INSTITUTO NACIONAL DE CÂNCER

MANUAL
INTERNATIONAL REGISTRIES

REDOME
INSTITUTO NACIONAL DE CÂNCER

Brazilian Registry of Voluntary Bone Marrow Donors (REDOME)
Instituto Nacional de Câncer José Alencar Gomes da Silva (INCA)
MINISTRY OF HEALTH

SUMMARY

Overview

As the third biggest voluntary donors registry in the world, REDOME is proud of being part of this international network, based on the mutual cooperation.

Driven by ethics and innovation, we understand the urgency to support patients and registries around the world, in the mission to offer the best alternative on hematopoietic stem cell therapy.

Donor safety is our priority and this document presents the main technical and logistic aspects that should be observed by international registries in the relation with REDOME.

Brazil is a continental country and a Program like REDOME has faced many challenges along its 30 years history.

We hope this initiative reinforces the role of REDOME on the international scenario offering hope to those who need.

Dra. Danielli Oliveira

REDOME

Introduction

The objective of this manual is to explain briefly the main aspects related to the process of donor selection and testing, hematopoietic stem cell collection and logistics, privacy and disclosure policy regarding REDOME donors.

These conditions are also available at WMDA website and can be clarified by our team during the operational process.

Deviations from these conditions must be evaluated by REDOME before the donation process starts.

1. Hematopoietic Stem Cell (HSC) REDOME Donors to International Patients

The selection of REDOME unrelated donors for transplantation should be in harmony with the recommendations stablished at international guidelines and consider the best practices and level of evidence indicating a clear benefit to the patients.

Clinical conditions not considered as part of transplant practice should be evaluated as a research project, according the international protocols and in obedience to the Brazilian health authority's regulation.

1.1 Criteria for receiving international requests

Any type of request from an international patient to a Brazilian donor can be sent to REDOME via EMDIS or by e-mail. If the request is sent via EMDIS, the messages are exchanged between the international bone marrow donor registries, according to the criteria previously established for EMDIS communication, but if the request is sent by e-mail, the criteria below are analyzed by our specialized team to attend each demand.

- Verification of the institution's credibility (Bone Marrow Donor Registries, Transplant/ Collection Centers, Donor Centers) in charge of making the requests within the WMDA website (WMDA Share).
- Analysis of the specific information that must be informed for each kind of request according to the international guidelines and considering the best practices and level of evidence indicating a clear benefit to the patients;
- Verification if the team can identify the specific person in charge of the request.
- Checking if the request form received respects the Brazilian legislation on data protection (LGPD) regarding data from donors and patients.
- Analysis of the financial information of the institution in charge of the invoice payment.

1.2 HLA Extended Typing

According international registry request, sent by EMDIS or e-mail, REDOME can proceed with extended HLA typing at high resolution for one or various of the following loci - HLA-A, -B, -C, -DRB1, - DPB1 and -DQB1.

In the absence of stored donor sample, a new sample from donor will be collected and the requesting registry will be informed about the occurrence.

1.3 HLA Confirmatory Typing (CT)

According international registry request, sent by EMDIS or e-mail, REDOME can proceed with confirmatory HLA typing at high resolution for the following loci - HLA-A, -B, -C, -DRB1, - DPB1 and -DQB1.

A new blood sample will be collected from the selected donor and the confirmatory typing can be performed by a Brazilian lab (ASHI or EFI accredited).

Alternatively, the international registry can order the shipping of blood samples for CT or other laboratorial tests and REDOME will arrange the logistic process.

1.4 Prescription

Prescription form must be sent to REDOME, at least 45 days before the collection date, in order to assure the intended collection plan.

Exceptions can be conducted by REDOME as urgent cases.

Prescriptions including two HSC sources are recommended in order to increase the number of available collection centers.

The Donor Final Clearance Approval (DFC) must be approved before by the transplant center before the donor mobilization or collection.

