**THE ORGANIZATIONAL ASPECTS OF HEMOVIGILANCE IN LEBANON**

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# **Part I: THE HEMOVIGILANCE STRUCTURE**

# **Definition:**

Hemovigilance (HV) is defined as « the set of procedures for monitoring, evaluating and preventing the incidents and adverse reactions which occurs in donors or in blood components (BCs) recipients ».

# **Scope of application:**

The HV covers the entire transfusion chain from the collection of BCs to the follow-up of the recipients. It also includes the epidemiological follow-up of donors.

# **Objectives:**

The main objectives of HV are:

*- To prevent the incidents and adverse reactions in donors and recipients*

*- To create a traceability from the blood donation to the administration of BCs to the recipient*

# **Action plan:**

In order to achieve the HV objectives, the action plan will be based on the following three main points:

*- The collection and the retention of information regarding all the steps of the transfusion chain*

*- The collection of information regarding all incidents occurring in recipients and donors*

*- Conducting studies regarding the conditions for the use of BCs in addition to epidemiological surveys*

**IV.1- The collection and the retention of information regarding the transfusion chain**

The collection and the retention of information begins from the time of blood collection to its administration to the patient.

**IV.2- The collection of information regarding all incidents occurring in recipients and donors**

The data collection depends on the obligation to report any transfusion incident by the stakeholders involved in the transfusion chain.

**IV.3- Conducting studies regarding the conditions for the use of BCs in addition to epidemiological surveys**

These studies will optimize the detection of the conventional transmissible agents and control the emerging ones.

*Thus, HV is an integral part of the pharmacovigilance policy relative to blood products of human origin.*

# **The Hemovigilance stakeholders**

**V.1. On the national level** (refer to Appendix I)

The Lebanese Committee of Blood Transfusion (LCBT) will establish the Hemovigilance system, in accordance with the Ministry of Public Health (MoPH), which includes the following activities:

* Establish the terms and the organizational aspects of the national HV, particularly its policy and the reporting/declaration system.
* Direct and coordinate the actions of the different involved stakeholders.
* Establish guidelines for the content and the procedures for exchanging BCs and information between the health care institutions (HC).
* Analyze the results of incidents and adverse reactions and suggest preventive measures.
* Inform the MoPH about the progress of hemovigilance at the national level.

**V.2- At the health care institution level**

In terms of hemovigilance, the regulations specify two categories of stakeholders in public and private health care institutions:

* Designated hemovigilance officers (HVO)
* Transfusion Safety and Hemovigilance Committees (TSHC)

**V.2.1- The HC-based Hemovigilance officer (refer to Appendix II)**

i- Establishing the HVO position:

At least one hemovigilance officer must be appointed in each public or private HC, irrespective of the presence or absence of a local blood transfusion center (BTC).

ii- Qualification and appointment of the HVO:

The HVO should be preferably a specialist doctor with competence in the field of transfusion. He/she will be appointed by the HC administration for a renewable period of three years. The HVO name must be communicated to the LCBT.

##### iii- The HVO responsibilities:

* Investigate transfusion incidents
* Report incidents related to the administration of BCs, or which occurred during donation (refer to Appendix IV and V)
* Collect and store the records regarding the exchanges of the HV information
* Report to the hemovigilance technical committee (HVTC) any difficulties susceptible to compromise the transfusion safety
* Ensure the implementation of training programs
* Collaborate with the distributing BTC to provide transfusion advice to the prescribers and the paramedical personnel
* Participate in the drafting of transfusion protocols

**V.2.2- Transfusion safety and Hemovigilance committee or TSHC (refer to Appendix III))**

i- Establishing the TSHC:

Health care institutions must establish this committee and define its role.

ii- Qualification and appointment of the TSHC:

This committee includes members involved in the transfusion activities with expertise in this field if possible (it can be the same as the HC transfusion committee). The members are appointed by the HC administration.

iii- The TSHC mission:

The mission of this committee is to define and develop the transfusion safety policy within the health care institution according to the standards published by the LCBT.

Its role consists primarily of:

* Implementing the Hemovigilance regulations
* Coordinating the Hemovigilance activities within the health care institution
* Implementing the LCBT reporting procedures
* Drafting the collaboration policy with the referral BTC, if necessary
* Developing and monitoring the operations of blood storage facilities
* Implementing a training program for professionals in the field of blood transfusion
* Drafting transfusion protocols

# **Part II: THE OPERATING PRINCIPLES OF HEMOVIGILANCE**

# **The HV system**

**I.1- Collection of information and mandatory reporting of incidents in the recipient**

Any practitioner who detects any adverse or unexpected reaction occurring during or following transfusion must report it to the local HVO (the health care institution’s HVO) where the BC was administered.

