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

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SCANDIA TRANSPLANT
Founded 1969 by the Nordic Council

1. RESPONSIBILITIES

The transplantation coordinator is responsible for

- adequate tests being requested and performed according to the protocol
- the results being 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
- acquiring the travelling history of the donor
- judging if a test can be postponed until after grafting
- judging if a mismatch can be accepted for the specific recipient.

Storing of serum: Adequate serum must be stored for 10 years for retrospective testing:

- Recipient centres should store pre-transplant recipient serum.
- Responsible donor testing centre* should store adequate donor serum when one or more organs are used for transplantation. This also applies if all organs are exported to other transplant centres.

Storing of bacterial or fungal species: In case of a donor with an infection with a multidrug-resistant bacterium or fungus, bacterial or fungal species should be stored at the responsible donor testing centre* (often at the local department of clinical microbiology) for potential further susceptibility testing.

*Responsible donor testing centre is defined as the centre performing the donor screening.

2. OVERVIEW OF BASIC SCREENING FOR INFECTIONS IN ORGAN DONORS

Category 1: Before organ procurement and/or transplant:

Anti-HIV, (HIV NAT), HBsAg, anti-HBc, anti-HCV, (HCV NAT), SARS-CoV-2 PCR

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

Anti-CMV, anti-EBV, anti-HSV-1/2, anti-Treponema pallidum (syphilis), anti-Toxoplasma

Category 3: In special situations / in certain risk groups:

Tuberculosis (TB) interferon-gamma release-assay, anti-HTLV-I/II, Plasmodium (malaria) PCR/LAMP, anti-Strongyloides, anti-Trypanosoma cruzi (Chagas disease)

3. BASIC SCREENING OF THE DONOR

3.1 Category 1: Screening before organ procurement and/or transplant

The following tests should be run before offering organs: **Anti-HIV, HBsAg, anti-HBc, anti-HCV, SARS-CoV-2 PCR**.

Additionally, strongly consider **HIV NAT** and **HCV NAT** tests before offering organs from donors at increased risk of HIV and HCV infections. Donors are considered at increased risk of HIV and

HCV if one of the following risk criteria exists during the 30 days before organ procurement:

- Sex with a person known or suspected to have HIV, HBV, or HCV infection (i.e., any method of sexual contact, including vaginal, anal or oral)
- Man who has had sex with another man (MSM)
- Sex in exchange for money or drugs
- Sex with a person who had sex in exchange for money or drugs
- Drug injection for nonmedical reasons
- Sex with a person who injected drugs for nonmedical reasons
- Incarceration (confinement in jail, prison or juvenile correction facility) for ≥ 72 consecutive hours
- Child breastfed by a mother with HIV infection
- Child born to a mother with HIV, HBV or HCV infection
- Unknown medical or social history.

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 recipients: Both HBIG and entecavir or tenofovir should be given.	Prophylactic antiviral treatment recommended when HBV DNA level on HBV NAT 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, HBV-naive anti-HBs-negative recipients should receive a single dose of HBIG before revascularisation, 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+ positivity is most probably due to previous immunisation of the donor.
Anti-HCV+	**All organs** can be used†. Priority should be given to recipients who are HCV NAT+.	Antiviral treatment against HCV should be initiated soon after transplantation if the donor is HCV NAT+.	
HCV NAT+	**All organs** can be used†. Priority should be given to recipients who are HCV NAT+.	Antiviral treatment against HCV should be initiated soon after transplantation.	
Anti-HIV+	Organs cannot be used, except for urgent organ need in anti-HIV+/HIV-NAT+ recipients†.		
HIV NAT+	Organs cannot be used, except for urgent organ need in anti-HIV+/HIV-NAT+ recipients†.		
SARS-CoV-2 PCR+	See section 4.1 Covid-19 in deceased organ donors.		

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

† It is recommended that recipients give an informed consent to the use of organs from donors with signs of chronic viral infections.

