International Haemovigilance Network survey on haemovigilance system methods

IHN Data Committee and Database Task Force

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Introduction

The International Haemovigilance Network (IHN) aims to promote and support high quality data collection and reporting. Knowledge of the context and working methods of haemovigilance systems (HVS) is necessary for understanding and assessing the systems' reports and recommendations.

Methods

A Task Force of experts from IHN member systems developed a list of data elements on

- Governance, activities and outputs of the HVS, starting from
- Items previously collected in the ISTARE database
- Items collected by the WHO Global Database on Blood Safety

In a pilot study (Q2 2023), IHN member HVS provided data about their system using an online data entry table. The pilot list was compared with WHO Global Benchmarking Tool with blood (GBT+) items to evaluate overlap.

Results

Table 1 Haemovigilance system responses

		European (EU/EEA)	Non European
Total		**13**	**4**
Years of existence	5 to 9	0	1
	10 to 19	6	2
	20 or more	7	1
Initiation	National and/or EU legislation	10	1
	Professional initiative	3	1
	Other		2
Managed by	Blood service	3	1
	Authority	8	1
	Professional expert bodies	1	1
	Other *Blood service+ MoH also involved*		1
Blood establishments in country	One	4	4
	2 to 10	3	
	11 to 50	3	
	Over 50	3	
Mandatory/voluntary	Mandatory	11	1
	Voluntary		2
	Other		
	** SAR/SAE reporting mandatory, reporting of non-serious cases professionally mandated*	2	
	** mandatory standards, voluntary reporting to HVS*		1
Recipient HV covered		**13**	**4**
Include error reporting/analysis		13	2
Safe to report		12	3
Include no harm/near miss		11	1
Include delay/did not transfuse		7 (1 no response)	1
Serious TR only collected		1 (EEA), 1 no response	0
Category assigned by reporter		11	3
Category assigned by HV system		3	1
Verification with supporting info – all serious		5	1
	- all reactions	8	3
Do shortages occur, Yes		5	3
Public report re recipients		11	3
Donor adverse reactions collected		**12**	**2**
Public report re donors		9	2

17 IHN member organisations responded (Table 1)

- Mature systems
- All: data quality verification of reported cases
- All: recommendations and/or safety alerts based on the vigilance data.

GBT+

The GBT+ assesses state of legislation and resources of the HVS. The IHN list has overlap with GBT+ regarding elements related to data quality verification, expert review and aligning with internationally recognised systems. These items were found to be widely implemented in the responding HVS.

Haemovigilance system - developments

A new national data set is being developed
Considering including anti-D immunoglobulin reports
Developing HV reporting, mainly SAE and near misses.
Definitions of currently uncategorised reactions (acute pain transfusion reaction)
Need harmonisation of SARE definitions
Disconnect from legislation to allow for more dynamic updating of form

Study CV events in blood donors
transfusion errors: need to create more evidence for (effective) safety measures e.g. benefit of electronic patient-identification

Move to electronic reporting, update form

Challenges - transfusion chain

Rapidly ageing population and potential decline in blood donor population. Increase plasma collection Update contingency plan for blood collection and blood product availability	5x
Lack of national transfusion guidelines, for instance Hb level Lack of national level quality indicators e.g. for outdating in hospitals Better Patient Blood Management Outdating Surveillance of transfusion in the clinical sphere	2x
Electronic identification for transfusion safety. Lack of national blood service Lack of communication between blood banks and hospital services e.g. untransfused surgeries Patient safety vs privacy e.g. allo-antibodies Hazards from hacks of digital systems	5x

Conclusions

Seventeen IHN member organisations responded to the survey. The majority function in a setting where reporting to the regulatory authority is mandatory, for at least the serious cases.

All responding HVS have data quality verification in place and make safety recommendations and/or issue alerts. The great majority cover donor adverse reactions as well as recipient reporting. The findings are consistent with the mature status of the responding HVS, indicating potential for the IHN to assist professionals and haemovigilance organisations where haemovigilance is less well developed.