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19th June 2019

Sabelina Smith
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Dear Sabelina

RE: OIA - Response

I am writing to respond to your request for release of information under the Official Information Act.

You have requested that New Zealand Blood Service (NZBS) provide information on the '*policy, process and procedures in place for when contacting clients that had an anomaly/condition identified on their blood during their annual check-ups. Could you please include copy of process, policies and procedures for 'cancer referral'.*

Potential donors are required to complete a Donor Questionnaire on each and every occasion they attend to donate blood. A copy of the questionnaire is freely available on the NZBS website (https://www.nzblood.co.nz/give-blood/donating/the-donation-process/donor-health-questionnaire/). We undertake a number of tests on the donation. The questionnaire identifies the nature of these tests and identifies that they 'will be notified if any important abnormalities are found'. In consenting to donate, the donor agrees to this. Any important abnormalities identified during testing are reviewed by a member of the NZBS medical team who will then notify the donor by letter. The content of the letter is determined by the nature of the findings.

NZBS undertakes annual testing of apheresis donors. Donors undergo a specific consent process before they donate by apheresis for the first time. Copies of the Apheresis Donor Information sheet (111I00801) and Consent form (111F03802) are provided. These notify the donor of this additional testing and identify that they will be informed about any significant abnormalities that might be found with these tests.

A member of the NZBS medical team reviews the results of the annual monitoring tests against a set of agreed Guidelines. These are contained in document number 111G08703 (copy provided). Where appropriate, standard letter templates are used to inform the donor of the results.

NZBS always sends letters directly to the donor. Information is only provided to a general practitioner, or other registered health care practitioner, with the specific written consent of the donor. Where appropriate, a request to do this will be included in the letter informing the donor of the results.

You have requested information on systems relating to ‘cancer referral’. The blood donor questionnaire specifically asks donors if they have ever had cancer. In common with other international blood services, NZBS does not allow individuals to donate if they have been diagnosed with a form of cancer. The rules used to determine eligibility for this are contained in a set of documents called the Collection Standards. A copy of the information relating to the rules on cancer is provided (107D002c09 - cancer). The donor is informed when they attend to donate, or contact us via our call centre, if a history of cancer will prevent them from donating.

Occasionally, though infrequently, the results of the tests performed at the time of donation will suggest the possibility that the donor has a form of cancer or other serious disease. When this occurs, the donor is notified using the systems identified above. The responsibility for management of the findings and onward referral for specialist care is the responsibility of the donor’s general practitioner.

Yours sincerely

Sam Cliffe
Chief Executive Officer
New Zealand Blood Service

Attachments: 111I00801
111F03802
111G08703
107D002c09 - cancer

APHERESIS DONOR INFORMATION SHEET

Thank you for volunteering to become an Apheresis Donor. This sheet is intended to inform you about the reasons for apheresis Donation, the practical procedures involved and the potential risks of undergoing apheresis. After reading this sheet, we will ask you to sign a consent form to undergo this procedure for the first time.

WHAT ARE THE ADVANTAGES OF APHERESIS DONATION?

As a blood donor you will be aware that you normally donate about 450mls of whole blood at each donation. You may also be aware that, ***after*** donation, each unit is separated into the various components of blood, including:

- red blood cells, which carry oxygen around the body
- platelet cells, which help the blood to clot; and
- plasma, the liquid part of blood which contains all of the clotting, immune and other proteins.

Each of these components is used separately to treat patients with a variety of disorders and much of the plasma collected is sent to Australia for manufacture into blood products for New Zealand patients.

The amount of blood that can be donated is limited by the loss of red blood cells because donors become anaemic if we remove too much blood. Plasma and platelets lost by blood donation are much more easily replaced by the donor than red blood cells and much larger quantities of these components can be donated safely if the red blood cells can be returned to the donor. This is what happens in an apheresis donation.

HOW DOES APHERESIS WORK?

Blood is removed from a vein and mixed with a substance called citrate to stop it clotting while in the blood collection set. It is then processed in the collection set to separate the red blood cells from the plasma and platelets. The components that are required are kept in the collection set and the red blood cells are returned to the donor. This process allows 2-3 times the usual volume of plasma and up to 12 times the usual number of platelets to be removed at a single donation, without making the donor anaemic.

WHAT ARE THE POSSIBLE PROBLEMS OR RISKS OF APHERESIS DONATION?