2. REDOME Donor Evaluation at Work Up

The clinical evaluation criteria applied to REDOME donors are determined by Brazilian health authorities (Ministry of Health and ANVISA) in order to assure the protection for donor and receptor.

REDOME donors are evaluated in transplant centers / collect centers by a specialized medical team responsible for applying a specific consent form.

During workup, REDOME donors have the opportunity to clarify doubts about the donation process.

2.1. Clinical Evaluation

The donor`s clinical evaluation includes

- anamnesis (medical history) – preexisting conditions (allergies, medications in use and previous medical procedures), risk factors for transmissible diseases, immunization, specific evaluation for Covid-19 risk factors and history.
- Laboratory tests, including infectious disease markers as described at the Donor Final Clearance (DFC) form.

2.2. Laboratory Tests

2.2.1. Blood Tests

- Complete blood cell count
- Coagulation tests – aPT/INR, TTP
- Blood typing ABO and Rh
- Hemoglobin electrophoresis in case of familial hemoglobinopathy or under request
- Pregnancy test (Beta HcG) (for female donors in fertility age)
- Urea
- Creatinine
- Sodium
- Potassium
- Magnesium
- Calcium
- Gama GT
- Alkaline phosphatase
- AST
- ALT
- Bilirubin total and Diretc
- Glucose
- Total protein and fraction

- Amylase
- Lipase
- Ferritin

2.2.2. Infectious Disease Markers

- HBs Ag
- Anti-HBs
- Anti-HBc
- Anti-HCV
- Anti-HIV 1 and 2
- NAT HCV
- NAT HBV
- NAT HIV
- Anti-HTLV I/II
- Syphilis (FTA-Abs or VDRL)
- Anti-CMV (IgM e IgG)
- Anti-EBV (IgM e IgG)
- Anti-Toxoplasmose (IgM e IgG)
- Anti-Chagas
- Malaria – for donors from endemic areas
- HSV1-2 (IgM e IgG) - Recommended

2.3. Other Exams (according the HSC source and the donor risk factors)

- Chest radiography
- Electrocardiogram

The workup process for donors directed to international process is similar to the process for Brazilian patients. The list of laboratory tests, including infectious disease markers, is determined by Brazilian health authorities.

Laboratory tests not included on standard workup can be ordered by international registries as well as the sending of blood samples. These requests will be evaluated by REDOME according

Donor will be considered eligible for HSC collection, after the complete evaluation by a medical professional from collection center, and according the standards stablished by Brazilian health authorities as well as WMDA recommendations.

3. Hematopoietic Stem Cell (HSC) Product Export

3.1. Collection and Exportation

REDOME will prepare the documents that allow the transport of HSC products from Brazil to another country.

The international registry is the responsible for arranging the logistics (flight and hotel) and indicating a courier to perform the collection the HSC product at the Brazilian collect center and to deliver it at the international transplant center.

The courier should be a professional with experience on biologic products transport experience and his/her personal contacts should be informed to REDOME previously.

The essential documents (declarations and forms) will be sent, by REDOME, to the collection center that is the responsible for delivering them on hand to the courier.

The documents needed to entrance in the destination country must be provided by the patient registry.

3.2. Use of the Collected Hematopoietic Stem Cells

The HSC product should be used exclusively for the purpose of hematopoietic stem cell transplantation for the designated patient.

In the case of cryopreservation, the international registry should communicate REDOME and a specific consent will have to be obtained from the donor.

In the case of extra HSC count, the exceeding product may be stored for future infusion to the same patient only.

No other use of the collected cells is permitted without previous authorization from REDOME.

Hematopoietic stem cells not used for the scheduled transplant should be disposed properly and alternative use are not authorized without previous consent from REDOME

REDOME must be informed about HSC product use and/or disposal and the corresponding date.