3.2 Category 2: Samples taken before donation, analysed as soon as possible (not necessarily before organ procurement and/or transplant)

Test	Interpretation of positive reaction	Comment 1
Anti-EBV+	Increased risk for EBV complications in anti-EBV-negative recipients.	Organs can be accepted regardless of the anti-EBV IgG status of the donor. Particularly important for paediatric recipients. All anti-EBV-negative recipients are at risk of post-transplant lymphoproliferative disease (PTLD). Suitable monitoring should be adopted in D+/R− recipients.
Anti-CMV+	Increased risk for infection and severe complications in anti-CMV-negative recipients.	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−.
Anti-Treponema pallidum+ (syphilis)	Indication for treatment and/or special follow-up.	Organs can be accepted regardless of test result.
Anti-HSV-1/2+	Consider HSV-specific prophylaxis for all anti-HSV-1/2 negative recipients who are not receiving antiviral medication for CMV prevention that has activity against HSV.	Organs can be accepted regardless of the anti-HSV-1/2 status of the donor. Suitable prophylaxis should be adopted in D+/R− recipients.
Anti-Toxoplasma+	Prophylaxis should be given to heart recipients that are anti-Toxoplasma negative (high risk of infection). Consider prophylaxis for other organ recipients that are anti-Toxoplasma negative.	Organs can be accepted regardless of donor and recipient serostatus. Trimethoprim-sulfamethoxazole is effective against Toxoplasma.

3.3 Category 3: Tests taken in special situations / in certain risk groups

Test	Comment
TB interferon-gamma release-assay	Only in donors with risk factors for TB. See section 4.3 Tuberculosis (TB) in deceased organ donors.
Anti-HTLV-I/II	Only in donors from areas with high prevalence of HTLV infection. See section 4.4 Geographically restricted infections.
Plasmodium (malaria) PCR/LAMP	Only in donors with residence, long-term stay, or recent travel history to highly endemic areas. See section 4.4 Geographically restricted infections.

Anti-Strongyloides	Only in donors originating from or frequently visiting areas with >5% prevalence. See section 4.4 Geographically restricted infections.
Anti-Trypanosoma cruzi	Only in donors originating from or with long-term stay (>3 months) in Latin America. See section 4.4 Geographically restricted infections.

4. SPECIFIC CONDITIONS

4.1 Covid-19 in deceased organ donors

All donors should be tested with SARS-CoV-2 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, transmission of infection is unlikely: consider accepting the organs.

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: consider accepting the organs, 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.

4.2 Active infections in the donor

4.2.1 Bacteraemia/Fungaemia

Individual assessment – organs may be accepted if the causing agent and its antibiotic/antifungal resistance is known and reveals a normal resistance pattern.

Adequate antimicrobial treatment must be initiated. The necessary length of treatment of the donor, and of the recipient after transplantation, will in each case depend on the causative agent and the clinical conditions. If possible, we recommend storing the infecting bacterial or fungal species for potential further susceptibility testing.

4.2.2 Multidrug-resistant (MDR) bacteria

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

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

If only colonisation with methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Enterococci (VRE) and MDR gram-negative bacteria, transplantation can be performed if the colonised site is sealed off from the donor organ, and the donor is without signs of systemic infection.

- If lungs are colonised with MDR bacteria, lungs should not be used.
- If urine is colonised with MDR bacteria, kidneys should not be used.
- If donor is infected with MDR organisms, there must be clear infection control and still a number of antibiotic alternatives in case of allergies, toxicities, interactions, etc.

4.2.3 Multi-system organ failure due to overwhelming sepsis, gangrenous bowel or similar condition

Not accepted

4.2.4 Disseminated mould fungal infection

Not accepted

4.2.5 Active disseminated viral infection due to Herpesviruses (HSV, CMV, VZV, EBV) or measles

Not accepted

4.2.6 Unknown CNS infection or non-treatable encephalitis

Not accepted

4.3 Tuberculosis (TB) in deceased organ donors

4.3.1 Donors with active TB

Organs are generally not accepted. If isolated pulmonary TB in donor, consider other organs than lungs in very urgent cases and if not multidrug-resistant TB. Chemoprophylaxis or treatment for active TB in recipient is recommended.

4.3.2 Donors with risk factors* for TB but without signs of active TB

TB interferon-gamma release-assay test is recommended. Results are normally available after transplantation and may help in the decision of whether to give chemoprophylaxis to the recipient.