- Some of the minor problems seen occasionally in normal donations may also occur from time to time with apheresis donations. Many of these relate to the use of a needle to puncture the vein of the donor and include pain, bruising, infection or minor damage to the nerves in the skin. Dizziness and fainting can also occur occasionally. These potential problems are no more common, and some may be less common with apheresis donations, than with ordinary whole blood donations.

- Apheresis donations take longer than normal donations and usually require:
    - 1-2 hours for platelet apheresis
    - 35-45 minutes for plasmapheresis

- Tingling in the fingers and around the mouth can occur when the red blood cells are returned to the donor. This is due to the infusion of citrate (which is mixed with the blood in the collection set to prevent clotting) with the red blood cells. Citrate is used as a fuel by the body and is rapidly removed from the blood stream, making this a very brief phenomenon. It can generally be overcome by slowing the rate of return of the red blood cells or by having a drink containing calcium.

- Despite the use of citrate, it is possible that the blood may clot while out of the body, preventing its return. However, this is very uncommon and the volume of blood that can be lost in this way is no more than that of a normal whole blood donation.

- Rare theoretical risks include the possibility that air might be introduced into the donor's blood stream but modern apheresis machines include alarms to prevent this and donors are monitored very closely during the procedure.

- All the tubing, needles, and bowls used in this process are sterile and disposable. A new blood collection set is used for each donation, avoiding any problems of contamination.

IS THE DONATION TESTED IN THE USUAL WAY?

The usual tests performed on normal blood donations will be performed, including screening tests for HIV (the AIDS Virus), Hepatitis B, Hepatitis C, HTLV and Syphilis.

Apheresis donors have a number of other monitoring blood tests performed occasionally to ensure that the levels of proteins in their blood and their blood counts remain normal.

Donors will be informed about any significant abnormalities that might be found with these tests.

OTHER IMPORTANT INFORMATION

We will normally conduct a brief physical check up before your first donation to ensure that there are no obvious problems with your health that might lead to difficulties during apheresis donation.

The products collected by apheresis may be used for transfusion to patients; for processing into blood components used by patients; for teaching; or for other laboratory uses.

Should you suffer any adverse effect as a result of undergoing apheresis you will be eligible for compensation in the same way that normal donors are.

If you have any concerns or questions about this procedure you may discuss them at any time with the nurse who will be carrying out the apheresis procedures or with a transfusion medicine specialist.

NATIONAL
111F03802

CONSENT FOR APHERESIS PROCEDURE

I _____ have given an apheresis information sheet to the donor and have provided an explanation in relation to the donation of plasma/platelets/white cells *(delete whichever is not applicable)* by apheresis.

This information included:

- The nature and the purpose of the apheresis procedure
- The practical procedures involved
- The possible side effects and risks of this procedure

I have also offered the donor the opportunity to ask questions and where the questions have been asked, I have answered them appropriately and to the best of my ability.

_____	_____	_____
Signature	**Designation**	**Date**

Donor Consent

If there is anything that you don't understand about the explanation or

If you want more information please ask before signing this form

I _____ have received, read and understood the information provided in relation to the apheresis procedure. I have been given the opportunity to ask questions and my questions have been satisfactorily answered.

I consent to the apheresis procedure and a medical assessment.

I consent to the administration of citrate and calcium and any alternative procedures or treatment that may be required during the course of the donation.

I consent to a blood sample being taken for HLA/HPA typing and for my name to be placed on a list of donors available to be called for specific platelet collection. (*Delete if not applicable)*

_____	_____
Donor Signature	**Date**

CONSENT FOR APHERESIS PROCEDURE

Donor ID Number

GUIDELINES FOR MEDICAL REVIEW OF ANNUAL APHERESIS BLOOD TESTS

REASON FOR ISSUE: **Removed a document that has been merged (DCR5078) and corrected eProgesa references (DCR10843). Included reference to 111P165.**

1. DESCRIPTION

Annual blood tests are a requirement for apheresis donors to continue donating. These test results have to be reviewed by a medical officer or transfusion medicine specialist. These guidelines are to assist that review and provide some consistency between reviewers and sites.

2. SCOPE

A number of factors affect the parameters measured, including gender, age, ethnicity, environment (e.g. altitude), timing of the sample, exercise as well as variations in analytical methods and technique. Normal ranges provided by laboratories may not have been developed for the population group of the donor being reviewed. As a result of this variation, these guidelines are intended only to assist medical officers and transfusion medicine specialists, not replace sound clinical assessment.

