WMDA Donor Medical Suitability Recommendations Main page

Disclaimer

These guidelines exist as an aid to organisations in assessing the medical suitability of their potential donors. Please be reminded that these guidelines are not intended to supersede local laws or requirements of national legislative bodies.

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About the WMDA donor medical suitability guidelines

Guidance provided by the World Marrow Donor Association (WMDA) aims to provide minimum standards by which potential donors should be assessed. The WMDA guidance reflects the consensus opinion of the WMDA donor medical suitability committee. The purpose of this guidance is to provide globally harmonised medical assessment criteria which simultaneously protect the interest of donors whilst ensuring the safety of cellular products across international boundaries.

Whilst this WMDA guidance is not specifically intended for related donors, those involved with the medical assessment of related donors should consider these recommendations.

How donor medical suitability is assessed

Two key concepts govern the assessment of donor health, namely restrictive criteria for donor risk and more permissive criteria for recipient risk

Donor risk

- Donation of hematopoietic stem cells (HSC) is an act of altruism, and may be to a recipient in a different country, with quite different moral, cultural and religious values.
- Whilst it is recognised that the process of donation carries a small but unavoidable risk of harm to the donor, it is both the moral and legal responsibility of donor registries and donor centres to minimise any avoidable risk. This includes medical conditions that may increase the risk of harm to the donor before, during, and after the collection of HSC.
- For this reason, medical criteria governing conditions that may increase donor risk are necessarily stringent, and certainly more so than would be the case if the individual were undergoing a procedure for therapeutic benefit.
- In many cases it is difficult to establish a rigorous evidence base as justification for the criteria. In such cases, expert opinion of the underlying physiology of disease will be sought, and combined with knowledge of the known physiological changes associated with donation, as well as experience gained through several decades of HSC donor follow-up and adverse event reporting.
- In general, if there is any doubt about the safety of the donor in the presence of a particular medical condition, it will be recommended that any donor with that condition be prevented from donating.

Recipient risk

- By contrast, our recommendations regarding conditions that may put the recipient at risk are more lenient.
- For many patients, an unrelated donor HSC transplant represents the only possibility of disease cure or long-term remission. Because of the diverse nature of HLA tissue-types, many patients will have a limited number of potentially matched donors. In such cases, donor medical conditions that may present a risk to the recipient alone should be reported to the transplant centre, who are best placed to make an informed risk-benefit judgement on whether to proceed with that particular donor.
- There are obvious exceptions to this, however, in particular the carriage of transmissible agents which may have more deleterious effects in the recipient. These include infectious agents such as HIV, viral hepatitis and HTLV, prion-related diseases such as Creutzfeld-Jakob Disease, and carriage of auto-reactive lymphocytes causing multi-system or severe single-organ autoimmune diseases, such as systemic lupus erythematosus, multiple sclerosis or inflammatory bowel disease.

Procedure for creating and reviewing the donor medical suitability guidelines

To create and support this resource, the WMDA has established the donor medical suitability committee. Members of the committee represent all major regions in the world, and are themselves overseen by numerous competent authorities within their country of practice. Committee members are actively involved in donor centre and/or registry operations with experience in matters concerning unrelated donor medical suitability. You can find the members here: https://share.wmda.info/x/So1JAQ.

Submitting a request for review

WMDA welcomes requests for review of individual medical conditions from all those with responsibility for HSC donors, related or unrelated. This may be a medical condition not covered by the current guidance, or a request for clarification or review of current guidance. Requests for new guidance, and feedback on existing guidance, are submitted to the donor medical suitability committee. Comments and justifications for the committee decision are documented, including justification for the decision. Regardless of the outcome, a formal response to the query is provided to the author of each submission in order to inform the registry/donor centre of the outcome of the discussion. Recommendations that are approved are posted to this website. Any controversies pertaining to the recommendations are added to the discussion section on the relevant page. You can click on the button on the right top corner of the page.

Add your question or recommendation at the question section or send an email to mail@wmda.info.

WMDA Recommendations for assessing donor medical suitability

Medical and lifestyle information at enrolment - updated!

Importance	Medical history	Examples of relevant conditions
Recommended	Transmissible and incurable infections with potential risk for the donor	HIV; HTLV
	Serious/inherited blood disorders	Sickle cell disease; thalassaemia major; inherited bleeding disorders
	History of major transplant	Organ; haemopoietic stem cell
	Known cardiovascular disease	Stroke; heart attack
Optional	Cancer	Haematological malignancies
	Autoimmune disease	Especially serious/systemic conditions like multiple sclerosis; systemic lupus erythematosus
	Transmissible infections	Hepatitis B, hepatitis C, syphilis, Chagas disease, malaria
	Potentially transmissible infections	CJD, tuberculosis
	Height and weight	BMI may reflect likely venous access
	General medical history	Past or current medical problems can predict fitness for donation and/or risk to a recipient
	Current medications	Lithium; teratogenic drugs
	Allergies	Especially allergens that may be encountered during donation – latex; anaesthetic

Minimum donor medical and lifestyle information requested at confirmatory/verification typing stage

