

Medical assessment tools and dilemma's

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MATCHIS

THE DUTCH CENTRE FOR
STEM CELL DONORS

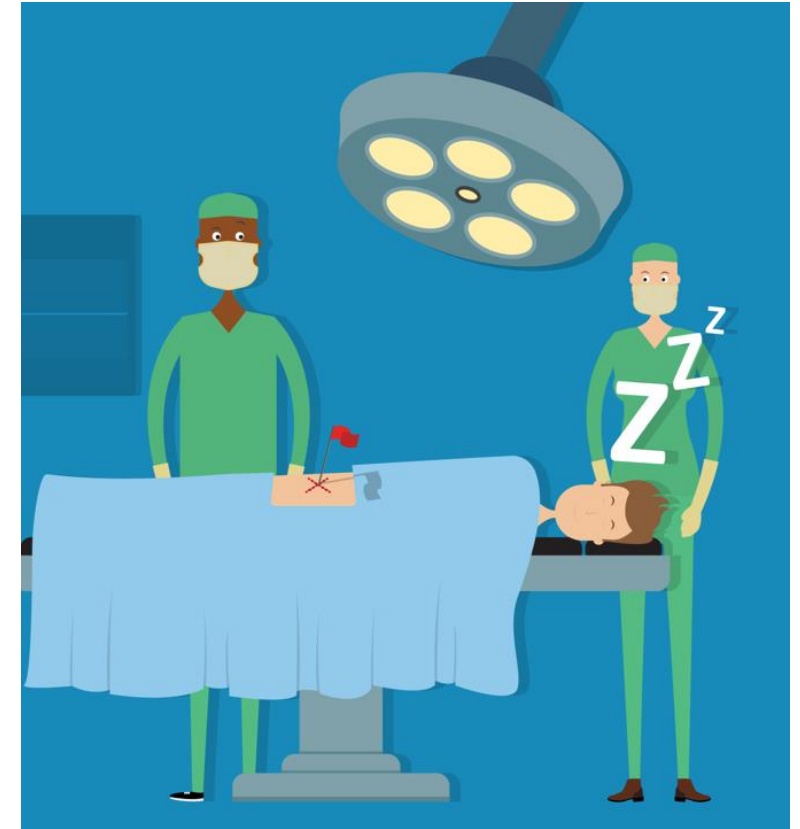
Principles of medical assessment

- Unrelated donation is altruistic and has no therapeutic benefit for donor
- Donor safety: precautionary principle
- Recipient safety: risk-benefit judgment by transplant physician
- No hard scientific evidence for most criteria



Short term risks: bone marrow

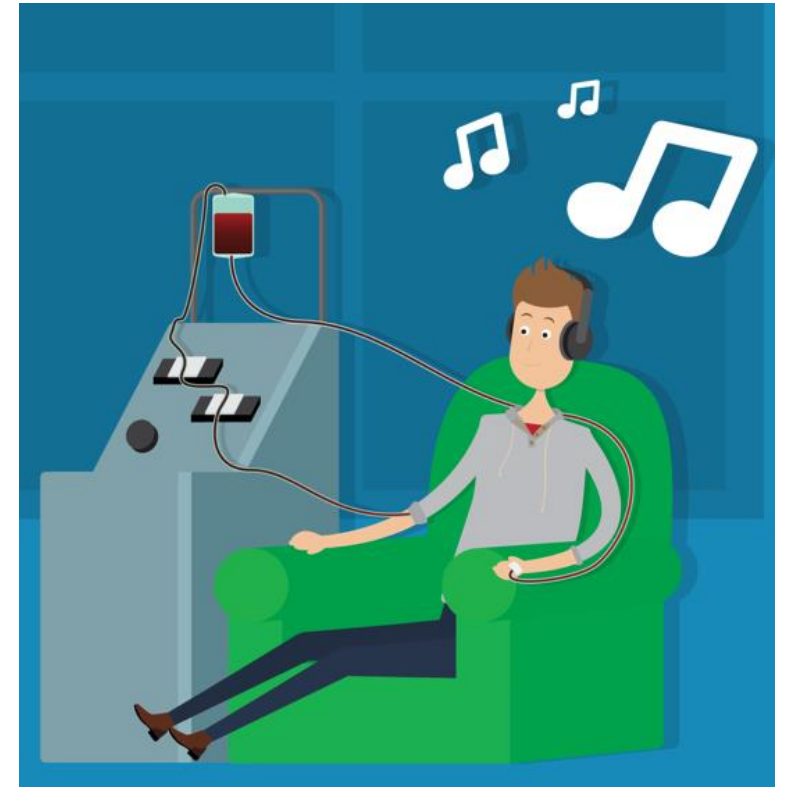
- Bone and soft tissue trauma
 - Hematoma, nerve injury
 - Internal, vascular trauma
- Anaesthesia risk
 - Cardiac complications
 - Respiratory complications
 - Thrombo-embolic complications
 - Allergic or other reactions to anaesthetic agents
- Hypovolemia or anemia



