

UPDATE ON COLLABORATIVE HEMOVIGILANCE ACTIVITIES IN LATIN AMERICAN COUNTRIES

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- No conflict of interest to declare

Latin America

Latin America is an ethnic-geographical concept that appeared in the 19th century to identify a region of the Americas with majority speaking languages derived from Latin (mainly Spanish or Portuguese and, to a lesser extent, French).

- The region comprises more than twenty million square kilometers of area corresponding to approximately 13.5% of the planet's emerged surface.
- It is made up of 20 countries where more than 650,000,000 people live.



Everything depends on the color of the glass you look at ...

While the most developed countries wonder where Hemovigilance is going or should go ...

- Many other less developed countries have not yet implemented a national Hemovigilance program.
- After more than 25 years of the creation of the first Hemovigilance system in Europe (France 1994), only 2 countries in South America have a consolidated national Hemovigilance system comparable to that of the countries with the longest experience in Hemovigilance.



Update on collaborative Hemovigilance activities in Latin American countries

I would like to explain to you some of the initiatives that have been taken to help LA countries implement Hemovigilance programs and, in particular, that of the development of an Ibero-American Manual of Hemovigilance.

- Some initiatives have been taken from the countries themselves: Ministries of Health, Scientific Societies, Blood transfusion professionals.
- International organizations such as WHO, PAHO and IHN have also been driving the development of Hemovigilance.
- The Blood and Tissue Bank of Catalonia (Spain) has been actively collaborating on different projects for the development of Transfusion Medicine in LA, and the elaboration of the Hemovigilance Manual is a clear example of this.



16TH INTERNATIONAL HAEMOVIGILANCE SEMINAR Barcelona_2014



IHN International
Haemovigilance
Network



ISBT International Society
of Blood Transfusion



Generalitat de Catalunya
Departament de Salut

**BANC DE SANG
I TEIXITS**



**16TH INTERNATIONAL
HAEMOVIGILANCE SEMINAR**
Barcelona March 5th - 7th, 2014

IHN International
Haemovigilance
Network

SETS Sociedad Española de Transfusión
Sanguínea y Terapia Celular

- Argentina
- Brasil
- Chile
- Colombia
- Costa Rica
- Cuba
- Guatemala
- Venezuela

- Educational session in Spanish (5 of March)
- Haemovigilance in Spain & Latin American countries (6 of March)

INV-21

HAEMOVIGILANCE IN LATIN AMERICA

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Introduction

Latin America (LA) is a region of approximately 20 million km² that extends from Mexico to Chile and Argentina. It consists of 18 Spanish-speaking countries and a Portuguese-speaking one. Although we have a lot of characteristics in common for historical reasons, each country has its own special features in geographic, cultural, social and economic terms.

In some countries, current legislation in Transfusion Medicine has required mandatory reporting of adverse transfusion reactions. However, Haemovigilance (HV) activity of varying magnitude started developing only a decade ago.

Objective

To describe the current situation of Haemovigilance in Latin America.

2014

- Survey with 7 questions
- Sent to 19 countries
- Answered by 13 of the 19 surveyed countries

Only Brazil (2006) and Colombia (2009) had a national well structured program of Hemovigilance.

Causes for the lack of implementation of an Hemovigilance system:

- **Political.** Lack of political will.
- **Resources.** Insufficient human and financial resources.
- **Culture of responsibility.** Fear of punitive actions.

The blood and tissue bank is committed to promoting the development of Hemovigilance in Latin America

2014

1

- Elaboration of an Ibero-American Hemovigilance Manual

2

- A group of experts in Transfusion Medicine from different LA countries invited to write the document

3

- Promotion of the Manual in congresses, courses, meetings, scientific societies, etc.

