

Haemovigilance Survey – Reference Document

World Health Organization (WHO) has established a working group on “Haemovigilance Tools” as an activity under the Action Framework to Advance Universal Access to Safe, Effective and Quality-Assured Blood Products 2020–2023 (Action Framework).

Under the Action Framework, WHO has prioritized effective blood safety surveillance/haemovigilance supported by comprehensive and accurate data collection systems within one of the six strategic objectives.

Towards this objective WHO seeks to develop a guidance document on stepwise development of a national haemovigilance system for use in Member States. The document is intended to build upon the 2016 WHO guidance entitled “A Guide to Establishing a National Haemovigilance System” moving from “what to do” to “how to do it.”

The WHO working group requests responses to the attached survey to help focus the work of this group. In order to capture a broad range of perspectives, the survey is being distributed concurrently through the WHO Regional Focal Points and the International Society of Blood Transfusion (ISBT) to policy makers, professionals working in the field, and other stakeholders.

This survey is distinct from GDBS. The results will remain confidential and will be used solely for development of haemovigilance tools.

Kindly provide your responses to this digital survey by 10th January 2021.

Note:

Haemovigilance is a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients and their follow-up. It includes the monitoring, reporting, investigation and analysis of adverse events related to the donation, processing and transfusion of blood, and taking actions to prevent their occurrence or recurrence. (A guide to establishing a national haemovigilance system, WHO 2016)

LINK TO THE DIGITAL QUESTIONNAIRE FORM:

<https://forms.gle/UgkoZSdX9FnVgqZE7>

(The above link can be circulated to all the stakeholders through Email)

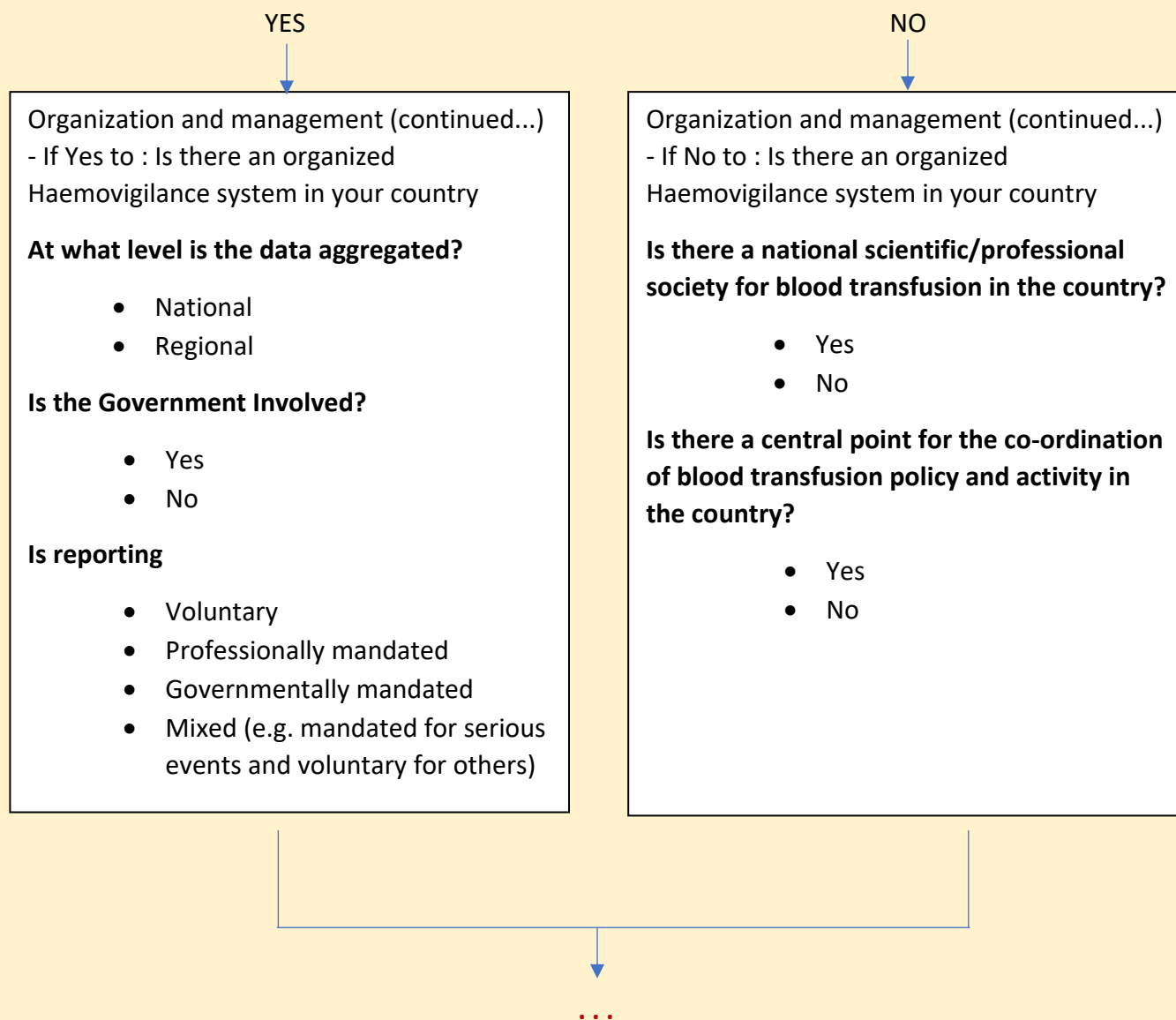
Details collected through the questionnaire form are:

Details of the Person/Organization submitting the response to the questionnaire

- COUNTRY
- Name of the Responding/Corresponding Person
- Organization and designation/position within organization of the Responding Person
- Contact Email
- Contact (Telephone) along with the Country Code

Organization and Management

1. Is there an organized Haemovigilance system in your country



Major challenges, Constraints and Strategies

2. What are the primary challenges and barriers to implementing a Haemovigilance system in your country?

- A. Need for Dedicated Financial provision/Financial Constraints/Limited Financial Resources
- B. Need for Organizational structure/Governing body/Central reporting authority
- C. Need for Government oversight
- D. Need to Identify all stakeholders/Service Providers and bring them common comprehensive system
- E. Lack of Trained personnel
- F. Unavailability of Technical/Subject Expertise for setting up of Haemovigilance system
- G. Lack of country specific Reporting formats and Guidance document
- H. Lack of Centralized Comprehensive Digital Data Capture System
- I. Unwillingness to participate /report in Haemovigilance
- J. Lack of Statistical and Analytical tool
- K. Other (Please Mention)

3. Please identify the top 3 priority areas for Haemovigilance technical support and/or capacity building in your country (select three (3) of the following):

- A. Financial
- B. Organizational/Administrative
- C. Legal Framework
- D. Country Specific Guideline & Guidance document creation
- E. Educational: Technical/Manpower skill development
- F. Infrastructural Support/Technology Upgradation
- G. Networking
- H. Statistical & Analytical tools
- I. Other (Please Mention)

4. Please identify the top 3 priority tools that would help implement a Haemovigilance program in your country (select three (3) of the following):

- A. Standard & Validated Definitions
- B. Guidelines/Guidance Documents
- C. Educational & Training modules
- D. Certified Technical Expertise
- E. Standardized Reporting formats
- F. Data Capture System
- G. Statistical & Analytical tool
- H. Organizational Structure for Networking
- I. Other (Please Mention)

5. For your country's three top priority tools, what format would be preferred:

Tool	Poster	Document	Video
A. Standard & Validated Definitions			
B. Guidelines/Guidance Documents			
C. Educational & Training modules			
D. Certified Technical Expertise			
E. Standardized Reporting formats			
F. Data Capture System			
G. Statistical & Analytical tool			
H. Organizational Structure for Networking			

Respondent can select multiple formats for the 3 selected top priority tools

If any other tool and format of the tool is anticipated, please specify _____

6. Is there anything else you would like the WHO Haemovigilance Tools Working Group to know about your country and its needs regarding implementation of Haemovigilance?

