famhp
federal agency for medicines and health products

Biovigilance Annual Report 2022

Key points

Biovigilance is the systematic monitoring (alerting, managing and preventing) of the risk (by serious adverse events and reactions) from the selection of the donor to the follow-up of the recipient in order to put collaboratively in place the necessary public health measures to make the application of different substances of human origin (tissues, cells, MAR) safer and more effective.

This report is a summary of all events and side effects related to the processing and application of human tissues and cells for the reporting period 2022 (January 1, 2022 to June 30, 2023). The data are reported to the Biovigilance Entity of the FAMHP in 2022 by 45 Belgian tissue establishments and hospitals, of which 23 establishments for reproductive human body material (REPRO) and 22 establishments for non-reproductive human body material (NON REPRO).

Abbreviations

FAMHP	Federal Agency for Medicines and Health Products
HSCs	Hematopoietic stem cells
ESB	European Sperm Bank
HBM	Human Body Material
RA	Rapid alert
REPRO	From the reproductive system
NON REPRO	Not from the reproductive system
SAE	Serious adverse event
SAR	Serious adverse reaction
SAR donor	Serious adverse reaction for donor
OHSS	Ovarian hyperstimulation syndrome

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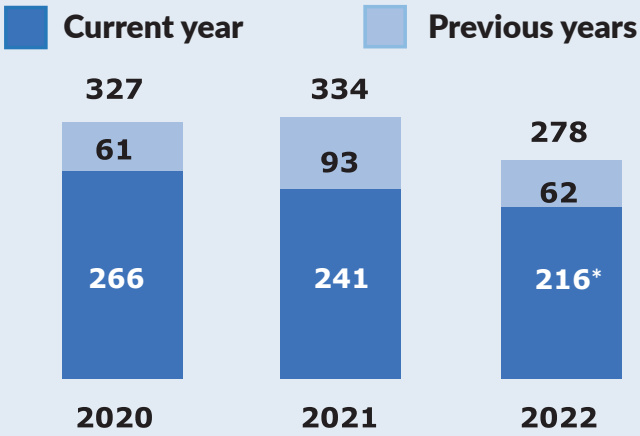
General information

Number of notifications



Number of notifications for the last 3 years including current year and previous years (occurrence from a previous year whose file was closed in the current year) notifications

*Late notifications (2022 notifications received and closed until June 30, 2023) = 34. Total for 2022: 216 + 34 = 250.

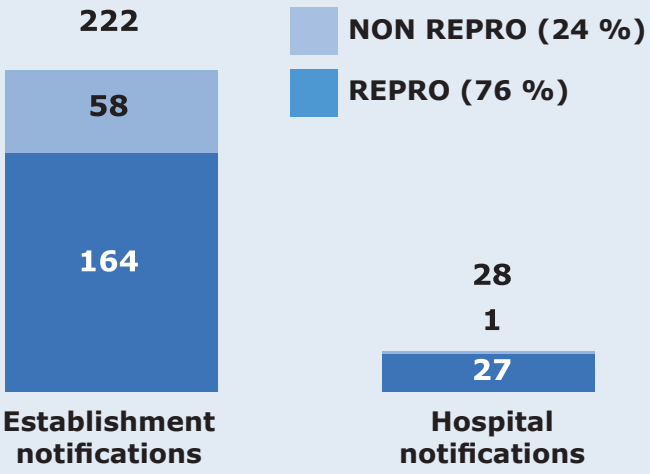
Number of notifications by type of notifiers

44/112 tissue establishments
222/250 notifications = 89 %

4/103 hospitals
28/250 notifications = 11 %

There are 12 different types of HBM in Belgium: reproductive system, stem cells and musculoskeletal system are the largest in terms of number of notifications.

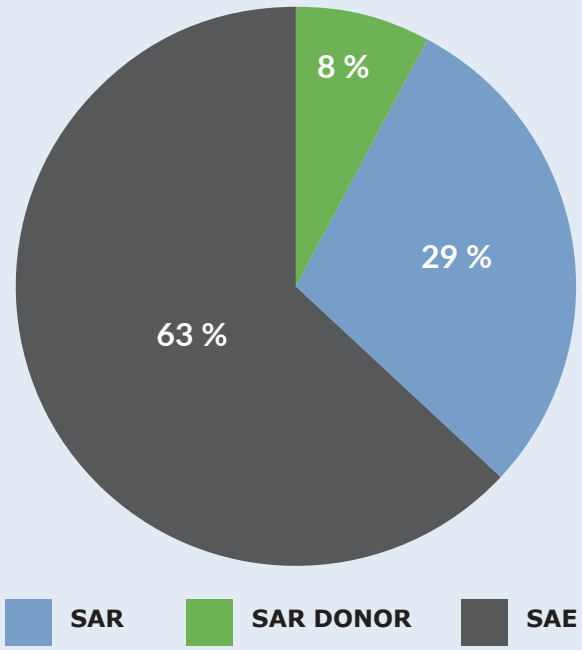
Type of HBM



Number of notifications by tissue establishments and hospitals and by type of HBM (REPRO, NON REPRO).
In total, there are 76 % of REPRO notifications and 24 % of NON REPRO notifications.

Classification of notifications received by type of occurrence (n = 250)

	Received	
Occurrence	Number	%
SAR	72/250	29 %
SAE	**157/250**	**63 %**
SAR donor	21/250	8 %
Total	250	100 %



Classification of notifications received by type of HBM (n = 250)

	Received	
Occurrence	**REPRO**	NON REPRO
SAR	**26,4 % (66/250)**	2,4 % (6/250)
SAE	**42,4 % (106/250)**	20,4 % (51/250)
SAR donor	**7.6 % (19/250)**	0.8 % (2/250)
Total	**76,4 %**	23,6 %

Evaluation

Reportable SARE are those "which may influence the quality and safety of tissues and cells and which may be attributed to the procurement, testing, processing, storage and distribution of tissues and cells, as well as any serious adverse reaction observed during or after clinical application which may be linked to the quality and safety of tissues and cells".
Evaluation is performed by evaluators of biovigilance. It consists to analyse all investigation results received in the investigation form and to determine if a link exists between the occurrence and the quality and safety of tissues and cells. If this link exists, the occurrence will be classified into SAE, SAR or SAR donor.

Classification of notifications after evaluation: REPRO (n = 191) and NON REPRO (n = 59)

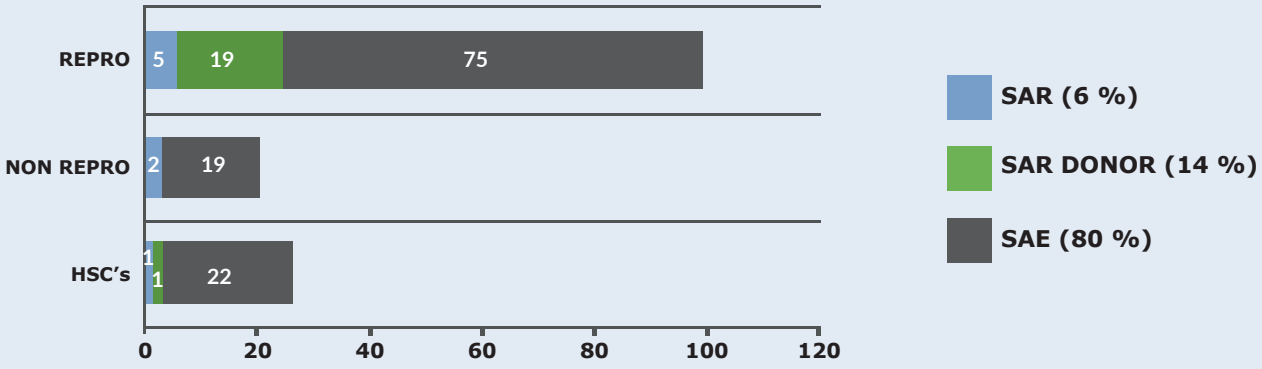
	Evaluated			
	REPRO		NON REPRO	
SAR	5/191	3 %	3/59	5 %
SAE	75[1]/191	39 %	40/59	68 %
SAR donor	191/191	10 %	1/59	1,5 %
No SAR	44/191	23 %	3/59	5 %
No SAE	29/191	15 %	11/59	19 %
No SAR donor	0/191	0 %	1/59	1,5 %
Open files	19/191	10 %	0/59	0 %
Total	191	100 %	59	100 %

n = 143

Occurrence	HBM type	Number	%
SAR	REPRO	5	3,5 %
	NON REPRO	2	1,5 %
	HSC's	2	1 %
SAE	REPRO	75[1]	52 %
	NON REPRO	18	13 %
	HSC's	22	15 %
SAR donor	REPRO	19	13 %
	HSC's	1	1 %
Total		143	100 %

Classification of notifications after evaluation: REPRO (n = 191) and NON REPRO (n = 59). SAE/SAR/SAR donor: when the investigation proves that it was a SAE/SAR/SAR donor. No SAE/no SAR/no SAR donor: when the investigation did not confirm the SAE/SAR/SAR donor. Open files: when the investigation form has not been received.

Classification by type of occurrence and type of HBM (n = 143)



[1] With 49 SAEs due to Rapid Alert notifications + 2 SAEs due to Belgian SAR (not notified to EU).

Serious adverse reactions (SAR) and serious adverse reactions for donor (SAR donor)

Unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of human body material that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

SAR REPRO

Classification of SAR REPRO by HBM category and reaction type (n = 5)

HBM category	Reaction type	Donor origin	RA	Number	%
Embryo (sperm donor + partner oocyte)	Transmitted genetic conditions	ESB	Yes	2	40 %
Sperm (donor)	Transmitted genetic conditions	Cryos	No	1	60 %
		Belgian banks	/	2	
Total				5	100 %

SAR NON REPRO

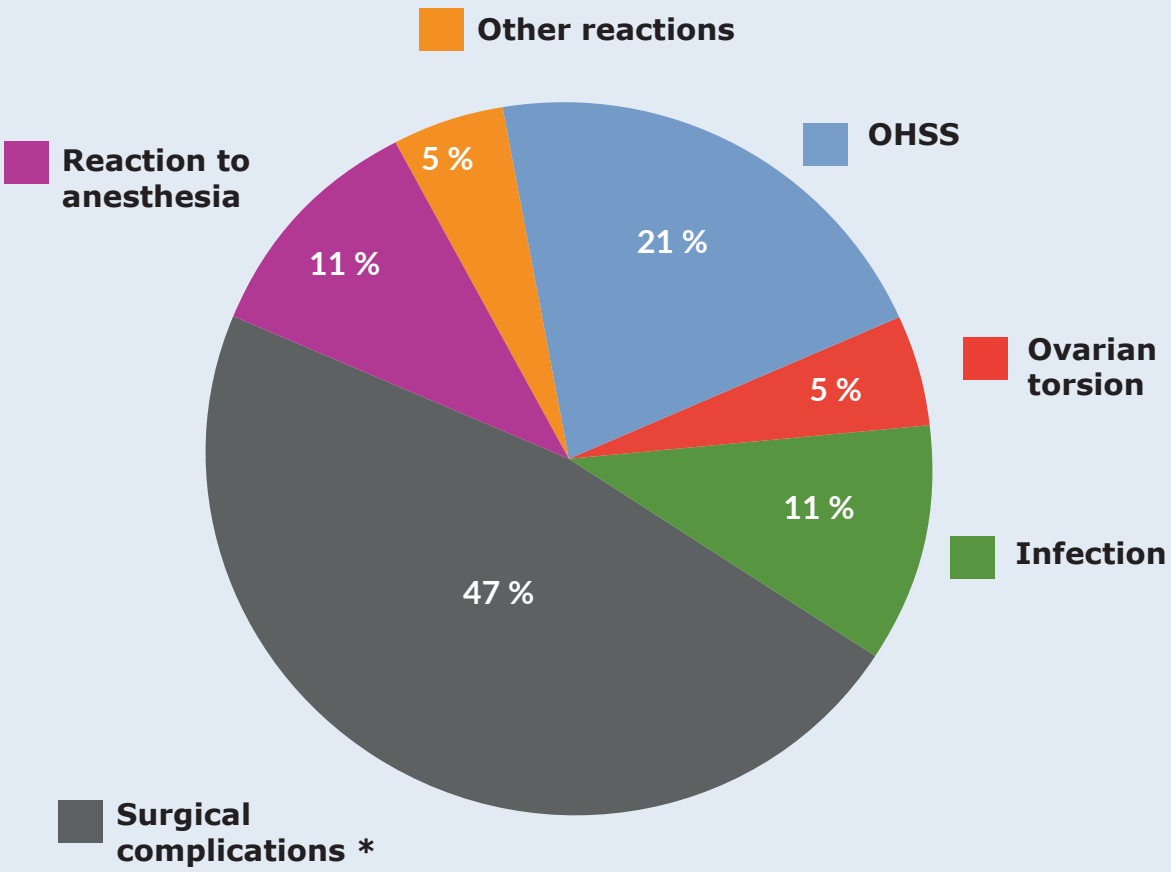
Classification of SAR NON REPRO by HBM category and reaction type (n = 2)