Ibero-American Hemovigilance Manual

2015



Coordination

- Eduardo Muñiz-Díaz (BST, Barcelona, Spain)
- Graciela León (Venezuela)
- Oscar Torres (Argentina)

Authors

- Hilda Ballester (Cuba)
- César Cerdas-Quesada (Costa Rica)
- Gabriela Dabusti (Argentina)
- Geni Neumann (Brasil)
- Ina Pérez (Perú)
- Julieta Rojo (Méjico)
- Sonia Rebollo (Colombia)

Presentation

- M^a Dolores Pérez-Rosales (PAHO)

Contents of the Ibero-American Hemovigilance Manual

1

Review of the main objectives and expected benefits of Hemovigilance systems

2

Standard definitions for surveillance of non-infectious adverse transfusion reactions and for surveillance of complications related to blood donation

3

Quality requirements to implement a Hemovigilance system

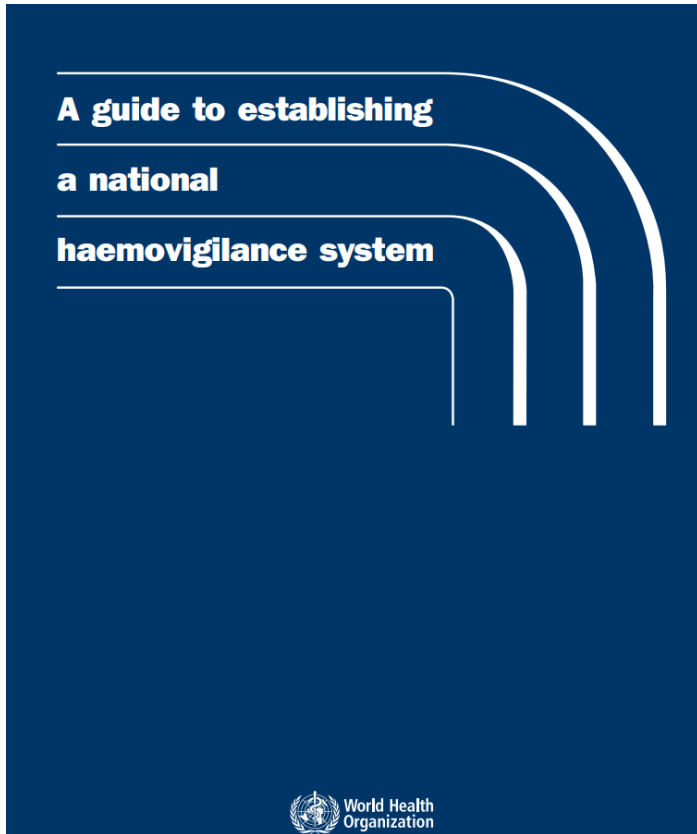
4

Forms for notification of transfusion reactions, errors (incidents and near misses) as well as complications of blood donation

“A guide to establishing a national Hemovigilance system”

WHO

2017



Translated into Spanish by the PAHO

The specific objectives are to provide:

- Policy guidance on establishing a Hemovigilance system as part of the national blood and health systems;
- Information and technical guidance on the specific measures and actions needed to implement a Hemovigilance system.

A new survey about Hemovigilance in Latin American countries



Latin America

2020

- A total of 19 countries were surveyed
- **17** countries responded

Survey on Hemovigilance in LA countries

2020

Does your country have a Hemovigilance (HV) program?

If YES:

- Who designed the HV programme: health authorities, the scientific society...?
- Does the program work across the country, in some region, in some hospitals?
- Is an annual HV report edited?
- Are the health authorities involved in or aware of the report?
- Are there any official regulations around HV and the obligation to participate in the program?
- Do you use the Ibero-American HV Manual distributed by GCIAMT?
- How do you value the operation of the HV program in your country on a scale of 1 to 10?

If NOT:

- In your opinion, what are the reasons why there is not yet a HV program in your country?
- Is there an imminent or medium-term project to implement HV in your country?

Five countries claim to have a national Hemovigilance system, but...



- Hemovigilance only works on a regular basis and with good level of participation in two of them: Colombia and Brazil
- In the remaining three countries (Argentina, Paraguay, Bolivia) the program does not properly work

BRAZIL



COLOMBIA



- Brazil (2006) and Colombia (2010) have a consolidated Hemovigilance program
- In both cases, health authorities designed the system and are involved in its development
- The program includes adverse reactions in patients and donors, but only Brazil reports errors
- Notification is mandatory in Brazil and voluntary in Colombia
- An annual HV report is published in the two countries
- Brazil scored the operation of the program at 6-7 and Colombia with an 8

ARGENTINA



- It was implemented by the scientific society (AAHITC) in 2014.
- No involvement of the health authorities.
- Voluntary notification.
- Operating level 4.