[free text]

Scope and Coverage (Optional follow-up questions if data are readily available)

7. Please provide the scope of Haemovigilance (if any) in your country:

7A. Does the system include collection of data on blood donor-related adverse events/adverse reactions?

YES _____ / NO _____ (No Here will guide you to 7B)

Optional follow-up questions if data are available:

- a. **If yes, do all blood collection centers participate?** [If “yes” goto 7B]
- b. **If the answer to 7.A.a. = no, what percentage participate, if any?**
- c. **Please describe/comment:** [→ goto 7B]

7B. Does the system include collection of data on recipient-related adverse events/adverse reactions?

YES _____ / NO _____ (No Here will guide to SUBMIT form → END)

Optional follow-up questions if data are available:

- a. **If yes, do all hospitals participate?**
- b. **If the answer to 7.B.a. = yes, Has the data of adverse reactions of transfusion been integrated into the hospital information system** [SUBMIT form → END]
- c. **If the answer to 7.B.a. = no, What percentage participate, if any?**
- d. **Please describe/comment:** [SUBMIT form → END]

Thank You for Your Contribution!

Directions for the stakeholders to submit their response to the Haemovigilance survey questionnaire

- This is a digital questionnaire
- You can access the questionnaire by clicking the link below

LINK TO THE DIGITAL QUESTIONNAIRE FORM:

<https://forms.gle/UgkoZSdX9FnVgqZE7>

- You can fill in the details through desktop/laptop or even a smartphone with internet connectivity.
- As you fill the details you will be guided to the subsequent pages/sections. Please click “NEXT” after completing entry in each page/section to navigate to further pages/sections. There are 13 pages/sections in the questionnaire form which navigates the respondent in a structured manner.
- The first 6 questions are mandatory fields to be filled. You can identify the mandatory fields by the red Asterix “*” at the end of the question. The questionnaire form will not allow you to progress further until you have filled relevant data in the mandatory fields before clicking “NEXT”.
- The section 7 is optional. if data is available, kindly fill up the relevant details.
- Wherever the “OTHER” option is available in the questionnaire form, you will get a free text space on clicking the “OTHER” option. You can type your responses in the free text space to submit details other than what is available in the multiple choices listed/provided.
- At the end of the questionnaire, you will find the “SUBMIT” button. By clicking the “SUBMIT” button you will be completing your response to the digital questionnaire form and your details will then be accessible to the WHO Regional Advisors.

Details of the Contact Person in case of any Query with the Haemovigilance Survey Questionnaire:

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WHO Regional Advisors

How to share the Haemovigilance survey questionnaire?

- The questionnaire can be shared with the stakeholders through mail. The link to the questionnaire is
LINK TO THE DIGITAL QUESTIONNAIRE FORM:
<https://forms.gle/UgkoZSdX9FnVgqZE7>
- By copying and pasting the above-mentioned link in the body of the mail communication, the questionnaire can be made accessible for responses from the stakeholders.
- This link will only enable them to submit their responses to the questions and they will not be able to edit or change the questions in the questionnaire form. So the link can be safely shared.

How to access the responses received to the Haemovigilance survey questionnaire?

- Once the respondent clicks on the submit button at the end of the questionnaire form, his/her response will be recorded. All the submitted responses by will be digitally recorded and listed in a google spread sheet.
- A separate link to access the spreadsheet will be sent to the Regional Advisors by e-mail through which the Regional Advisors will be able to review the details.
- The Regional Advisors will also be able to download the responses in to an excel sheet and apply suitable statistics.
- The spreadsheet link is particularly for the Regional Advisors only. This should not be shared with any of the respondents.