The HV officer will conduct an investigation and complete the transfusion incident form or TIF, which serves as the basis for the online reporting system to the LCBT. If the BC origin was from a referral BTC, the local HVO will conduct an investigation in collaboration with the HVO of the referral BTC (co-signature) and complete the TIF. If both are the same person, then his/her signature alone on the TIF is sufficient.

Appendix IV describes the content of the TIF and the notification and reporting procedures.

**I.2- Collection of information and mandatory reporting of a serious adverse reaction in a blood donor**

Any health care professional who detects or is informed about a serious adverse reaction occurring in a blood donor must report it to the HVO of the HC in which the donation took place. The latter will conduct an investigation and complete the serious adverse donor reaction form (SADRF) which shall be transmitted to the LCBT according to the applicable procedure.

Appendix V describes the contents of the SADRF form and the notification and reporting procedures. In particular, it defines the serious situations related to the incident that must be reported, and the respective levels of responsibility.

**I.3- Traceability**

***I.3.1- Definition:***

This refers to the possibility, based on the recorded donor ID, to:

* Quickly retrieve the history, the use, or the location of a BC at all stages of its collection, preparation, distribution, delivery, and/or the recipient(s) to whom it was administered.

This refers to the possibility, based on the recorded recipient ID, to:

* Quickly retrieve the history regarding all the stages of collection, preparation, distribution, and delivery of the BC, and/or the corresponding donor(s).

***I.3.2- Objective:***

The objective is to identify the donor, or the recipient based on the blood component reference or identification number, for example:

* Following the detection of a transfusion transmissible disease in a transfused patient, the donor needs to be identified in order to offer him the appropriate tests.
* Similarly, following the detection of an abnormal test result in a donor that could pose a risk to the recipient, the donor's previous donations need to be traced. Subsequently, the HC needs to be informed about these components, who will also have to be able to identify the previous recipients in order to offer them the appropriate tests.

***I.3.3- Follow-up method:***

Tracking BCs from the donor to the recipient requires:

- The identification of the BC through a unique reference number assigned, in accordance with the applicable regulation, by the BTC.

 - The distribution of individual BCs (by name): to note that each BC is only issued based on an individual medical prescription; the distribution should identify for each issued BC, the prescribing physician, the patient concerned and the HC.

***I.3.4- Special case: procurement of BCs from a reference BTC (distributor):***

In this case, it is mandatory for each public or private health care institution, to sign an agreement with the reference BTC in order to ensure the BCs traceability and to respect the national HV regulations.

#### I.3.5- The health care institution and the reference BTC responsibilities:

 - The health care institution shall provide the LCBT with the name(s) of the reference BTC(s) from whom supplies will be obtained according to the collaboration agreement established between these two parties.

 - The reference BTC shall provide the LCBT with the name(s) of the health care institution(s) that it supplies according to the collaboration agreement established between these two parties.

This arrangement, which describes the BC distribution circuits, must ensure the transparency of the distribution and therefore the follow-up of each BC, from the donor to the transfused patient.

***I.3.6- Information exchange procedures:***

Reference BTCs and health care institutions must establish systems for recording, collecting and exchanging information related to the BCs.

Reference BTCs are thus required to collect and retain information starting from the identification of the donor and the acceptance of the donation to the identification of the prescriber and the patient to whom the product has been administered or the identification of the health care institution where the transfusion took place.

Health care institutions must collect and retain, among other things, the blood component ID (of the reference BTC), its storage and transport conditions, the patient and the prescriber IDs, and any resulting transfusion related adverse reaction.

If a product has been prescribed for one patient but administered to someone else, it is of utmost importance that this procedure rectifies the identity of the transfused patient.

The standard collaboration agreements, drafted by the LCBT, will specify the content as well as the procedures for collecting and transmitting the information between the reference BTC and the health care institutions in normal circumstances and in the event of a transfusion incident. Particular attention should be paid to the quality of the information exchanges.

I.4- Epidemiological surveys and studies

The LCBT suggest to the Director General of the MoPH launching epidemiological surveys and studies regarding the conditions for the use of BCs. Subsequently, the results will be disseminated to the HV stakeholders.

# **Patient Rights:**

Each recipient has the right to be informed about the administered BC(s) and the possible adverse reactions. An informed consent, signed by the recipient, must precede the transfusion procedure.

# **Appendix I: THE LEBANESE COMMITTEE OF BLOOD TRANSFUSION (LCBT))**

This committee was nominated in 2011 by the MoPH to support and guide the project of improving the transfusion practices in Lebanon. Its mission, within the context of implementing the Hemovigilance policy, is to:

1. Suggest the organizational aspects of the national Hemovigilance and its operating procedures, in particular, the design of the online reporting system
2. Collect the transfusion related incidents and adverse reactions that were reported by the HVO
3. Discuss the most significant cases of adverse reactions and incidents, reported by the local HVO, and suggest, if necessary, additional investigation and follow-up measures
4. Advise the Director General of Health regarding the measures required in order to prevent, reduce or eliminate the risks related to BCs
5. Ensure the quality of the monitoring system and its continuous improvement
6. Guide the improvements in the reporting and the data collection systems
7. Ensure the consistency of the HV document set
8. Identify the issues in the field of transfusion safety
9. Suggest, to the Director General of Health, the investigations and studies that are considered useful for the HV practice s
10. Monitor the literature for the national and international publications related to HV data and encourage their scientific exploitation/analysis
11. Analyze the outcomes of the transfusion related incidents and adverse reactions in order to prepare an annual report on HV and submit it to the MoPH
12. Hold an annual meeting for all HVOs in order to present the report and discuss the HV issues

# **Appendix II: THE HEMOVIGILANCE OFFICER (HVO) OF THE PUBLIC, PRIVATE OR THE COLLECTING HEALTH CARE INSTITUTION**

**Background:**

A specialist physician with expertise in transfusion and HV. The officer is appointed for a renewable period of three years by the HC administration, after consulting the TSHC (which he/she is usually its coordinator). His/her name is communicated to the LCBT within 3 days following the appointment. He/she will regularly attend the annual HV meetings and, if necessary, the training seminars organized by the MoPH.

**Missions:**

1. Participate in drafting and monitoring the protocols related to the use of BCs in the HC
2. Participate in the meetings of the clinical wards which use BCs
3. Participate in the continuing education and training sessions for the BCs prescribers and users in the various HC wards (neonatology, pediatrics, intensive care, anesthesia, hematology, etc.)
4. Ensure the collection and the storage of data:
	* Verify whether the applicable regulations are implemented
	* Establish a system that allows the traceability of BCs in the health care institution
5. Assume responsibility regarding the activities of transfusion safety:
	* Monitor the circuits
	* Monitor the storage conditions
	* Monitor the conditions for the return of unused BCs
	* Monitor the perioperative autologous transfusion practices
6. Report and monitor any adverse reaction:
	* Perform the necessary upstream or downstream transfusion investigations
	* Complete the transfusion incident form (TIF) and the serious adverse donor reaction form (SADRF)
	* Report the recipient's incident on the MoPH's electronic platform
	* Report the serious donor incident to the health care institution
	* Implement corrective actions
7. Participate in the epidemiological surveys established by the LCBT
8. Act as the secretary of the TSHC and participate in the HV meetings of the health care institution (as a coordinator)
9. Report to the LCBT any difficulty that could compromise the transfusion safety and participate in its annual meetings
10. Suggest, if needed, to the LCBT all measures that could improve the quality, the reliability, or the consistency of the HV system

The HVO can be the director of the HC-based BTC, if needed; however, it is recommended that another specialist physician with expertise in the field of HV assume this role.

It is also recommended to assign a qualified physician to act as a replacement in the absence of the HVO. The identity of this person is communicated to the HC and the LCBT.

Regarding the health care institution that only collects blood, the mission of its HVO is limited to items 4, 5, 6, 7, 9 and 10.

