Canadian Blood Services
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2017-07-28
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REF: H-1718-OTTCBB

Ms. Anita Mahadeo
Regulatory Compliance & Enforcement Specialist
Regulatory Operations and Regions Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Ms. Mahadeo:

Re: Responses to Health Canada Inspection of Licensed Activities at Ottawa Cord Blood Bank from 2017-06-19 to 2017-06-23

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-07-10.

Section 55 – Records

1. **The establishment's records were not accurate, complete, legible and/or indelible. For example:**
   a) The Clinical Transplant Facility on the Cord Blood Unit Suitability Assessment and Release form was not accurate for three units distributed (C064314001196, C064315001266, and C064315002612). The form indicated that the Clinical Transplant Facility was CBS care of the transplant facility.

   The forms were error corrected on 2017-07-19.

   On 2017-07-11, a review of the process regarding the use of "CBS C/O (transplant facility)" was completed with all the OneMatch staff who manage Canadian Blood Services' Cord Blood Unit (CBS' CBU) shipment requests. OneMatch staff will ensure they review and correct the 'Ship-to' field, if necessary, for any new CBS' CBU shipment requests received.

   The process will also be reviewed with the Canadian transplant centres at the next scheduled meeting on 2017-09-12.

   b) For C064314001196, the collection site documented on the Cord Blood Transport Form for maternal samples was not accurate.

   The collection site on the Cord Blood Transport Form was corrected on 2017-07-19 with the verifiable information from the maternal donor profile.

   c) The initials and copy identifier recorded on the green label for a Recruitment Criteria for Cord Blood Donation job aide (J800034, Version 2014-01-02) in use at a retrieval site were not indelible. Personnel indicated that the recorded initials and copy identifier were wiped off from the use of disinfectant wipes to clean the form.

   An assessment of all sites was performed on 2017-07-04 to identify any similar occurrences.

Copies where the document control stamp was on the exterior of the laminate were returned and will be replaced by 2017-07-30. For future controlled documents requiring lamination, the document control stamp will be applied on the document prior to lamination.

d) The Assessment field on the Validation of Skills Record for a Nurse Specialist (signed April 28, 2016) was not completed (i.e., satisfactory, unsatisfactory or action required was not indicated). It is acknowledged that the Nurse Specialist completed the required training.

The Validation of Skills Record was corrected on 2017-07-04 upon confirmation of performance from the review of the Nurse Specialist's training records.

A review of all Cord Blood Bank & Stem Cell Manufacturing validation of skills records was completed on 2017-07-04 and no other occurrences were discovered.

e) The Equipment Logbook Summary Form for the Sepax 2 S-100, R1233, was not complete. The Completed by and Date Completed fields were blank.

The staff involved reviewed the Equipment Logbook Summary Form and documented the review on the form on 2017-07-12. All staff will be reminded to follow Good Documentation Practices at the next staff meeting which will take place by 2017-08-31.

Section 73 – Standard Operating Procedures

2. The standard operating procedures were not kept up to date. For example, the establishment's standard operating procedures (e.g., the Medical Conditions Chart) did not clearly indicate that the following would lead to the exclusion of the donor:
a) Known or suspected sepsis at the time of donation. It is acknowledged that the cord blood bank will not collect cord blood if it is known that the maternal/ infant temperature is above 102 degrees Fahrenheit or 39 degrees Celsius (e.g., this is stated in the job aide entitled Recruitment Criteria for Cord Blood Donation, J800034).

b) Active encephalitis of infectious or unknown etiology. The Medical Conditions Chart did not clearly indicate to defer if not fully recovered. Instead, it stated that the donor is eligible if fully recovered, and that the underlying condition may be reason for deferral.

c) Neurological disease of an unestablished etiology. It is acknowledged that some diseases were addressed such as multiple sclerosis and Parkinson's disease.

Combined Response for 2a, 2b and 2c

Our maternal infant assessment and eligibility process is currently under review as part of a working group. The Medical Conditions Chart, Standard Operating Procedures and Job Aids will be part of this assessment expected to be completed by 2018-03-31.

The Medical Conditions Chart will be revised during this time to clearly indicate that the following conditions would lead to exclusion of the donor:

- *known or suspected sepsis at the time of donation*
- *active encephalitis of infectious or unknown etiology if not fully recovered and,*
- *neurological disease of an unestablished etiology.*

Until the Medical Charts is revised, controls are in place to prevent a collection with the identified conditions. This includes an assessment and evaluation of the mother during health interview and medical chart review as well as completing a medical inquiry for assessment and eligibility determination.

If you require clarification or further information, please do not hesitate to contact the undersigned. **Please reference the above CBS control number in any correspondence.**

Sincerely,

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affairs
Fax Number: 613-739-2505

cc: Hugo Tremblay
Supervisor – Blood Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch