Global Database on Blood Safety (GDBS) 2008

Global Database on Blood Safety

The World Health Organization (WHO) programme on Blood Transfusion Safety would appreciate your kind cooperation in completing this questionnaire which has been designed to obtain information for the WHO Global Database on Blood Safety.

The GDBS was established by WHO to address global concerns about the availability, safety, and accessibility of blood for transfusion. It covers the four major components of the integrated strategy for blood safety advocated by WHO:

- The establishment of well-organized, nationally-coordinated blood transfusion services with quality systems in all areas
- The collection of blood from voluntary non-remunerated blood donors from low-risk populations and the phasing out of family/replacement and paid donation
- The screening of all donated blood for transfusion-transmissible infections, including HIV, hepatitis B and C, syphilis and other infectious agents; blood grouping and compatibility testing
- A reduction in unnecessary transfusions through the effective clinical use of blood.

The objective of the GDBS is to collect and analyse data from all Member States of WHO in order to enable the Organization to:

- Obtain the best available information on blood transfusion services in each Member State
- Assess the global situation on blood safety, availability and access and monitor trends and progress
- Identify priority countries for support and technical assistance
- Plan research and develop appropriate strategies to address specific needs.

The GDBS was initiated in 1998. GDBS reports are available on the WHO website (http://www.who.int/bloodsafety/global_database/) and from WHO Headquarters and Regional Offices. Please contact WHO if you need further information or assistance in completing the GDBS questionnaire.

Data collection for the period January 2008–December 2008

The GDBS questionnaire should be completed by an authorized person in the Ministry of Health or the National Blood Transfusion Service. Please provide details of the person who completes the questionnaire so that WHO can make contact, if necessary, for clarification and further information.

The questionnaire should be completed with data for the period January to December 2008. If calendar year information is not available, please provide information for the nearest 12-month period (e.g. April 2008 to March 2009), and indicate the period covered on the form.

Data collection questionnaire

The GDBS questionnaire for 2008 is available in both electronic and printed forms in all six official languages used by WHO: Arabic, Chinese, English, French, Russian and Spanish.

You are requested to complete the electronic version of the questionnaire, if possible.

If you prefer to complete the paper version of the questionnaire, a copy of the questionnaire can be downloaded from the WHO website (http://www.who.int/bloodsafety/global_database/).

If you are using the paper version of the questionnaire, please enter data for all questions, except those that contain a grey box. The calculations for these questions will be made by WHO.

Options of “Yes” and “No” are offered for responses to qualitative questions. If you feel that a “Yes” or “No” answer alone is insufficient to capture some aspects of the situation in your country, please provide further information in the “Comment” box at the end of the questionnaire. Information provided through the “Comment” boxes is an essential part of the data collected through this questionnaire.
Annex 1 contains a list of definitions for terms shown in italics in the questionnaire.

In order to promote standardization, questions that may be subject to different interpretations are marked with a superscript number and further information is provided at the bottom of the relevant page.

Before submitting the completed questionnaire, please check that all questions have been answered.

**Returning the GDBS questionnaire**

When you have completed this questionnaire, please return it to the World Health Representative in your country by **15 December 2009**. Please also send a copy to:

- WHO Regional Office
- WHO Headquarters.

The contact details of all World Health Representatives are available on the WHO website ([http://www.who.int/countries](http://www.who.int/countries)). If there is no WHO Country Office in your country, please send the completed questionnaire directly to the appropriate WHO Regional Office at the address given in Annex 2, with a copy to WHO Headquarters.

Blood Transfusion Safety  
Department of Essential Health Technologies  
World Health Organization  
20 Avenue Appia  
CH-1211 Geneva 27, Switzerland  
Fax: +41 22 791 4836  
E-mail: bloodsafety@who.int
## Global Database on Blood Safety (GDBS)

### Section 1: Administrative information

**Information provided by:**

1.1 Name

1.2 Title

1.3 Position

1.4 Organization

1.5 Address

1.6 Country

1.7 Tel. no.  

1.8 Fax no.

1.9 E-mail

1.10 Date

1.11 Total population (please give year and source)

1.12 Period covered by report

1.13 Number of **blood centres** in the country

1.14 Number of blood centres covered by this report

1.15 Is there a mechanism to assess the national requirement for blood?

1.15.1 If yes, approximately how many units of whole blood were needed to cover the national requirement for blood in 2008?

### Section 2: Organization and management

**Policy and Structure**

2.1 Is there a unit within the Ministry of Health (or other government department) with responsibility for overseeing all activities related to blood transfusion?

2.1.1 If yes, name of the unit:

2.1.2 Name of the officer in charge:

2.2 Is there a **national blood policy**?

2.3 Is there a **national blood strategy or strategic plan**?

2.3.1 If yes, has its implementation been initiated?

2.4 Is there specific legislation covering the safety and quality of blood transfusion?

2.4.1 If yes, please give document reference number:

2.5 Has the Ministry of Health constituted a **national blood authority** (or equivalent) with responsibility for policy development and decision-making on issues pertaining to blood transfusion?

2.5.1 If yes, please provide a separate list showing the membership of this body

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1 Please provide data for the period **January 2008** to **December 2008**. If data for this period are not available, please provide data for the nearest 12-month period (e.g. April 2008 to March 2009).

2 Please refer to the definition of “blood centre” in Annex 1. Blood banks that **ONLY** store, check compatibility and issue blood should not be categorized as blood centres.
2.6 Is there a (national) expert panel(s) to advise on technical and medical issues related to the safety, sufficiency, availability and quality of blood transfusion? □ □ □

2.7 Is there a national blood transfusion service (NBTS)? □ □ □
   2.7.1 If yes, name of national director/chief executive officer: __________________________

2.8 Has the government delegated any responsibility for the NBTS/blood transfusion services to a non-governmental organization? □ □ □
   If yes:
   2.8.1 Name of the organization(s): __________________________
   2.8.2 Role of the organization(s): __________________________

2.9 How is the responsibility for the operation of the NBTS/blood transfusion services distributed? For each category, please indicate the number of each type of blood centre.

<table>
<thead>
<tr>
<th>Management responsibility</th>
<th>Stand-alone blood centres</th>
<th>Hospital-based blood centres</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government</td>
<td>□ □ □</td>
<td>□ □ □</td>
<td>□ □ □</td>
</tr>
<tr>
<td>Non-governmental/non-profit organizations</td>
<td>□ □ □</td>
<td>□ □ □</td>
<td>□ □ □</td>
</tr>
<tr>
<td>Commercial (for profit) organizations</td>
<td>□ □ □</td>
<td>□ □ □</td>
<td>□ □ □</td>
</tr>
</tbody>
</table>

2.10 Is there a national system of data collection and analysis for the NBTS/blood transfusion services? □ □ □

2.11 What is the estimated total funding (in US dollars) for operating the blood centres covered in this report (including staffing and operations)? US$ □ □ □
   2.11.1 Estimated total funding from national government US$ □ □ □
   2.11.2 Estimated total funding from fees and cost recovery US$ □ □ □
   2.11.3 Estimated total funding from external donors US$ □ □ □

2.12 What is the approximate cost (in US dollars) of producing a unit of whole blood/red blood cells? US$ □ □ □

2.13 Is a specific budget provided for the NBTS/blood transfusion services? □ □ □

2.14 Does any international agency/organization/institution provide technical support to the NBTS/blood transfusion services? □ □ □
   2.14.1 If yes, name of agency: __________________________

2.15 Does any international agency/organization/institution provide financial support to the NBTS/blood transfusion services? □ □ □
   2.15.1 If yes, name of agency: __________________________

Quality Systems

2.16 Are there national standards for the operations of the NBTS/blood transfusion services? □ □ □

2.17 Is there a designated national quality manager for the NBTS/blood transfusion services? □ □ □

2.18 How many blood centres have a quality system? □ □ □

2.19 Is there a national system of audit of the NBTS/blood transfusion services? □ □ □

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3 Blood banks that ONLY store, check compatibility and issue blood should not be categorized as blood centres.
2.20 Is there a national external quality assessment scheme/external evaluation of performance for:
   2.20.1 Transfusion-transmissible infections
   2.20.2 Blood group serology and compatibility testing

2.21 Is there a national haemovigilance system?

2.22 Is there a mechanism for the regulation of the NBTS/blood transfusion services?
   If yes:
   2.22.1 Is there a system of regular inspection of the NBTS/blood transfusion services?
   2.22.2 Is there a national regulatory agency for the NBTS/blood transfusion services?
   2.22.3 Is there a system for mandatory registration or licensing of the NBTS/blood transfusion services?
   2.22.4 Number of registered/licensed blood centres

2.23 Are blood centre staff subject to certification?
   2.23.1 If yes, number of certified staff

2.24 Did stocks of any of the following consumables run out during the reporting period?
   2.24.1 Blood collection bags
   2.24.2 Test kits for transfusion-transmissible infections
   2.24.3 Reagents for routine blood grouping
   2.24.4 Others (please specify):

Education and Training

2.25 Is there a programme of continuing education for personnel involved in blood transfusion?

2.26 Are there educational programmes in blood transfusion medicine/science leading to a nationally-recognized university degree/diploma?

2.27 Does your country have the capacity to provide education and training in blood transfusion for other countries?

2.28 Does your country need support in establishing education and training programmes in blood transfusion?

Section 3: Blood donors and blood collection

3.1 Is there a national blood donor programme?

3.2 Is there a designated national blood donor programme officer/manager?

3.3 Is a specific national budget provided for the blood donor programme?

3.4 Was World Blood Donor Day celebrated in your country during the reporting period?

3.5 Are information and education materials available for blood donors?

3.6 Are there national criteria for assessing the suitability of donors for blood donation?

3.7 How many blood centres use standard operating procedures (SOPs) or local written instructions for:
   3.7.1 Blood donor recruitment
   3.7.2 Pre-donation counselling and donor selection
   3.7.3 Blood collection and donor care
   3.7.4 Post-donation counselling

3.8 How many blood centres maintain records of the following?
   3.8.1 Blood donor recruitment
   3.8.2 Pre-donation counselling and donor selection
   3.8.3 Blood collection and donor care
   3.8.4 Post-donation counselling
### Questionnaire on Blood Safety

#### Section 3: Blood Donor Management

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.9 Do blood donors have a haemoglobin/haematocrit estimation done before blood donation?</td>
<td></td>
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<tr>
<td>3.10 Is there a register/database of blood donors?</td>
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<tr>
<td>If yes, at what level is the register/database of blood donors maintained?</td>
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<td></td>
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<tr>
<td>3.10.1 National</td>
<td></td>
<td></td>
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<tr>
<td>3.10.2 State/provincial/regional</td>
<td></td>
<td></td>
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<tr>
<td>3.10.3 Individual blood centre or hospital</td>
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<tr>
<td>3.11 How many blood donors\footnote{4} donated whole blood during the reporting period?</td>
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<tr>
<td>3.11.1 Total number of donors who donated whole blood</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.11.2 Total number of voluntary non-remunerated donors who donated whole blood</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.12 How many deferrals were there from whole blood donation, by types of deferral?</td>
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<tr>
<td>3.12.1 Permanent deferral</td>
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<tr>
<td>3.12.2 Temporary deferral</td>
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<td></td>
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<tr>
<td>3.13 How many deferrals were there from whole blood donation, by reasons for deferral?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.13.1 Low haemoglobin</td>
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<td></td>
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<tr>
<td>3.13.2 Other medical conditions</td>
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<td></td>
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<tr>
<td>3.13.3 High-risk behaviour</td>
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<td></td>
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<tr>
<td>3.13.4 Travel and other reasons</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.13.5 Total number of deferrals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.14 How many whole blood donations were collected, by types of donation?</td>
<td></td>
<td></td>
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<tr>
<td>3.14.1 Voluntary non-remunerated donations</td>
<td></td>
<td></td>
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<tr>
<td>3.14.2 Family/replacement donations</td>
<td></td>
<td></td>
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<tr>
<td>3.14.3 Paid donations</td>
<td></td>
<td></td>
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<tr>
<td>3.14.4 Others (please specify):</td>
<td></td>
<td></td>
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<tr>
<td>3.14.5 Total number of donations</td>
<td></td>
<td></td>
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<tr>
<td>3.15 How many whole blood donations were collected from:</td>
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<td></td>
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<tr>
<td>3.15.1 Male donors</td>
<td></td>
<td></td>
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<tr>
<td>3.15.2 Female donors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.16 How many whole blood donations were collected from:</td>
<td></td>
<td></td>
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<tr>
<td>3.16.1 Donors under 18 years</td>
<td></td>
<td></td>
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<tr>
<td>3.16.2 Donors aged 18 to 24 years</td>
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<td></td>
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<tr>
<td>3.16.3 Donors aged 25 to 44 years</td>
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<td></td>
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<tr>
<td>3.16.4 Donors aged 45 to 64 years</td>
<td></td>
<td></td>
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<tr>
<td>3.16.5 Donors aged 65 years or older</td>
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<td></td>
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<tr>
<td>3.17 How many whole blood donations were collected from first-time voluntary non-remunerated donors?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.18 Number of whole blood donations collected per 1000 population</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.18.1 If this report does not cover all whole blood donations that were actually collected in your country, please estimate the percentage that this report covers.\footnote{5}</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.18.2 Adjusted whole blood donations per 1000 population</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\footnote{4} When the number of donors is counted, donors who donated whole blood on more than one occasion in the reporting period should only be counted once.

\footnote{5} This information is used to generate an adjusted blood donation rate per thousand population in 3.18.2 if less than 100% of whole blood donations collected were reported through this GDBS questionnaire.
3.20 Are any blood donations collected through apheresis procedures?  
If yes, how many apheresis donations\(^6\) were collected by types of donation?  
3.20.1 Voluntary non-remunerated apheresis donations  
3.20.2 Family/replacement apheresis donations  
3.20.3 Paid apheresis donations  
3.20.4 Others (please specify):  
3.20.5 Total number of apheresis donations  
3.20.6 Total number of donors\(^7\) who donated through apheresis procedures during the reporting period

3.21 What was the number of whole blood donations that were NOT collected in sterile, disposable, plastic blood collection bags?

3.22 Is there a system of recording adverse blood donor reactions?

3.23 Is the prevalence of transfusion-transmissible infections monitored in the blood donor population?

3.24 Is there a donor notification system for:  
3.24.1 HIV results  
3.24.2 Hepatitis B results  
3.24.3 Hepatitis C results  
3.24.4 Syphilis results

3.25 How many blood centres have a system of post-donation counselling of blood donors who test positive for transfusion-transmissible infections?

**Section 4: Screening for transfusion-transmissible infections**

4.1 Please specify the laboratory tests required in your country as minimum requirements for screening donated blood for transfusion-transmissible infections (TTIs):  

<table>
<thead>
<tr>
<th>Test</th>
<th>Ab</th>
<th>Ag</th>
<th>Combined Ag + Ab</th>
<th>NAT</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-I/II</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Hepatitis B</td>
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<td>Hepatitis C</td>
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<tr>
<td>Syphilis</td>
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<tr>
<td>Chagas disease</td>
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</tr>
</tbody>
</table>

\(^6\) When multiple blood components (such as platelets and plasma) are collected through one apheresis procedure, the number of donations should only be counted as “1”.  
\(^7\) When the number of apheresis donors is counted, donors who donated on more than one occasion in the reporting period should only be counted once.
### 4.1.6 Malaria
- Ab
- Ag
- NAT
- Others (please specify):

### 4.1.7 HTLV I/II
- Ab
- Others (please specify):

### 4.2 How many blood centres perform laboratory screening of blood donations for transfusion-transmissible infections?

### 4.3 How many blood centres use standard operating procedures or local written instructions for laboratory screening of blood donations for transfusion-transmissible infections?

### 4.4 How many blood centres maintain records of laboratory screening of blood donations for transfusion-transmissible infections?

### 4.5 How many blood centres participate in an external quality assessment scheme/external evaluation of performance for transfusion-transmissible infections?

### 4.6 How many donations (whole blood and apheresis) were screened for the following transfusion-transmissible infections?

<table>
<thead>
<tr>
<th>TTI markers</th>
<th>Screening test reactive</th>
<th>Confirmatory test positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B</td>
<td></td>
<td></td>
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<tr>
<td>Hepatitis C</td>
<td></td>
<td></td>
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<tr>
<td>Syphilis</td>
<td></td>
<td></td>
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<tr>
<td>Chagas disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaria</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HTLV I/II</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 4.7 How many donations (whole blood and apheresis) were: (a) reactive in the screening test; and (b) positive in the confirmatory test?

<table>
<thead>
<tr>
<th>TTI markers</th>
<th>Screening test reactive</th>
<th>Confirmatory test positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td></td>
<td></td>
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<tr>
<td>Hepatitis B</td>
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<td></td>
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<tr>
<td>Hepatitis C</td>
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<tr>
<td>Syphilis</td>
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<tr>
<td>Chagas disease</td>
<td></td>
<td></td>
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<tr>
<td>Malaria</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HTLV I/II</td>
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</tbody>
</table>

### 4.8 What was the prevalence of the following TTI markers in donated blood during the reporting period?

<table>
<thead>
<tr>
<th>TTI markers</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>HIV</td>
<td></td>
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<tr>
<td>Hepatitis B</td>
<td></td>
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<tr>
<td>Hepatitis C</td>
<td></td>
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<tr>
<td>Syphilis</td>
<td></td>
</tr>
</tbody>
</table>

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* Please leave the box blank if the test is not mandatory.

* Please leave the box blank if confirmatory testing is not performed.
### 4.9 Details of blood centres/laboratories in which screening for TTIs is performed: number of donations tested, use of standard operating procedures (SOPs) and participation in external quality assessment/external evaluation of performance

<table>
<thead>
<tr>
<th>Blood centre/laboratory ID</th>
<th>Total donations</th>
<th>N° of donations screened for each TTI</th>
<th>SOPs used</th>
<th>Participate in EQA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>HIV</td>
<td>HBV</td>
<td>HCV</td>
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</tbody>
</table>

Please add an additional sheet if more entries are required.

### 4.10 Were any blood units issued without screening due to:

- 4.10.1 Non-availability of test kits/reagents
- 4.10.2 Emergency situations
- 4.10.3 Staff shortages
- 4.10.4 Equipment failure/breakdown/power loss
- 4.10.5 Other reasons (please specify):

### Section 5: Blood group serology testing of blood donations

<table>
<thead>
<tr>
<th></th>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1 How many blood centres perform blood group serology testing of blood donations?</td>
<td></td>
<td>%</td>
</tr>
<tr>
<td>5.2 How many blood centres use standard operating procedures or local written instructions for blood group serology testing of blood donations?</td>
<td></td>
<td>%</td>
</tr>
<tr>
<td>5.3 How many blood centres maintain records of blood group serology testing?</td>
<td></td>
<td>%</td>
</tr>
<tr>
<td>5.4 How many blood centres participate in an external quality assessment scheme/external evaluation of performance for blood group serology?</td>
<td></td>
<td>%</td>
</tr>
</tbody>
</table>

### Section 6: Blood component preparation, storage and transportation

<table>
<thead>
<tr>
<th></th>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1 How many blood centres prepare blood components?</td>
<td></td>
<td>%</td>
</tr>
<tr>
<td>6.2 How many whole blood donations were separated into components?</td>
<td></td>
<td>%</td>
</tr>
<tr>
<td>6.3 How many units of blood components were prepared from whole blood donations?</td>
<td></td>
<td>%</td>
</tr>
</tbody>
</table>

**Component**

- 6.3.1 Red cell preparations
- 6.3.2 Platelet concentrates
- 6.3.3 Plasma
- 6.3.4 Fresh frozen plasma
- 6.3.5 Cryoprecipitate

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10. If units of whole blood used for component preparation are not 450 ml, please indicate the volume that is used in your country in the “Comment” box.

11. If platelet concentrates are pooled, the total number of the original platelet concentrates that were pooled should be counted. For example, if 6 units of platelet concentrates were pooled into one bag, this should be counted as 6 platelet concentrates rather than 1.
6.4 How many units\(^{12}\) of blood components were prepared through apheresis procedures?

6.4.1 Apheresis red cells

6.4.2 Apheresis platelets\(^{13}\)

6.4.3 Apheresis plasma

6.5 How many blood centres use standard operating procedures or local written instructions for the preparation of blood components?

6.6 How many blood centres maintain records of blood component preparation?

6.7 How many blood centres store whole blood and blood components in temperature-monitored equipment?

6.8 How many blood centres transport whole blood and blood components in temperature-monitored equipment?

6.9 How many blood centres store test kits and reagents in temperature-monitored equipment?

6.10 How many units of whole blood were discarded due to faulty collection?

6.11 How many units of whole blood and blood components were discarded due to other reasons?

<table>
<thead>
<tr>
<th>Component</th>
<th>TTI</th>
<th>Processing problem</th>
<th>Storage problem</th>
<th>Transport problem</th>
<th>Date expiry</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.11.1 Whole blood</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.11.2 Red cells</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.11.3 Platelets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.11.4 Plasma</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.11.5 Fresh frozen plasma</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.11.6 Cryoprecipitate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Section 7: Hospital transfusion process and clinical use of blood & blood components**

7.1 How many hospitals in your country perform blood transfusion?

7.2 How many district/first-referral level hospitals perform blood transfusion?

7.2.1 How many district/first-referral level hospitals performing blood transfusion had uninterrupted access to supplies of blood and blood products?

7.3 Are there national guidelines on compatibility testing?

7.4 Which of the following are required in compatibility testing?

7.4.1 ABO cell/forward grouping on patient’s sample

7.4.2 ABO serum/reverse grouping on patient’s sample

7.4.3 RhD typing on patient’s sample

7.4.4 Antibody screen on patient’s sample

7.4.5 Cross-match between donor cells and patient serum

7.4.6 Electronic selection of compatible units (“computer crossmatch”)

---

\(^{12}\) When a single apheresis procedure produces more than one type of component (e.g. plasma and platelets), all units of components should be counted.

\(^{13}\) One unit of apheresis platelets usually contains 200–450 x 10\(^9\) platelets.
7.5 How many hospitals have blood banks that perform compatibility testing?  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.5.1 How many hospital blood banks use standard operating procedures or local written instructions for compatibility testing?  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.5.2 How many hospital blood banks maintain records of compatibility testing?  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.5.3 How many hospital blood banks participate in an external quality assessment scheme/external evaluation of performance for compatibility testing?  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.5.4 How many hospital blood banks store whole blood and blood components in temperature-monitored equipment?  

| Yes | No |

7.6 Is there a system of regular inspection of the hospital blood banks?  

| Yes | No |

7.7 Are there national guidelines on the appropriate clinical use of blood?  

| Yes | No |

7.8 How many hospitals performing blood transfusion have, or participate in:  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.8.1 Hospital transfusion committee  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.8.2 System for monitoring clinical transfusion practice  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.8.3 System for reporting adverse transfusion incidents  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.9 How many patients were transfused?  

| Male | Female |

7.10 How many patients were transfused by age and gender?  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.11.1 Whole blood  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.11.2 Red cells  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.11.3 Plasma and fresh frozen plasma  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.11.4 Platelets, whole blood-derived  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.11.5 Platelets, apheresis  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.11.6 Cryoprecipitate  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.12 How many hospitals use standard operating procedures or local written instructions for the transfusion of blood to patients?  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.13 How many hospitals maintain records of blood transfusion to patients?  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

7.14 How many serious adverse transfusion incidents or reactions were reported?  

<table>
<thead>
<tr>
<th>N°</th>
<th>Per cent</th>
</tr>
</thead>
</table>

Section 8: Fractionated plasma products

8.1 Is there a national plan for the provision of fractionated plasma products?  

| Yes | No |

8.2 Are plasma products imported from abroad?  

| Yes | No |

8.3 Is plasma fractionation carried out within the country through the public/not-for-profit sector?  

| Yes | No |

8.4 Is plasma fractionation carried out within the country through the for-profit sector?  

| Yes | No |

8.5 Is plasma sent for contract fractionation in another country?  

| Yes | No |

8.6 Is there a mechanism for the regulation of fractionated plasma products?  

| Yes | No |
8.7 What was the total volume of plasma used for fractionation?\(^{14}\)

<table>
<thead>
<tr>
<th></th>
<th>Recovered plasma</th>
<th>Apheresis plasma</th>
</tr>
</thead>
<tbody>
<tr>
<td>litres</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8.8 Was there a surplus of plasma in excess of national needs for transfusion and fractionation?

- [ ] Yes
- [ ] No

If yes, how was surplus plasma utilized?

- [ ] Donated to another country/organization
- [ ] Sold to another country/organization
- [ ] Discarded
- [ ] Other (please specify):

8.9 Was there a surplus of fractionated plasma products in excess of national needs?

- [ ] Yes
- [ ] No

If yes, how are these products utilized?

- [ ] Donated to another country/organization
- [ ] Sold to another country/organization
- [ ] Discarded
- [ ] Other (please specify):

8.10 What was the number of plasmapheresis donors?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Voluntary non-remunerated plasmapheresis donors</td>
</tr>
<tr>
<td></td>
<td>Paid plasmapheresis donors</td>
</tr>
</tbody>
</table>

\(^{14}\) This figure should include all plasma used for fractionation within the country and / or sent for contract fractionation. If plasma was imported for fractionation during the reporting period, it should also be included here.
Comments
Please use the space below and attach additional pages, if necessary, to provide any further relevant information or comments on the GDBS questionnaire.
Annex 1

DEFINITIONS

For the purposes of this questionnaire, the following definitions should be used in answering the questions.

Audit: Systematic, independent and documented examination to determine whether activities comply with a planned and agreed quality system.

Blood bank: A laboratory or part of a laboratory within a hospital which receives and stores screened blood and components from a blood centre, performs compatibility testing and issues blood and components for clinical use within the hospital. It may be called a hospital transfusion laboratory.

Blood centre: A facility which carries out all or part of the activities for donor recruitment, blood collection (whole blood and, in some cases, apheresis), testing for transfusion-transmissible infections and blood groups, processing into blood components, storage, distribution to hospital blood banks within a defined region, and liaison with clinical services. Blood centres may be stand alone or hospital-based. The following should NOT be categorized as blood centres:
- Mobile or fixed blood collection sites/rooms which are operated as part of a blood centre
- Hospital blood banks which only store, check compatibility and issue screened blood.

Blood donors
- Voluntary non-remunerated blood donor: A person who donates blood (and plasma or cellular components) of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money.
- Family/replacement blood donor: A person who gives a replacement unit of blood only when a family member or friend requires transfusion.
- Paid “donor”: A “donor” who gives blood for money or other form of payment.
- Autologous donor: A patient who donates his/her blood to be stored and reinfused, if needed, during surgery.

Blood transfusion service (BTS): A generic term to describe an organization that is involved in the provision of blood for transfusion, regardless of whether it is nationally coordinated or not. BTS activities can be carried out through a single blood centre or through a network of several centres.

District/first-referral level hospital: A hospital at the first referral level that is responsible for a district or a defined geographical area containing a defined population and governed by a politico-administrative organization such as a district health management team.

External quality assessment (EQA): The external assessment of a laboratory's performance using samples of known, but undisclosed, content and comparison with the performance of other laboratories. An external quality assessment scheme is a recognized scheme for organizing EQA. This can be a local scheme or may be organized at national, regional or international levels.

Fractionated plasma products: Human plasma protein products prepared under pharmaceutical manufacturing conditions. Plasma products include albumin, immunoglobulin and coagulation factors VIII and IX.

Haemovigilance: A set of surveillance procedures for the monitoring, reporting and investigation of adverse events (reactions and incidents, including near-misses) covering the whole transfusion chain, from the collection of blood and its components to the follow-up of recipients, intended to collect and assess information and to prevent their occurrence or recurrence.

National blood authority: The highest policy formulation and decision-making body under the Ministry of Health for issues pertaining to blood transfusion services in the country. All major stakeholders in the blood transfusion process are usually represented in this authority. May also be referred to as the national blood committee or national blood council.

National blood policy: A statement of intent by the Ministry of Health that defines the organizational, financial and legal measures that will be taken to ensure the quality, safety, availability and accessibility of blood transfusion within the country.

National blood programme: A programme under the Ministry of Health with overall responsibility for the planning, implementation and monitoring of all activities related to blood transfusion throughout the country. Responsibility for the implementation of the blood programme may be fully or partially delegated to a governmental or non-governmental organization designated as the national blood transfusion service.
National blood strategy or strategic plan: A structured series of steps that provide a pathway for the national blood programme to achieve its policy objectives.

National blood transfusion service (NBTS): The organization with statutory national responsibility for the provision of blood for transfusion, and liaison with clinical services. The NBTS coordinates all activities concerned with blood donor recruitment and the collection, testing, processing, storage and distribution of blood and blood products, the clinical use of blood and surveillance of adverse transfusion events. Activities are carried out within a network of national/regional/provincial blood centres and hospital blood banks.

National clinical transfusion committee: A national committee that receives reports from hospital transfusion committees, collates national information on transfusion activity, and may determine national guidelines for clinical transfusion practice. The NCTC may also have a role in the liaison with educational institutions and the preparation of educational materials.

(National) expert panel: A (national) panel of experts in blood transfusion medicine and/or science that meets on a regular basis to advise on matters associated with the safety, sufficiency, availability and quality of blood transfusion.

Quality-assured testing: For the purpose of data collection, testing in a quality-assured manner is defined as “testing performed in a laboratory that:

- Uses documented standard operating procedures
- Participates in an external quality assessment scheme”.

Quality manager: The appointed, responsible and authorized individual within a blood transfusion service or blood centre with responsibility for developing and managing the quality system.

Quality policy: A document that defines the goals and objectives of a blood transfusion service or blood centre with regard to quality, and makes a commitment to meeting stated requirements and an undertaking to drive continuous improvement throughout the activities. It must be suitable for the organization and provide a framework for establishing, communicating and monitoring performance against agreed quality objectives.

Quality system: The organizational structure, process, procedures and resources needed to implement quality requirements. A blood centre with a quality system should have, at minimum, the following elements:

- Documented quality policy, quality manual/standard operating procedures/work instructions that cover all important areas of the centre
- Organizational structure that defines the authority, responsibility and reporting relationship of all positions in the centre
- Programme for staff training and competency assessment
- System of monitoring and continual improvement, including participation in an appropriate external quality assessment scheme and an internal audit programme that is conducted regularly.

Serious adverse incident: A case where the patient is transfused with a blood component that did not meet all the requirements for a suitable transfusion for that patient, or was intended for another patient and that might lead to death or a life-threatening, disabling or incapacitating condition or which results in, or prolongs, hospitalization or morbidity. A serious adverse incident may be due to transfusion errors or to deviations from standard operating procedures or hospital policies that have led to mistransfusion. It may or may not lead to a serious adverse reaction.

Serious adverse reaction: An undesirable response or effect in a patient associated with the administration of blood or blood components that is fatal, life-threatening, disabling or incapacitating or which results in, or prolongs, hospitalization or morbidity.

Standard operating procedure (SOP): Written instructions for the performance of a specific procedure in a standardized manner.

Surplus of plasma: Plasma collected in a country that is surplus to the country's needs for direct transfusion and for fractionation to meet the country's own requirements for plasma derivatives.
Annex 2

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