical history important for interpretation of reactive IGRA test. If untreated latent infection in the donor, treatment of the recipient should be considered, especially for lung recipients. If no treatment is given, clinical monitoring is important.
Anti-HSV IgG+	HSV-specific prophylaxis should be considered for all HSV-1/2 seronegative recipients who are receiving organs from seropositive donors but who are not receiving anti-viral medication for CMV prevention that has activity against HSV.	Organs can be accepted regardless of the anti-HSV-1/2 IgG status of the donor. Suitable prophylaxis should be adopted in D+/R- recipients.

Covid-19 in deceased organ donation

All donors should be tested with SARS –CoV-2 RT-PCR (PCR) in upper respiratory airways at time of procurement. Lung donors should be tested with PCR from BAL at least within 72 hours but ideally as close to organ recovery as possible.

For donors previously known to have had a positive Covid-19 test and with negative PCR at time of procurement:

1. If no end-organ failure or thrombosis due to Covid-19 AND Covid-19 is not a contributory cause of death, transmittance of infection is unlikely, and the donor should be considered for organ acceptance

For donors with positive PCR at time of procurement:

1. No end-organ failure or thrombosis due to Covid-19 AND Covid-19 is not a contributory cause of death:
 - a. Transmission of infection is unlikely, and donors should be considered for organ acceptance except lungs and intestines:
 - i. Lungs should not be accepted.
 - ii. Theoretically transmission of infection may be possible through intestinal transplantation, and potential risks vs benefits should be balanced carefully.
2. End-organ failure or thrombosis due to Covid-19 OR Covid-19 is a contributory cause of death:
 - a. Organ donation not suitable.

Active infections in the donor

Septicaemia/Candidemia: Individual assessment – organs may be accepted if the causing agent and its antibiotic/antifungal resistance is known and reveals (near) ‘wild type’ pattern. Adequate antimicrobial treatment must be initiated. The necessary length of treatment of the donor, and post-tx of the recipient, will in each case depend on the causative agent and the clinical conditions. If possible, we recommend that the infecting bacterial or fungal species is stored for potential further susceptibility testing.

Multiresistant bacteria: We recommend classification following Magiorakos A-P et al (CMI 2012; 18:268-28) since the organisms will be increasingly difficult to treat with increasing grading.

Individual assessment – organs may be accepted if antibiotic resistance is known, and adequate antimicrobial treatment has been given. We recommend that the infecting bacterial or fungal species is stored for potential further susceptibility testing.

If only colonization with MRSA, VRE and multiresistant gram-negative bacteria, transplantation can be performed if the colonized site is sealed off from the donor organ, and the donor is without sign of systemic infection’.

If lungs are colonized with MDR bacteria, lungs should not be used.

If urine is colonized with MDR bacteria, kidneys should not be used.

If donor is infected with MDRO - There must be clear infection control and still a number of antibiotic alternatives in case of allergies, toxicities, interactions etc.

Donors with multi-system organ failure due to overwhelming sepsis, gangrenous bowel or similar condition: Not accepted

Donors with active tuberculosis: Normally not accepted but can be considered in urgent cases and if not multiresistant TB. Lungs (or additional organ in case of military TB) cannot be accepted.

Donors with disseminated mold fungal infection: Not accepted.

Donors with active disseminated viral infection due to Herpes viruses (HSV, CMV, VZV, EBV), measles: Not accepted.

Donors with unknown CNS infection, or non-treatable encephalitis: Not accepted

GEOGRAPHICALLY RESTRICTED INFECTIONS

Certain geographically restricted infections pose risks for complications after transplantation. This issue has become more relevant in the last decades due to immigration from and travels to regions where these infections are endemic. The travel history of the donor will guide in the risk assessment.

