Canadian Blood Services BLOOD PLASMA STEM CELLS ORGANS & TISSUES

60 020
Stem Cell Registry Transplant Centre Reference Manual

Section 6 – Requesting a Donor for Work-up

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Approval Signatures	Date
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Approved by Manager, Quality Assurance see attached email approval	2020-04-08

Revision History

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1	0	CR #17603: New document created from UBMTC0101 as per corporate LINK project	2020-06-29

OVERVIEW

1. Work-up Request

The Canadian Blood Services Stem cell Registry (stem cell registry) will coordinate the work-up of Canadian or international unrelated donors upon receipt of a formal request from the Canadian transplant centre.

Work-up requests for Canadian Blood Services Stem Cell Registry donors are subject to review and approval by the stem cell registry Medical Review Panel in the following cases:

- Patient's disease not listed in **60 019**, *Stem Cell Registry Medical Conditions Chart, Appendix 3, List of Standard Diagnoses for Allogenic Stem Cell Transplant*
- Additional products will be requested as part of a planned protocol
- Additional donation request from the same donor
- Request is unusual.

The work-up of a donor may take approximately four to six weeks from the date of request to product collection. This time frame may vary depending on donor and collection centre or international registry availability. The stem cell registry should be notified immediately if there may be changes in the patient's condition that would result in a postponement or cancellation of the transplant. Additionally, in order to ensure timeliness of processing requests, the transplant centre should ensure adequate coordinator coverage to be able to reply to stem cell registry queries within 1 business day.

The collection centre or international registry may have varying procurement techniques including the filtering, media, additives and anticoagulants used. Any additional information or specific criteria that are required should be requested at the time of work-up activation to ensure the collection centre or international registry can accommodate the additional requirements.

Donors who are approaching the maximum age to donate require consideration on suitability because a subsequent donation may not be possible.

To request a donor participation in research, refer to Section 13, *Research Requests*.

2. Simultaneous Verification Typing /Work-up

In urgent situations, a simultaneous verification typing/work-up of a donor may be requested; however; the risk associated with the potential discovery of a typing discrepancy or donor information that is considered a risk to the recipient must be carefully considered. The request may be declined subject to the international registry policy. The transplant centre must submit the verification typing results to the stem cell registry prior to donor clearance.

3. Back-up Donors

The Canadian Blood Services Stem Cell Registry strongly recommends that the transplant centre requests at least one back-up donor be placed on hold. Canadian Blood Services Stem Cell Registry donors may be held for a maximum of three months from the date of the extended reservation request. Extensions to this time period may be requested if accompanied by a rationale indicating the proposed date of transplant and the patient's medical status. Reservation depends on the willingness of the donor. The policies may vary for international registries.

A transplant centre may request up to 2 Canadian Blood Services Stem Cell Registry donors for work-up per patient. The number of donors permitted for work-up may vary with the international registry policies. Written rationale must accompany the work-up request for a 2nd donor.

4. Infectious Disease Markers (IDMs)

Once selected for work-up, donors will be tested for infectious disease markers (IDMs) within 30 days of the collection.

The IDM testing for Canadian Blood Services Stem Cell Registry donors is performed by Canadian Blood Services and the results are provided to the transplant centre at the time of donor clearance.

4. Infectious Disease Markers (IDMs) ***(continued)***

IDM testing for international donors is performed as per international registry policy. Canadian Blood Services Stem Cell Registry will forward the completed *Infectious Disease Marker Testing to be Performed at Work-up* form to the transplant centre on behalf of the international registry. This form may contain additional information including tests that were unable to be performed, additional tests performed other than those listed or; any day of collection testing. If the international registry is not able to perform all the required testing the transplant centre can request additional precollects.

IDM testing performed by the transplant centre, with abnormal or reactive results must be reported to Canadian Blood Services Stem Cell Registry, except for CMV status.

5. Donor Clearance

Any concerns raised by the collection centre or international registry prior to donor clearance will be documented and communicated immediately.

The transplant centre must not start patient preparative conditioning until all donor clearance documents have been provided by the stem cell registry.

The transplant centre physician is responsible to determine the final decision to proceed with a donor. When applicable, the transplant centre will complete the documentation for exceptional distribution as per the ***Health Canada Safety of Human Cells, Tissues and Organs for Transplantation Regulations.***

PROCESS

6.1. Requesting a Donor for Work-up	6.1.1. Activate the donor for work-up, complete and send the following forms to stem cell registry: • *Workup Request and Prescription for HPC, Marrow; HPC, Apheresis and/or MNC, Apheresis or international registry* equivalent if applicable, ***Note[1]:*** *Refer to Appendix 1: Recommended Procedure for Calculating Total Nucleated Cells.* ***Note[2]:*** *If cryopreservation requested, indicate in Stem Cell National Systems Solution (SCNSS) as per* ***15 701*** *Stem Cell National Systems Solutions User Manual, Section 16* • HLA laboratory typing reports for patient and donor • Research information and donor consent to participate, as per *Section 13, Research Request* if applicable.
6.2. Receive Information from Stem Cell Registry	6.2.1. Receive confirmation if donor willing to proceed with collection and additional donor information, if provided. • If collection centre or international registry is unable to accommodate the requested collection date(s), negotiate mutually acceptable dates. 6.2.2. Receive work-up schedule, completed *Infectious Disease Marker Testing to be Performed at Work-up* form, if applicable and courier instructions, if available. 6.2.3. Confirm acceptance of the collection date(s) and provide the date the patient will begin preparative conditioning if applicable and planned infusion date. 6.2.4. Receive courier waybill/tracking number for pre-collect samples, if applicable. 6.2.5. Receive completed *Qualification of an External Collection, Processing and/or Testing Facility* form or international registry equivalent, if provided.