# **Appendix III: TRANSFUSION SAFETY AND HEMOVIGILANCE COMMITTEE (TSHC)**

The TSHC and its coordinator are appointed by the hospital administration for a fixed term and is composed of the following members:

* + The director of the health care institution or his representative
	+ The president of the medical committee or his representative
	+ The BTC director /HVO
	+ Physicians representing the following departments: surgery, pediatrics, anesthesia-intensive care, infectious diseases, gynecology-obstetrics
	+ Representatives of the medical and technical staff (BTC staff, nursing staff, quality department…)
	+ Other members may be designated by the hospital administration

**The TSHC mission** is to supervise the transfusion safety and HV policy which includes the following tasks:

1. Ensure the proper use of blood and blood components
2. Identify the problems in transfusion therapies, suggest or improve protocols and recommend corrective actions when appropriate
3. Review all transfusion related adverse reactions and provide recommendations when appropriate
4. Review the BTC statistics (recipients, donors, products prepared, inventory status...) at the local level or on the MoPH electronic platform and make recommendations
5. Ensure that the policies and procedures regarding the BCs distribution center, clinical wards and medical staff are in accordance with the current regulations, if any, or the selected international standards; review all protocols periodically and adjust them if needed
6. Review the relationship between the BCs distribution center, clinical wards, and donors
7. Supervise the transfusion safety program and the quality of blood components
8. Assist the HC in their efforts to procure BCs (donor recruitment, mobile clinics, choice of the reference BTC...) and in the policy regarding the promotion of blood donation
9. Validate the agreements and the collaboration protocols between the health care institution and the reference BTC(s)
10. Disseminate information regarding the new advances in the field of blood transfusion
11. Establish a training policy on transfusion

The responsibilities of the TSHC coordinator (HVO):

1. Set the meeting agenda, the frequency (quarterly) and date of meetings; notify the members of this committee and ensure the required quorum
2. Write the minutes and store them
3. Ensure the coordination and the follow-up of the actions decided by this committee

# **Appendix IV: THE CONTENT AND THE PROCEDURES FOR REPORTING AN ADVERSE REACTION IN A BLOOD COMPONENT RECIPIENT**

* + - 1. ***General information:***

« Any physician, pharmacist, dental surgeon, midwife, or nurse who has knowledge that one of his/her patients is receiving a blood component and notices an unexpected or undesirable reaction due or likely to be due to this blood component, must report it without delay to the HVO of the health care institution where that product was administered ».

The latter will conduct the appropriate investigations and examinations in the concerned clinical ward. He/she completes the TIF, a copy of which is attached to the recipient medical record, informs the distributor center, and reports the incident to the LCBT using the MoPH's electronic platform.

Whenever a transfusion incident occurs, the organization and the functioning of the traceability system and, more globally, the transfusion safety, should be evaluated. This evaluation must be carried out by the HVO, in collaboration with the TSHC. The HVOs, whenever appropriate, submit suggestions to the committee for corrective and preventive action in order to increase the system efficiency, and particularly to train the staff of the ward where the incident occurred.

***2. The content of the transfusion incident form (TIF)***

Completing the TIF is **mandatory**, regardless of the incident's severity. Its purpose is to record the incident and to initiate an analysis of its imputability within **72 hours** (refer to the levels of imputability in Appendix V).

The TIF should include all the investigation elements and should refer to the list of adverse reactions in the recipient to conclude it (Document: the list and codes for transfusion incidents in the recipient). This form concerns both **immediate** reactions which occurred during or within **eight** **days** following the blood transfusion, and **delayed** reactions which occurred afterwards.

Regarding the section on blood components that may have caused the incident, the name/type of the transfused BCs must be recorded, as well as the one that was responsible for the adverse transfusion reaction along with the identity of the reference BTC. The HVO shall assign an 8-digit serial number while completing each transfusion incident form (refer to TIF User Guide).

***3. Notification procedures***

The person who notices the incident has a period of **eight hours** to inform the HVO, using any locally available means (telephone, fax, e-mail…), which in turn notifies the HVO of the reference BTC if necessary.

***4. Reporting procedures***

The HVO must conduct an investigation, within 72 hours following notification, and complete the TIF which he/she signs alone or jointly (if the BC origin was from a reference BTC) with the corresponding HVO., Based on the results of the investigations and the information included in the TIF, the HVO will submit an online report within the same 72-hour period, using the specific electronic platform, to the LCBT (see guide for online reporting). The latter can immediately inform the Director of Health if deemed necessary. The online report specifies the clinical signs and the incident severity, the diagnosis retained and its degree of imputability. The time frame for reporting the incident should not exceed 72 hours (as this could jeopardize patient safety), but the investigation may extend beyond this period if necessary.

Therefore, the LCBT will receive all reports, regardless of the incident severity, including those involving or potentially involving the safety of at least one other recipient, as well as incidents that might be related to transfusion equipment (including blood bags).