4. Cord Blood Unit (CBU) Export

4.1. HLA Confirmatory Typing (CT)

REDOME can perform CT for CBU from attached samples (segments) using high resolution methodology for the following loci - HLA-A, -B, -C, -DRB1, -DQB1, - DPB1.

Alternatively, the international registry can order the shipping of blood samples for CT or other laboratorial tests and REDOME will arrange the logistic process.

The sending of CBU samples or maternal samples is conditioned to the availability of viable samples. This request should be formalized to REDOME using the form **FOR002 - Cord Blood Sample Request**

4.2. Unit Shipment

A CBU should be requested using the form **FOR003 – Cord Blood Unit Request** and after the approval of CBU report by the international transplant center.

The CBU must be delivered at the transplant center before the patient conditioning starts.

The CBU should be used exclusively for the purpose of hematopoietic stem cell transplantation for the designated patient.

Cord Blood Unit not used for transplantation of the designated patient must be properly disposed.

REDOME should be informed of the use and/or disposal of all cell components from CBU and the corresponding date.

5. Confidentiality and Disclosure

REDOME guarantees the condition of anonymity between voluntary donor and recipient.

Voluntary donation of non-related hematopoietic stem cells (HSC) is an anonymous process. The confidentiality aims to protect donor and receptor

ensuring donor autonomy and integrity in accordance with legal and ethical aspects, avoiding any kind of pressure under the donor, such as financial and emotional blackmail.

The exchange of anonymous letter between donor and recipient is permitted 1 year after the infusion. The correspondence will be verified by REDOME.

Exchange of gifts is not allowed.

Disclosure and exchange of patient and donor information can be requested by the donor, patient or patient's legal guardians, only 18 months after the infusion date.

All the requests should be sent to postransplante@inca.gov.br.

The anonymity is also assured during CBU donation and any kind of contact is authorized between recipient and CBU donor or mother.

5.1. Information Available During the Donation

Donor and patient will be oriented about not sharing in social media any information that allow their identification (date and local of donation);

After the collection, REDOME will contact the donor to inform his/her the date of HSC infusion;

After six months from the transplant date, the donor can request information about the patient's health status.

One year after the transplant, donor and patient can exchange letters monitored by REDOME and respecting the anonymity restrictions, if the international registry also allows it.

5.2. Disclosure of Personal Information

The disclosure of personal information between patient and donor and breaking the confidentiality process is allowed eighteen months after the transplant.

Donors and receptors must be informed that close contact and personal conversation or meeting is voluntary and a personal decision from donor and recipient that will be respected by REDOME.

In the case of one of the parts (patient or donor) is not allowed to the revelation, the process will be interrupted, but it will be requested again in the future.

After disclosure process request, the patient´s physician will have to send an updated health status report indicating that the recipient is in good conditions to proceed with the revelation process. The absence of medical evaluation about the disclosure process will interrupt the process.

A specific consent form will be addressed (by e-mail) to the donor or the patient enrolled on the international disclosure process. This document must be signed and returned to REDOME.

Once all the previous steps have been fulfilled, the donor and recipient meeting will be authorized and concluded by REDOME.

6. Cancellation requests guidelines

If a service, previously informed on our fee schedule has been performed, we cannot cancel it, as we have already had costs involved, but the international donor registry receives a message via EMDIS or by e-mail informing we are not able to cancel it.

- For CT blood samples, we charge the service, in case the transport has already been provided;
- For HLA or IDM exams, we charge the service, in case the results are already available;
- For workups, we have different values, depending on the stage of the process. In case the request is canceled before the donor's exam, we charge a value, and in case it is canceled after the donor's exam, we charge another amount.

Closing Remarks

Thanks for your attention on reading this manual.

If you have any questions during the process you can contact REDOME by email at redome.internacional@inca.gov.br or contact the case manager designated for each request.

Telephone: +55 (21) 3207-4706 / +55 (21) 3207 – 4711

Site: http://redome.inca.gov.br/

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