Short term risks: PBSC and lymphocyte collection

- G-CSF
 - Increased immune response, allergic, anaphylactic reactions
 - Increased activity of coagulation system
 - Spleen enlargement, rare cases of rupture
- Apheresis
 - Hypocalcaemia
 - Trauma due to venepuncture or CVC

Drop in platelet count



Long term risks for donors

- G-CSF: filgrastim (Neupogen), lenograstim (Granocyte)
 - Increased risk in haematological malignancy is not confirmed
 - No evidence of chromosomal instability
 - Applicability of findings for biosimilars is not established yet
- Bone marrow collection
 - Long-standing pain

Risks for recipients: transmission of disease

- Infectious diseases
 - Similar to blood transfusion, but note:
 - composition of product differs (mononuclear cells) AND
 - recipient is immunocompromised.
 - Reports: Hepatitis B,C, HTLV type I, malaria, syphilis, Chagas, brucellosis.
 - Globally and locally relevant infectious diseases
- Malignancy
 - Reports of transmission of haematological malignancies

Risks for recipients: transmission of disease

- Autoimmune disease
 - Reports: thyroid disease, type I diabetes, immune thrombocytopenia, vitiligo and psoriasis.
- Inherited diseases
 - If affected gene within hematopoietic pool such as: hemoglobinopathies, inherited BM failure syndroms etc.

Medical assessment during recruitment

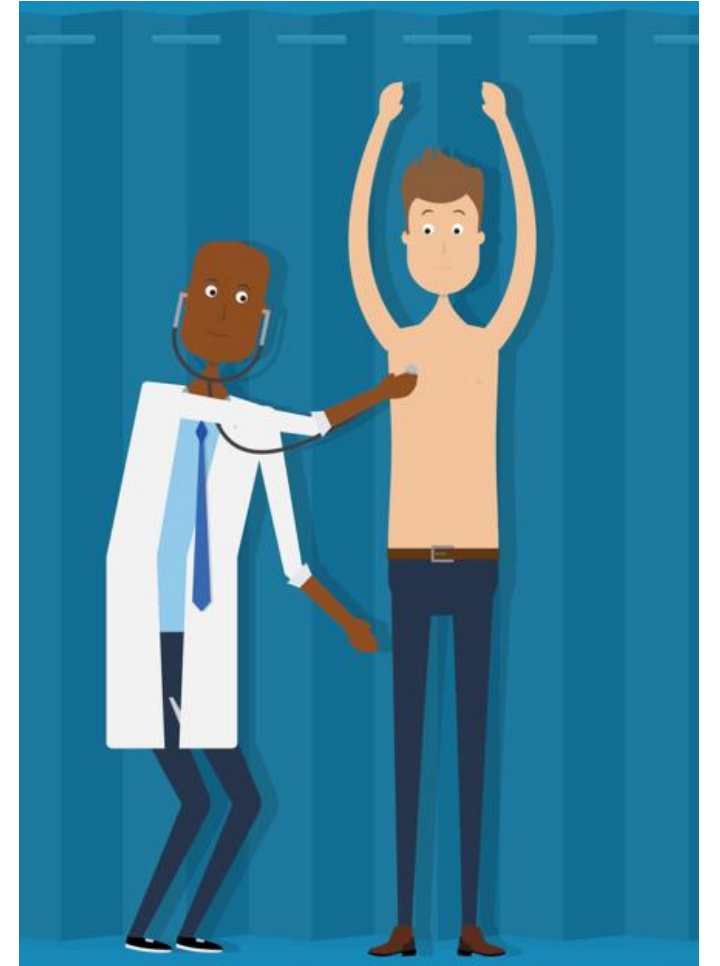
- Donors with a high probability of being readily available for patients
- Transient versus permanent 'conditions'
- Efficient use of limited resources
- Informing the donor about the procedures and the need to provide relevant medical data