General recommendation:

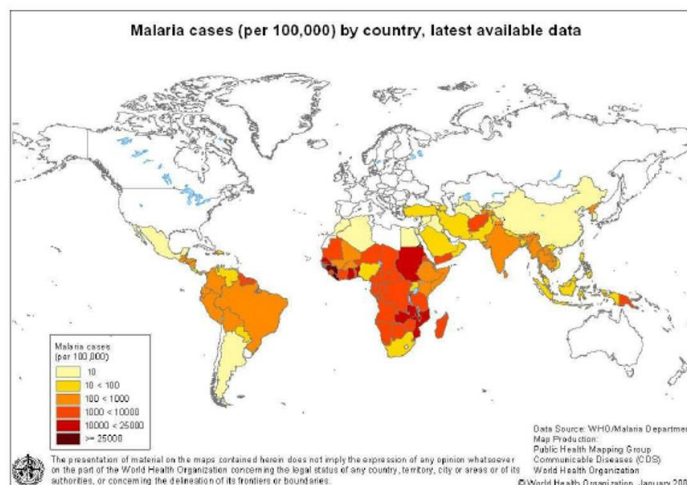
In the case of a donor with a recent travel history and signs of acute infection, a transplant infectious disease expert should be consulted. More exhaustive information on geographically restricted infections with potential implications in organ transplantation is found in the European *Guide to the Quality and Safety of Organs for Transplantation* (Table 8.8) by EDQM.

Specific recommendations:

Hemorrhagic fever Travelers or residents returning from an area with an ongoing outbreak should be deferred from donation of any organ for two months after return.

HTLV-I/II Anti-HTLV-I/II testing of donors from areas with high prevalence of HTLV-I/II infections (*Japan, South America, the Caribbean, the Melanesian islands, Papua New Guinea, the Middle East, Western, Central, and Southern Africa*) is recommended. If serology is positive, organs are not accepted.

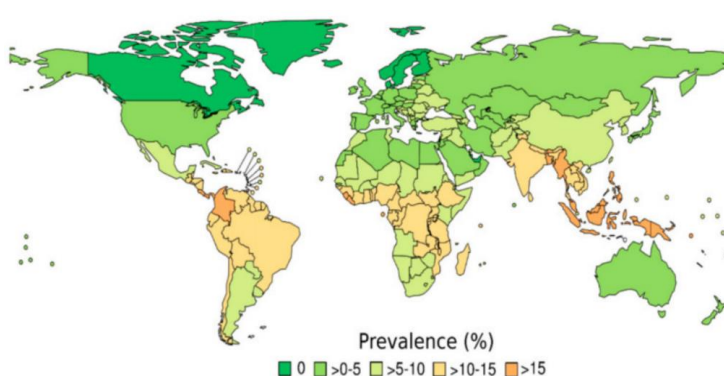
Malaria Donors with residency or long term stay in Sub-Saharan Africa during the past five years should be screened for asymptomatic malaria by PCR/LAMP. Febrile donors with recent stay (last 6 months) in any malaria-endemic region (see map below) should also be screened for active malaria by microscopy. In the case of any positive malaria-test, donor (if possible), and recipient should



receive adequate treatment. Organs from donors who died from malaria should not be accepted.

Strongyloides stercoralis

Donors originating from or frequently visiting areas with >5% prevalence (see map below) should be screened for *Strongyloides* infection using serology. If IgG is positive (results will be obtained after transplantation), the recipient should receive treatment to prevent hyperinfection due to donor derived *S. Stercoralis*.



Chagas disease

Donors originating from or with long-term stay (>3 months) in countries with risk for transmission of *Trypanosoma cruzi* (Latin America) should be tested for *Trypanosoma cruzi* IgG. Positive tests should be confirmed by another serologic method due to sub-optimal specificity of single tests. Recipients receiving organs from a seropositive donor should be monitored by regular PCR for *T. cruzi* post-transplant. Heart and intestine from donors with known chronic Chagas disease should not be accepted.

These recommendations were proposed by the ScandiTransplant ID group in May 2023.

It is a revision of previous recommendations