PARAGUAY



- It was implemented as a pilot program by health authorities in 2015.
- It works in a limited number of hospitals.
- Mandatory notification of adverse reactions in patients.
- Operating level 3.

BOLIVIA



- It was implemented by health authorities in 2014.
- No involvement of health authorities in monitoring program compliance.
- Voluntary notification.
- Operating level 1

In five more countries, Hemovigilance is only partially implemented

2020



- In **Guatemala**, 33% of public hospitals are working
 - The initiative has emerged from healthcare professionals.
 - Health authorities are not involved and there is no regulation on Hemovigilance
- **Chile** has a register for notification of adverse effects designed by the Ministry of Health
 - Notification is mandatory
 - Only the public health system is participating

In five more countries, Hemovigilance is only partially implemented

2020



- In **Cuba** there is a system in the province of Matanzas
 - A doctoral thesis based on this regional program has been carried out
 - The program has not spread to other provinces
- In **Uruguay** there is a Hemovigilance system in the Department of Maldonado
 - In the rest of the country, notification of serious adverse reactions is mandatory, although there is no national Hemovigilance program
- In **Mexico**, Hemovigilance programs are working in some hospitals
 - There are also regulations requiring notification of adverse transfusion reactions
 - AMMTAC is doing an important educative task and promoting Hemovigilance benefits

The remaining seven countries do not have a Hemovigilance system, although...

2020



- **Ecuador** and **Panama** have regulations requiring notification of adverse transfusion reactions
- In **Peru** and the **Dominican Republic**, a project related to Hemovigilance may be developed in the coming months...
- In **Costa Rica**, **Honduras** and **Venezuela**, there is no medium-term project on Hemovigilance
- No response was obtained from **El Salvador** and **Nicaragua**

In summary, in 2020:

Peru and Dominican Republic hope to develop a project in the coming months

Ecuador and Panama have regulations requiring notification

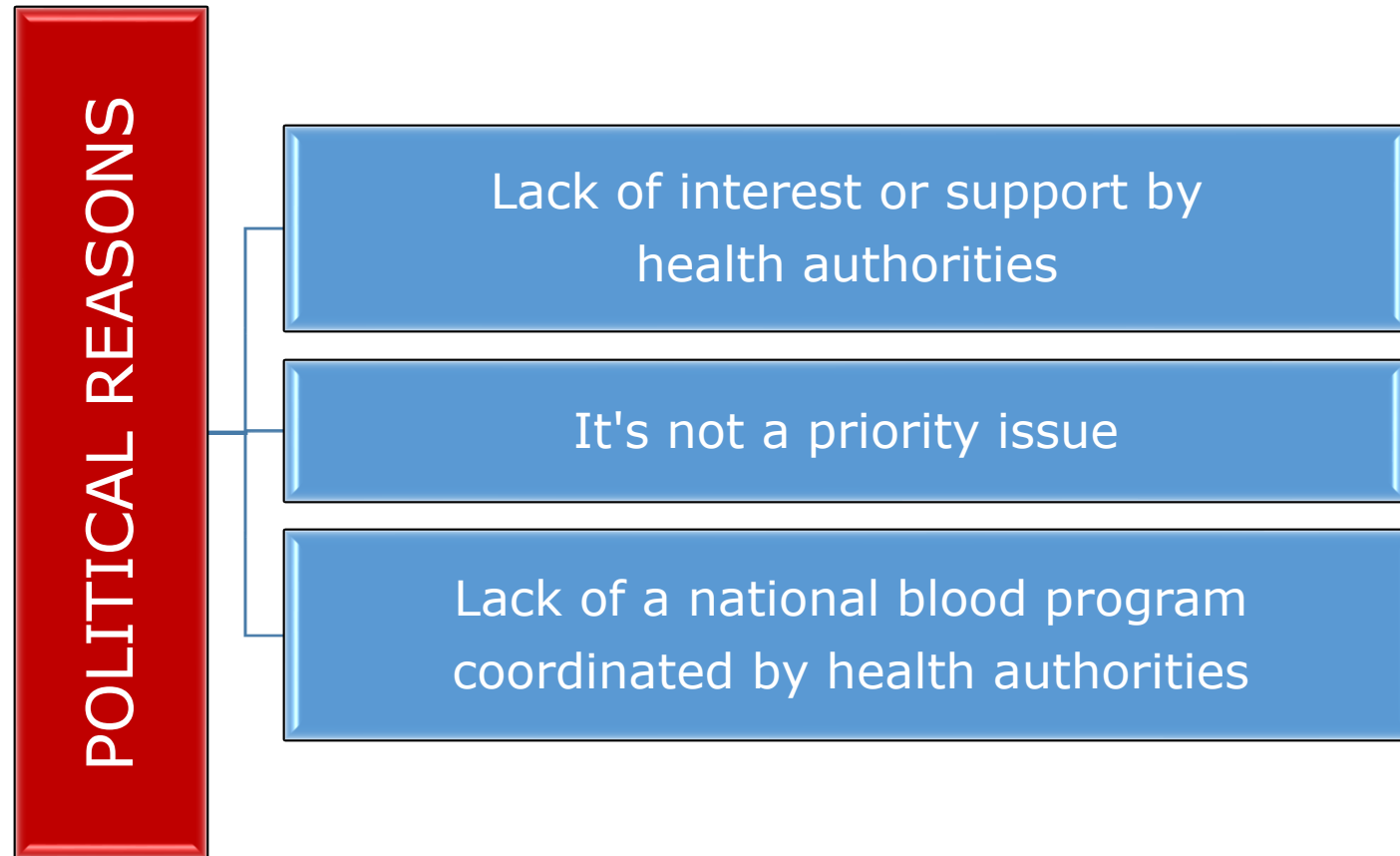
Cuba, Chile, Guatemala, Mexico and Uruguay have a program partially implemented (public hospitals, some regions)