3. RELATED DOCUMENTS

107M095 Apheresis Donors – Consent and Assessment
107M121 Selection of Donors for Hyperimmune Plasma and Cyroprecipitate
111F112 Letters to Apheresis Donor
111P165 Policy for Collection and Transfusion of Plasma Fresh Frozen Apheresis Leucocyte Depleted Low IgA

4. REFERENCE RANGES

Medical laboratories generally provide normal ranges that include 95% of the population. They are calculated from the arithmetic mean ± 2 standard deviations (SD). These ranges are referred to as the reference ranges. The acceptable limits include 99% of the population and are calculated from the arithmetic mean ± 3 SD. To derive the acceptable limits (mean ± 3SD), assuming a Gaussian distribution, calculate 1SD (the difference between the higher and lower ranges divided by 4) and add to the higher range and subtract from the lower. This may be necessary for each age and gender specific range. It is recommended that the laboratory performing the tests send the reviewing MO/TMS a full set of reference ranges for all tests concerned so that the necessary acceptable limits can be calculated.

5. PROCEDURE - GENERAL PRINCIPLES

5.1 A single value outside the reference range (2SD) but within acceptable limits (3SD)

This should prompt a review of the donor history and, if appropriate, follow-up tests (eg blood film or ferritin). Suspension or withdrawal is not necessary in the majority of cases.

5.2 Two consecutive values of the same test parameter or 2 concurrent different parameters falling outside the reference range (2SD) but within acceptable limits (3SD)

This should prompt a review of the donor history and, if appropriate, follow-up tests (eg blood film or ferritin). If the finding cannot be explained by physiological variation, the donor should in most cases be suspended for 3 months. A standard letter should be used to communicate abnormal test results and should include a copy of the test results.

5.3 A third consecutive value outside the reference range but within acceptable limits
If this is not explained by physiological variation, it would normally lead to withdrawal of the donor. A standard letter should be used to communicate abnormal test results and should include a copy of the test results.

5.4 Any parameter outside the acceptable limits (3SD)
These values are likely to be of significance. Review the donor history. Consider follow-up tests (eg blood film review, or ferritin if abnormal haematological parameter). A MO/TMS with experience in apheresis may accept the donor if the abnormality can be explained by physiological variation (e.g. exercise). If the abnormality is felt to be significant, the donor may need to be contacted for an urgent repeat sample. Permission must be obtained before contacting the donor's family doctor. A standard letter should be used to communicate abnormal test results and should include a copy of the test results.

5.5 Unacceptable progressive change in a parameter value
MOs/TMSs with experience in apheresis may be concerned about the rate or degree of change in a parameter even when it remains within normal limits (eg a fall in Hb from 150g/l to 115g/l may give rise to concern). It is difficult to cover all such eventualities in guidelines and decisions in such cases should be guided by clinical judgement.

6. PROCEDURE – SPECIFIC TESTS

6.1 Haemoglobin
Donors must meet the minimum haemoglobin to donate as specified in the NZBS Collection Standards. Other than this requirement, assessment is as outlined in section 5.

6.2 Platelets
Platelet counts are measured to determine suitability to donate platelets, as outlined in 107M095 – Apheresis Donors – Consent and Assessment.

Counts below the reference range should be assessed as outlined in section 5.

Because elevated counts may represent a transient acute inflammatory reaction, levels above the reference range should be assessed as for IgG (section 6.7). Consider checking a ferritin level for persistently elevated platelet counts as iron deficiency frequently provokes a thrombocytosis.

6.3 Other FBC results (e.g. MCV)
As most laboratories provide a Full Blood Count and not just haemoglobin and platelet values, abnormalities of other parameters may be discovered. These should only be actioned if regarded as clinically significant and requiring referral to the donor's family doctor. The laboratory's haematologist can be consulted for advice on such parameters.

6.4 Albumin
A raised albumin is caused by prolonged venous stasis or dehydration and does not require any follow-up.

Assessment of a low albumin is as outlined in section 5.

6.5 Total Protein
Albumin makes up more than half of a normal total protein level. Accordingly, only globulin portion of the total protein level should be assessed. This should be assessed as for IgG (section 6.7).