PROCESS

6.2. Receive Information from Stem Cell Registry (cont.)	6.2.6. Contact Canadian Blood Services Stem Cell Registry immediately for request to cryopreserve entire product. 6.2.7. Receive decision from Canadian Blood Services Stem Cell Registry if request approved or denied. If denied, inform the stem cell registry if proceeding with work-up. 6.2.8. If requesting to postpone or cancel, refer to Section 14, *Postponements and Cancellations*
6.3. Receive Notification of Donor Clearance	6.3.1. Receive the following stem cell registry donor clearance documents or international registry equivalent: • Applicable Prescription Verification, if provided • IDM Results • *Collection Centre Donor Medical Examination* • *Collection Centre Donor Medical Review* form • *Health Screening Questionnaire* (Canadian Blood Services Stem Cell Registry donors only) • Signed donor consent to participate in research study as per Section 13, *Research Requests*, if applicable. 6.3.2. Refer to Section 14, *Postponements and Cancellations* for additional information pertaining to donor clearance in the case of a postponement.
6.4. Donor Findings Associated with Recipient Risk	6.4.1. Evaluate the risk for the patient, following requirements for Exceptional Distribution as per Health Canada **Safety of Human Cells, Tissues and Organs for Transplantation Regulations** as applicable. 6.4.2. Complete transplant centre section of the *Collection Centre Donor Medical Review* or international registry equivalent, if provided and forward to stem cell registry to confirm if proceed with collection or cancel the work-up request and release donor.

PROCESS

6.4. Donor Findings Associated with Recipient Risk (*continued*)	6.4.3. Complete and maintain Exceptional Distribution documentation in the patient's record.
6.5. Review of Prescription Verification	6.5.1. Sign the Prescription Verification form, if provided. Send to stem cell registry prior to starting patient preparative conditioning.
6.6. Courier Details	6.6.1. Complete and send the following forms, or international registry equivalent to stem cell registry: • *Pre-Transplant Work-up Courier Details* • Copy of the courier itinerary 6.6.2 Receive *Courier Letter* and airport notification memo, if applicable.
6.7. Product Receipt and Infusion	6.7.1. Complete the *Transplant Centre Product Infusion Record* and send to stem cell registry. Refer to Section 4, *Requesting Patient Searches* to update the patient search status. 6.7.2. Inform the stem cell registry if product was discarded. 6.7.3. Report immediately any product integrity issues or any unexpected recipient adverse reactions/events associated with the infusion of the product. Refer to Section 11, *Quality/Adverse Event Reporting*.

APPENDIX 1: RECOMMENDED PROCEDURE FOR CALCULATING TOTAL NUCLEATED CELLS

1. Enter the desired number of nucleated cells per kg recipient weight. A typical cell dose might be 3.0×10^8 cells/kg.

2. Enter the recipient's weight in kilograms.

3. Multiply the desired cells per kg by the recipient's weight. Enter the result as the total nucleated cells required for the recipient.

4. Enter the number of additional nucleated cells to be used for quality assurance/transplant centre laboratory.
5. Add lines 3 and 4 together, the sum equals the TOTAL nucleated cells requested from the donor.

A sample calculation:

3.0×10^8 nucleated cells/kg
x 78.2 kg
$= 234.6 \times 10^8$ nucleated cells
+ 1×10^8 cells for quality assurance/transplant centre lab
$= 235 \times 10^8$ total nucleated cells requested

In addition, an estimate can be made on the minimum marrow volume based on the total nucleated cell count (using an average 0.22 cells/ml). The maximum volume removed from the donor should not exceed 20 ml/kg of donor weight.

The remaining sections of the prescription must be completed in accordance with transplant centre requirements. Spaces are provided for pre-collection blood samples, peripheral blood samples and marrow tubes requested on the day of collection and any specific instructions for media or anticoagulants to be added to the marrow.

ASSOCIATED DOCUMENTS:

F800879, *Infectious Disease Marker Testing to be Performed at Work-up*

F801503, *Workup Request and Prescription for HPC, Marrow; HPC, Apheresis and/or MNC, Apheresis*

F801505, *Pre-Transplant Workup-Courier Details*

F801507, *Transplant Centre Product Infusion Record*

F801509, *Prescription Verification - HPC, Marrow*

F801510, *Prescription Verification - HPC, Apheresis & MNC, Apheresis*

F801541, *Collection Centre Donor Medical Review*

F801542, *Collection Centre Donor Medical Examination*

F801554, *Health Screening Questionnaire*

F801606, *Qualification of an External Collection, Processing and/or Testing Facility*

15 701, *Stem Cell National Systems Solutions User Manual, Section 16*

60 019, *Stem Cell Registry Medical Conditions Chart, Appendix 3, List of Standard Diagnoses for Allogenic Stem Cell Transplant*

60 020, Section 4, *Requesting Patient Searches*

60 020, Section 7, *Requesting a Cord Blood Unit*

60 020 Section 11, *Quality/Adverse Event Reporting*

60 020, Section 12, *Search and Transplant Related Costs*

60 020, Section 13, *Research Requests*

60 020, Section 14, *Postponements and Cancellations*