4.3.2.a Donor history of treatment for active TB but no documented information that can assure a complete treatment course

The organ previously affected by TB should not be accepted. Other organs can be accepted. Infectious disease specialist should be consulted about indication for chemoprophylaxis to the recipients. See Table 6 in Morris et al. (Am J Transpl 2012; 12:2288-2300) for details.

4.3.2.b Donor history of treatment for active TB with assured complete treatment course

All organs can be accepted. Infectious disease specialist should be consulted about indication for chemoprophylaxis to the recipients based on donor history and result of TB interferon-gamma release-assay test where applicable. See Table 6 in Morris et al. (Am J Transpl 2012; 12:2288-2300) for details.

4.3.2.c Other risk factors for TB*

As in section 4.3.2.b Donor history of treatment for active TB with assured complete treatment course.

*Risk factors for TB:

- Residence in country with high TB prevalence (Latin America, Africa, Asia, Eastern Europe, and Greenland)
- Homelessness
- Alcoholism
- Age >70
- Known TB exposure
- History of previous treatment for active TB or for latent TB
- Chest radiograph showing apical scarring/fibrotic lesion in a donor with other risk factors for TB

4.4 Geographically restricted infections

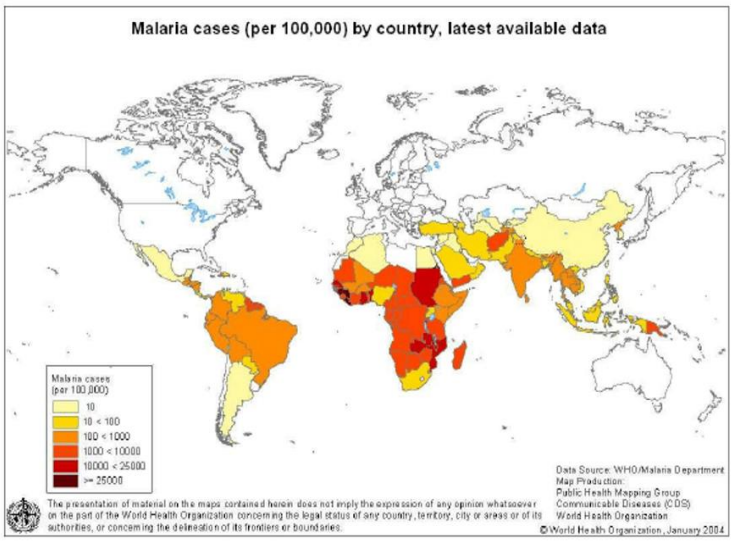
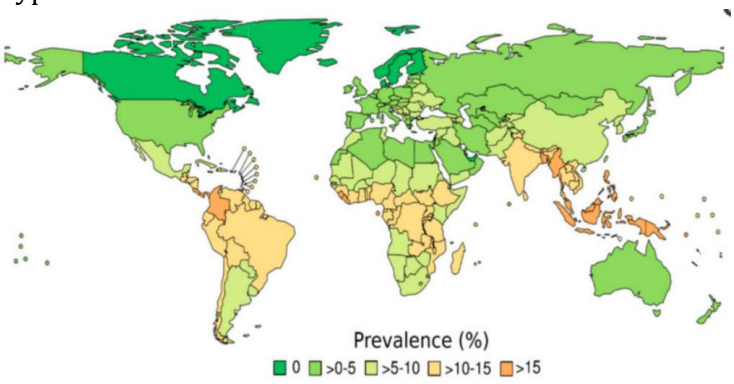
Certain geographically restricted infections pose risks for complications after transplantation. This issue has become more relevant in the last decades due to immigration from and travels to regions where these infections are endemic. The travel history of the donor will guide the risk assessment.

4.4.1 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.

4.4.2 Specific recommendations

Haemmorrhagic 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, Melanesian islands, Papua New Guinea, Middle East, western, central, and southern Africa)* is recommended. If anti-HTLV-I/II is positive, organs are not accepted.

Malaria	Donors with residence 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 using anti-Strongyloides. 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 anti-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 Scandiatransplant ID group on 11 April 2024.
They are a revision of previous recommendations.