6.6 IgM

IgM is not a requirement for annual testing (see section 7).

6.7 IgG

Levels below the reference range should be assessed as outlined in section 5.

Raised levels may represent a transient acute inflammatory reaction. Accordingly, a donor with raised IgG outside the acceptable limits range (i.e. >3SD) should:

- On the first occasion, have IgG and serum protein electrophoresis tested in 3 months time. A monoclonal band requires referral to a haematologist and a permanent deferral.
- On the second consecutive occasion, be considered for a 3 month suspension with retesting before being accepted for apheresis.
- On the third consecutive occasion, be considered for deferral of the donor and referral to the donor's family doctor.

As immunoglobulin levels may fluctuate with intercurrent infections, action should only be taken for consecutive results.

6.8 IgA

IgA is not a requirement for annual testing (see section 7). It is useful to identify IgA deficient donors (IgA below the level of detection) on the first set of annual tests in order to provide components for patients with anti-IgA antibodies. See 111P165 for more details.

6.9 Specific antibody quantitation

The levels of these specific antibodies determine whether or not a donor's plasma is suitable for hyperimmune immunoglobulin production (see 107M121 Testing for Hyperimmune plasma). Donors should not be deferred on the basis of a fall in these levels.

6.10 Fibrinogen

Fibrinogen is measured to determine the suitability of making cryoprecipitate from the donor's plasma, as outlined in 107M095 – Apheresis Donors – Consent and Assessment. Levels below the reference range should be assessed as outlined in section 5. Because elevated levels may represent a transient acute inflammatory reaction, levels above the reference range should be assessed as for IgG and IgM.

7. RESULTS OF TESTS OTHER THAN THOSE MANDATED

Requesting tests other than those required for annual checks on plasmapheresis and plateletpheresis donors or for testing for hyperimmune plasma, as specified in the respective national SOPs, must be actively discouraged. Similarly, laboratories reporting results of tests that have not been requested must be asked to only report what has been requested.

Results of tests other than those mandated should only be actioned if regarded as clinically significant and requiring referral to the donor's family doctor. Examples of such tests are IgA and IgM levels.

8. WHOLE BLOOD DONATION

Provided the abnormality identified on annual testing does not reveal an abnormality precluding the donor from donating whole blood, a donor who is no longer able to make apheresis donations can give whole blood. An example of an abnormality where the donor

could donate whole blood is a low IgG level. An example of an abnormality where the donor would be permanently deferred from all types of donation is a monoclonal paraprotein.

9. REFERENCES

- Gesinde M. Guidelines on managing apheresis donors MPD/DSD/CS/013/02. Sept 2003. National Blood Service (UK) Internal Document.
- European Directorate for the Quality of Medicines and Healthcare of the Council of Europe (EDQM). The guide to the preparation, use and quality assurance of blood components. 14th edition. Council of Europe; 2008.

A-Z GUIDELINES (C)

DONOR EVENT	CODE	EXPLANATION & CLARIFICATION	ACTION	POST DONATION WITHDRAWAL			
				ePrognosa Allows Issue of Previous Donation	Withdraw Components	Notify Clinician	CSL Action Required
CANCER	**M07P**	These specific malignancies rarely metastasise. But treatment carries drug and infection risks. See also: CYTOTOXIC DRUGS	Successful treatment of basal cell carcinoma (rodent ulcer), squamous cell carcinoma of the skin and carcinoma in situ of cervix (also known as CIN-III or CIS), accept. If on treatment, awaiting treatment or not yet discharged from medical care, defer for 2 years	Yes	From date of diagnosis	No	No
	M00X	Risk of transmission by blood.	Solid tumours including melanoma: accept if successfully treated and clear of disease for at least 5 years. Otherwise defer permanently.	Yes	From date of diagnosis	No	No
	M00X	Risk of transmission by blood.	Haematological malignancies including leukaemias, lymphomas, myelomas, Monoclonal Gammopathy Of Uncertain Significance (MGUS): defer permanently	Yes	From date of diagnosis	No	No
	M03N	This is a pre-malignant condition	Precancerous conditions (e.g. cervical dysplasia CIN-1 and CIN-II) on treatment or under investigation, defer for 1 year	Yes	From date of diagnosis	No	No
	M00Y	See also AWAITING RESULTS OF TESTS	If in doubt about nature of tumour, refer to MO	Yes	From date of onset of symptoms	-	-