

NATIONAL HAEMOVIGILANCE DATA COLLECTION GUIDELINES

DECEMBER 2015

VERSION 1

CODE: LCBT-HV 007

TRANSFUSION ACTIVITIES DOCUMENTS

NATIONAL HAEMOVIGILANCE DATA COLLECTION GUIDELINES

1. Budget for blood donor recruitment

This is the necessary budget to cover expenditures incurred by actions implemented to attract blood donors, including promotion of blood donation, all forms of media, posters, brochures and others.

The answers are yes or no.

2. Blood donor retention strategy

This is a written approach defined to encourage repeat donations that can be applied at various stages of the donation process: in the reception zone, during the medical interview, as part of the post-donation information management, in the refreshment area, through the maintenance of donors' records, through regular contacts with donors.

This is any action improving donor satisfaction and encouraging repeat donation.

3. Total number of blood/blood product units received from other transfusion centers (TC)

These blood products can be whole blood, red blood cells concentrates, fresh frozen plasma, or apheresis platelet concentrates.

The percentage is calculated from the addition of blood products collected from both the center and other TCs.

Labile blood products (%) = $\frac{\text{total number of blood products from another TC}}{\text{total number of blood products} + \text{total number of blood products from other TCs}} \times 100$

4. Number of whole blood or apheresis platelet donors during the year (excluding autologous donors)

All blood donors are unpaid. There are two types of donors:

- Voluntary Donors are those who donated blood on their own initiative.
This type of donors includes first-time donors or repeat donors. Repeat donors are counted only once.
- Replacement donors are those who donated blood at the request of the patient's family.

Voluntary donors or family replacement donors include both whole blood donors and apheresis donors.

Note: the question is the number of donors, not the number of units collected (donations).

5. Number of whole blood or apheresis donations during the year by donation type (excluding autologous donors)

The same methodology applies, but the number of units collected (donations) must be reported, not the number of donors. Donors may donate several times throughout the year; units collected from the same donor are counted individually.

6. Number of deferred donors: reasons for deferral (pre-donation)

This is the number of deferred donors for any clinical, biological (...) reason.

These donors are deferred either permanently or temporarily (for a fixed duration).

The total number of donors permanently and temporarily deferred is equal to the number of cases reported in question 7 (contraindication to donate blood).

7. Number of deferred donors: contraindications

In line with the previous question, please specify the contraindications that justified deferral of the blood donor.

The percentage is calculated from the total number of potential donors (Accepted + Deferred) compared to the number of deferred donors.

Deferred donors (%) = $\frac{\text{total number of deferred donors}}{\text{total number of potential donors (Accepted + Deferred)}} \times 100$

8. Gender distribution of blood donors

9. Age distribution of blood donors

10. Number of pre-operative autologous blood donations

This is the number of donations from patients donating blood for themselves.

11. Screening of transfusion-transmissible infections

For screening tests, specify the method and equipment used. It is not a confirmatory test if a test is repeated using the same methodology, with the same or different equipment. .

12. In case of a reactive test result for transfusion-transmissible infection, do you perform further testing to confirm the result?

The confirmatory test is a second-line test: *Western blot* test to *confirm HIV* or HCV infection, neutralization tests for Hepatitis B surface Antigen (HBsAg), detection of viral genome by polymerase chain reaction (PCR) *tests* for the various serologic markers.

The answers are yes or no:

13. In the case of positive serologic results

If other methods or second-line tests are used to confirm results, then the answer to the previous question is YES. Please specify which confirmatory test is used in the table.

14. Do you have a notification procedure relating to blood donation?

If so, this is a notification procedure to report positive serology tests results for transfusion-transmissible infections to:

- The Ministry of Health (through the dedicated form)
- The donor, who should be informed

For each test, please answer yes or no.

15. Do you have a guidance and follow-up procedure for donors with positive serology results after testing for transfusion-transmissible infections?

Is a donor with positive serology result assisted and advised on what action to take? Is there a written and consistently applied procedure?

16. Prevalence of syphilis among blood and platelet donors

This is to determine the number and percentage of cases of blood or platelet transfusion-transmitted syphilis infections.

17. 18. 19. Prevalence of infections

This is to determine the number and percentage of cases of blood or platelet transfusion-transmitted HIV, HBV and HCV infections.

For each marker, please specify the number and percentage.

20. Number and percentage of blood donations separated into their components

This is to determine component preparation post whole blood donation.

Please specify how many whole blood donations are separated into components compared with total number of whole blood donations.

Whole blood donations

Separated into their components (%) = $\frac{\text{number of whole blood donations separated into components}}{\text{total number of whole blood donations}} \times 100$

21. Number of blood components prepared from whole blood donations

This question applies to blood components from whole blood donations only, excluding blood components collected by apheresis.

22. Number of blood component units from apheresis donations

This question applies to blood components from apheresis donations only, excluding therapeutic apheresis (plasma exchange...).

23. Number of whole blood donations/red blood cell concentrates discarded due to following reasons

This is the number of whole blood donations or red blood cell concentrates that cannot be released for transfusion and are therefore discarded. The total number of discarded units is itemized into categories listed in the table and must match the sum of cases reported in each category.

24. Number of transfused blood units and blood component units (excluding autologous blood donations)

This is to determine how many units are transfused by blood component type.

25. Number of whole blood donations or leukoreduced red blood cell concentrates (RBCC)

This is to determine the number and percentage of whole blood donations and leukoreduced RBCC compared with the total number of transfused units.

Please write which percentage of units were leukoreduced at the blood transfusion center (BTC) and at bedside.

26. Number of adverse transfusion reactions reported within the year

Please write how many adverse transfusion reactions were reported in each category of transfusion reactions listed in the table.

27. If available and operational, please specify which blood bank activity IT equipment is used.