***5. Fate of the paper and electronic reporting forms***

Transfusion Incident forms (TIF) are kept, either as hard or soft copies, in accordance with the applicable regulation:

* within the transfused patient's medical record
* by the HVO (TSHC)/reference BTC if necessary

The TIF represents the internal reference document for the health care institution which includes all the elements of the investigation and can be reviewed if needed.

Electronic reports on the platform can be consulted at any time by the reporting party. An annual statistical summary is issued and can be consulted individually by each center.

***6. Implementing the reporting procedure***

In order to organize the HV procedures, it is the responsibility of the hospital administration to convene its key practitioners and health care personnel with the TSHC to ensure the implementation of the HV rules and procedures and to coordinate the HV activities within its premises.

# **Appendix V: THE CONTENT OF THE SERIOUS ADVERSE DONOR REACTION FORM (SADRF) AND ITS SUBMISSION PROCEDURES**

***General information:***

A serious adverse reaction in a blood donor is « an incident related or possibly related to the blood collection resulting in death or life-threatening, disabling or debilitating conditions, or causing hospitalization or any other morbid condition requiring referral for medical consultation ».

The reference BTC officer, in which the serious adverse donor reaction occurred, proceeds with the appropriate investigations and examinations. He/she will then complete the serious adverse donor reaction form (SADRF).

Following the occurrence of a serious adverse reaction, the organization and the procedures for blood/blood components collection and, more broadly, the safety at the various stages of the transfusion chain that may impact the donor, may be evaluated.

***2. The content of the SADRF***

Completing the SADRF **is mandatory for all serious adverse reactions**, as defined in the preceding paragraph, which occurred in a donor during the blood donation process. Its purpose is to identify the serious adverse reaction and analyze its imputability, in order to determine the cause and prevent its recurrence. The SADRF will refer to the list of serious adverse reactions in donors for concluding the investigation (document: the list and codes for serious adverse reactions in donors).

The imputability levels are classified according to the following criteria:

* Imputability 0 – Excluded or unlikely: when there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the donation of blood or blood components; or, when the evidence is clearly in favor of attributing the adverse reaction to causes other than the blood or blood components
* Imputability 1 - Possible: when the evidence is indeterminate for attributing adverse reaction either to the blood or blood components or to alternative causes
* Imputability 2 - Probable: when the evidence is clearly in favor of attributing the adverse reaction to the blood or blood component
* Imputability 3 - Certain: when there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component
* Imputability NA - Non assessable: when there is insufficient data for imputability assessment

***3. Notification procedures***

Any health care professional who detects or is informed about a serious adverse reaction that occurred in a blood donor shall report it without delay, by any locally available means (telephone, fax, e-mail...), and within a maximum period of **eight hours** to the HVO of the reference BTC where the donor presented. This notification shall be made, immediately, in cases of death or when the adverse reaction is likely to occur in other donors.

The HVO completes the SADRF, dates it and signs it. He/she has a period of one month maximum to conduct and finalize the investigations and submit the report to the LCBT according to the applicable procedure. Reporting shall be affected immediately in case of the donor's death, whenever the serious adverse reaction is made known to the public, or when the HVO considers it necessary, particularly if there are problems which could jeopardize the transfusion safety. The LCBT, if deemed necessary, may immediately inform the Director General of Health.

Whenever the SADRF needs to be modified due to information obtained after its submission, the amended form, signed by the concerned HVO, will be sent to the above-mentioned party.

***4. Retention of the SADRF***

The HVO shall ensure that the serious adverse reaction form is placed in the Donor's file. In case of modifications in the recorded information, the latest version of the SADRF should be inserted in this file.

The SADRFs are kept, either as hard or soft copies, in accordance with the applicable procedure:

* Within the donor file at the reference BTC
* By the HVO of the reference BTC
* by the LCBT

**Supplementary report:**

Whenever additional details, other than those already included in the SADRF, are needed to analyze the serious adverse reaction, a supplementary report will be kept as described above.

**Abbreviations:**

BC: Blood Components

BTC: Blood Transfusion center

HC: Health care institution

HV: Hemovigilance

HVO: Hemovigilance officer

LCBT: Lebanese Committee of Blood Transfusion

MoPH: Ministry of Public Health

SADRF: Serious Adverse Donor Reaction Form

TIF: Transfusion Incident Form

TSHC: Transfusion safety and Hemovigilance Committee