Medical assessment during selection

- Obtain additional information relevant for selection
 - CMV, ABO, CCR5
 - sensitisation history (pregnancy, transfusions)
 - Weight of the donor, expected cell count product
 - Recipient risk issues
- Information about availability
 - Stem cell source (medical or personal reasons)
 - Previous donations
 - Agenda

Medical assessment during Work-up

- Donor information – questionnaires, history taking
- Laboratory investigations
 - Infectious Disease Markers
- Chest X-ray, ECG
- Other: abdominal ultrasound
- Decisions regarding donor safety should be made by physician not involved with care for recipient



Criteria and tools

- https://wiki.wmda.info/index.php?title=Main_Page
- Registry assessment tools (e.g. NMDP)
- Criteria with regard to local endemic transmittable diseases (travel)
- Maps
 - <http://atlas.ecdc.europa.eu/public/index.aspx>
 - <https://wwwnc.cdc.gov/travel/>

Dilemmas

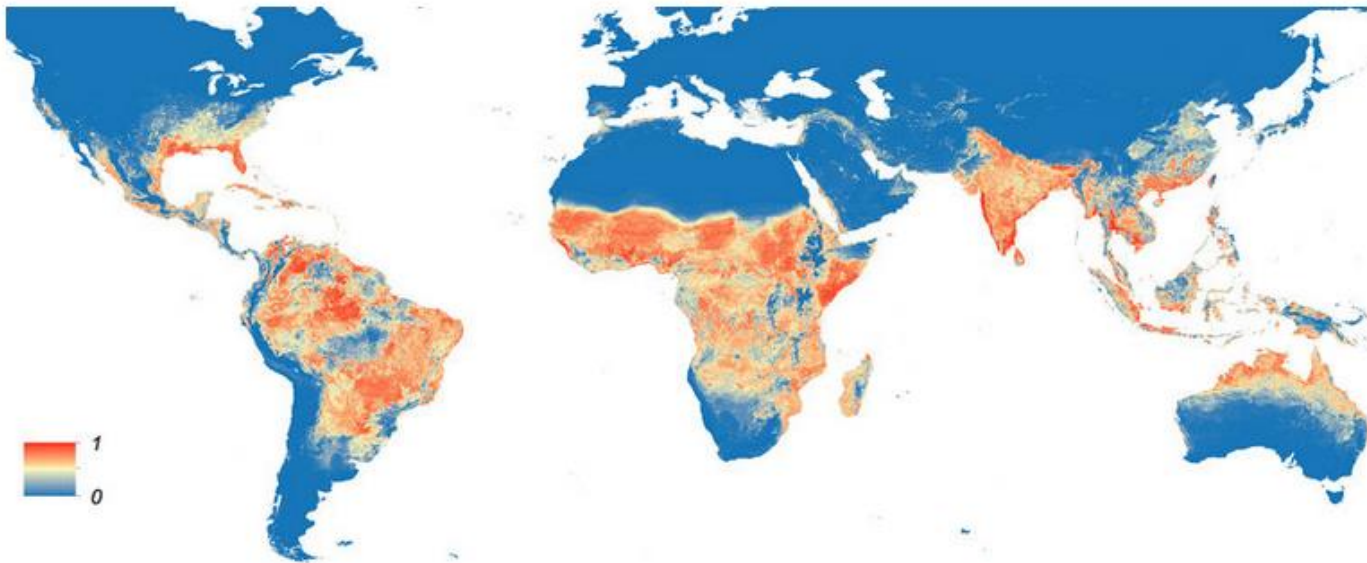
- Discrepancies between assessment tools
 - Thrombosis
 - Malignancies
- Diseases with unknown origin
 - Fibromyalgia
- Diseases with high incidence but mild symptoms that can potentially worsen due to donation
 - Eczema
 - Astma

Dilemmas

- Very rare diseases or genetic disorders
- Risk factors
 - Hypertension
 - Obesity
- Psychiatric disease
 - Impact of donation - postponements
 - Impact of deferral
 - Reliability

Travel and import

- Not only previous but also planned travel
- Import issues: ongoing exposure



This map shows the predicted distribution of *Aedes aegypti*, the mosquito that carries Zika virus. The redder the area, the higher the probability.

eLife

Current and future challenges

- Emerging infections
- Increasing number of young donors
 - More travel
 - Busy donor agendas
- ➡ Risk factors for transmittable disease and scheduling may impact selection
- Biosimilars
 - Need for long term follow-up
- Prove that it is safe