Argentina, Bolivia and Paraguay have a national program but it does not work properly

Brazil and Colombia have a well-structured Hemovigilance system

No Hemovigilance and no news about future projects on HV in the remaining 5 countries

What are the difficulties that prevent the implementation of a greater number of Hemovigilance programs in Latin America?



Although many professionals and some scientific societies are pushing, all Latin American countries agree that the **active involvement of health authorities is essential** for the advancement, development and consolidation of Hemovigilance in Latin America

Update on collaborative Hemovigilance activities in Latin American countries

- In recent years, many professionals involved in blood transfusion as well as scientific societies of some LA countries have taken the initiative, but this have not been enough to consolidate and to extend the program to the whole nation.
- The Ibero-American Hemovigilance Manual and the Guide provided by WHO have been adopted as references for the establishment of HV programs.
- The many lectures, seminars, courses and meetings on Hemovigilance have served:
 - to let the professionals involved know about it
 - to create a culture of Hemovigilance
 - to learn about the benefit it represents for patients and donors



Update on collaborative Hemovigilance activities in Latin American countries

- However, Hemovigilance does not advance at the desired rate, nor is it advancing equally in all Latin American countries.
- It is necessary for health authorities to commit themselves to the design of Hemovigilance programs and their development and to ensure their compliance.
- After all these years we know that without the encouragement and support of health authorities, it will not be possible to advance in the implementation of Hemovigilance programs in all LA countries.



Update on collaborative Hemovigilance activities in Latin American countries

- Who should negotiate with these health authorities?
- What role should organizations such as WHO or PAHO continue to play?
- How ISBT and IHN can contribute to the development of Hemovigilance in Latin America?
- What else can we do together?



Update on collaborative Hemovigilance activities in Latin American countries

- We must, together, find the answer to these questions.
- Otherwise, Hemovigilance will continue to be an extraordinary tool for transfusion safety, but only within the reach of the most favored countries.
- The countries that now say they feel at a crossroads regarding Hemovigilance.



Thank you for your attention!



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Update on collaborative Hemovigilance activities in Latin American countries

- While in the more developed countries Hemovigilance seems to be at a crossroads, the less developed ones have not yet been able to lay the foundations for the creation of a well structured Hemovigilance program.
- In Latin America, only 2 countries have implemented a program comparable to that of the countries where Hemovigilance programs have been consolidated.