Medical history	Examples of relevant conditions or questions
Cancer	
Autoimmune disease	Ankylosing spondylitis; Crohn's disease; ulcerative colitis; myasthenia gravis; rheumatoid arthritis; sarcoidosis; SLE; multiple sclerosis; scleroderma/CREST. Any other autoimmune condition
Infectious diseases, including being a sexual partner of an infected individual	HIV, Hepatitis B, Hepatitis C, HTLV, syphilis
Infectious diseases, others	CJD (including familial and exposure risk, e.g. neurosurgery, use of pituitary hormone), Chagas disease, tuberculosis, malaria
Back problems	Any acute or chronic back complaint, including cause, investigations, duration, medication and impact on activities of daily living
Hypertension	Most recent blood pressure readings; medications; degree of control
Cardiac disease	Coronary artery disease; evidence of valve disease, e.g. murmur; arrhythmia
Asthma	Degree of control; medications; use of oral steroids; hospital admissions; intensive care admissions/ventilation
Epilepsy	Medications; date of last seizure
Pregnancy	Number of pregnancies, including miscarriage; current/recent pregnancies; breastfeeding.
Blood transfusion	Receipt of a blood transfusion. Ask year and place of transfusion.
Any other medical history	The potential donor should be asked if they have any other past or current medical problems
Height and weight	
High risk sexual behaviour	As defined by the registry's national competent authority
Non-prescription parenteral drug use	
Alcohol consumption	
Tattoo, acupuncture or body piercing	When and where. Establish if at an establishment registered according to national regulations
Current medications	
Allergies	

Medical assessment at work-up - updated!

Medical history as per Table 2, plus:	
Travel history	Identify travel to areas with endemic malaria and/or arboviruses such as West Nile virus; dengue; Zika
Place of birth	Identify donors born in an area with endemic Chagas' disease
Sexual history	Identification of high-risk sexual behaviour, including within groups associated with a higher prevalence of blood-borne infections
Examination	General (including height and weight); cardiovascular (including blood pressure); respiratory; gastrointestinal; neurological
Laboratory investigations (see Table 4 for infectious disease markers)	
Haematology	Full blood count; coagulation screen (including PT, APTT and fibrinogen); ESR; blood film; haemoglobin electrophoresis or high-pressure liquid chromatography
Biochemistry	Urea and electrolytes; liver function tests; LDH; ferritin; random glucose; beta-HCG (for females of child-bearing age)
Optional tests	Chest x-ray; electrocardiogram; urinalysis

Recommended minimum testing for infectious disease markers

Stage	**Infectious disease**	**Recommended validated assay**
Recruitment	Nil	Nil
CT-stage	HIV	HIV antibody
	Hepatitis B	Hepatitis B surface antigen
	Hepatitis C	Hepatitis C antibody
Work-up	HIV	HIV 1,2 antibody
		p24 antigen
		HIV RNA
	Hepatitis B	Hepatitis B surface antigen
		Hepatitis B surface antibody
		Hepatitis B core antibody
		Hepatitis B DNA
	Hepatitis C	Hepatitis C antibody
		Hepatitis C RNA
	HTLV I+II	HTLV I+II antibody
	Syphilis	Validated serological testing algorithm

Repeating assessments required in the event of a delay to collection - updated!

Time from work-up medical assessment to collection	Repeat assessments required
<=30 days	None
>30 days, <90 days	Required: • Infectious disease markers • Risk assessment[1] for transmittable disease • Full donor history if subsequent donation Optional[2]: • Full donor history if first donation • Physical examination • All laboratory testing excluding haemoglobinopathy screening Additional testing (per discretion of physician in charge)
>=90 days, <6months	Required: • Infectious disease markers • Risk assessment for transmittable disease • Full donor history if subsequent donation • All laboratory testing excluding haemoglobinopathy screening Optional: • Full donor history if first donation • Physical examination Additional testing (per discretion of physician in charge)
>=6 months	Required: • Infectious disease markers • Full donor history including risk assessment for transmittable disease • Physical examination • All laboratory testing excluding haemoglobinopathy screening Optional (per discretion of physician in charge): • Additional testing that was performed at the original work-up, such as chest X-ray, ECG or urinalysis.

[1]Risk assessment does not necessarily mean a full risk questionnaire, but means a risk assessment based on local policies, endemic risks and previous individual risk assessments and/or infectious disease marker results. Especially in young donors, a travel history seems appropriate.

[2]Optional: per discretion of the donor physician in charge or as required by standards or (national) legislation.

Recommended intervals between HPC donations and other blood(product) donations

A WMDA working group is currently reviewing an article that was written on the subject of subsequent donations. Read more on the project and find the article on this page in Share.

WB to HPC interval	If a donor reports donating WB within the last 3 months, report to collection centre physician
Plasmapheresis or plateletphereris to HPC interval	2 weeks
HPC(A) to WB interval	Advise donor to wait 3 months (i.e. equivalent to one WB => WB interval)
HPC(M) to WB interval	Advise donor to wait 6 months (i.e. equivalent to one WB => WB interval)
HPC(A) to plasmapheresis interval	Advise donor to wait 2 weeks (i.e. a typical plasmapheresis => plasmapheresis interval)
HPC(M) to plasmapheresis interval	Advise donor to wait 4 weeks (i.e. a typical WB => plasmapheresis interval)
HPC(A) to plateletpheresis interval	Advise donor to wait 2 weeks (i.e. a typical plateletpheresis => plateletpheresis interval)
HPC(M) to plateletpheresis interval	Advise donor to wait 4 weeks (i.e. a typical WB => plateletpheresis interval)

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