HBM category	Reaction type	Number	%
Bone and other musculoskeletal tissue	Graft failure/delayed engraftment	2	100 %

SAR donor

Classification of SAR donor by HBM category and reaction type (n = 19)

HBM category	Reaction type	Number	%
Oocyte: general (7) + partner (12)	OHSS	4	21 %
	Ovarian torsion	1	5 %
	Infection	2	11 %
	Surgical complications*	**9**	**47 %**
	Reaction to anesthesia	2	11 %
	Other reactions	1	5 %
Total		19	100 %



* Discomfort, bleeding, haematomas and bladder puncture.

Serious adverse events (SAE)

Any untoward occurrence associated :

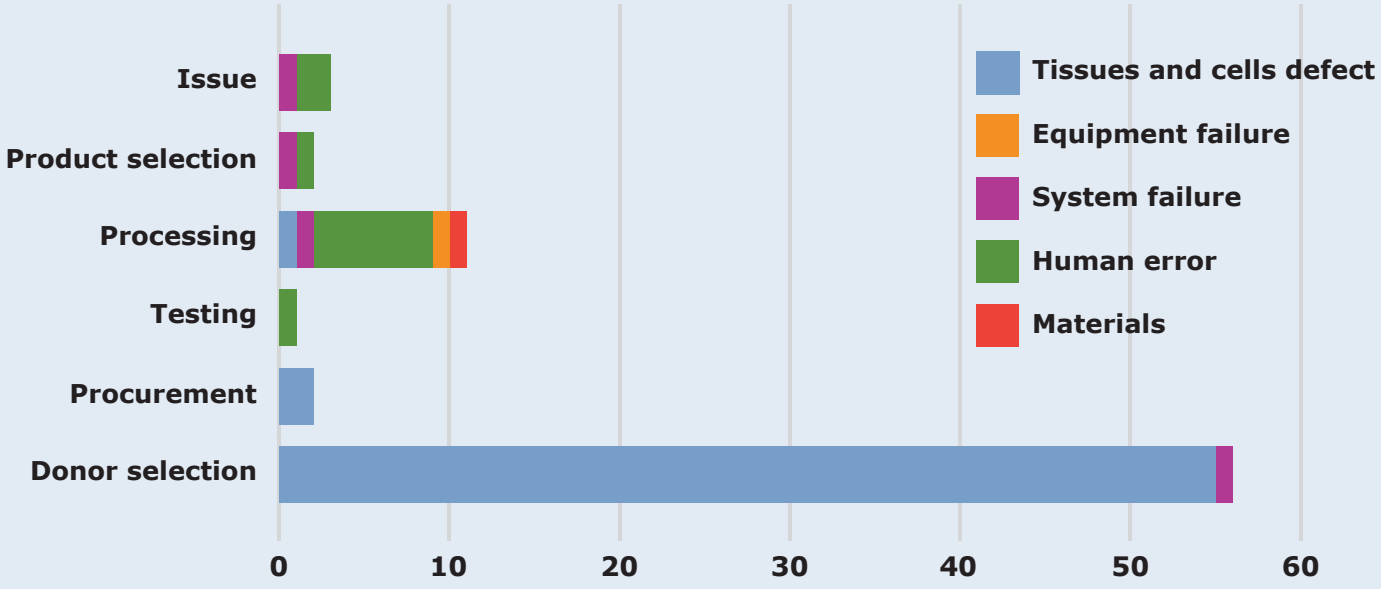
- either with the procurement, that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for the donor or which might result in, or prolong, hospitalisation or morbidity;
- or with the procurement, testing, processing, storage or distribution of human body material, that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for the patient or which might result in, or prolong, hospitalisation or morbidity.

REPRO

Classification of SAE REPRO by HBM category and subcategory (n = 75)

HBM category	HBM subcategory	Number	%
Sperm	**Donor**	**57**	**76 %**
Oocyte	General	1	4 %
	Partner	2	
Embryo	General	4	20 %
	Partner gametes	11	
Total		75	100 %

Classification of SAE REPRO by activity and category (n = 75)[1]



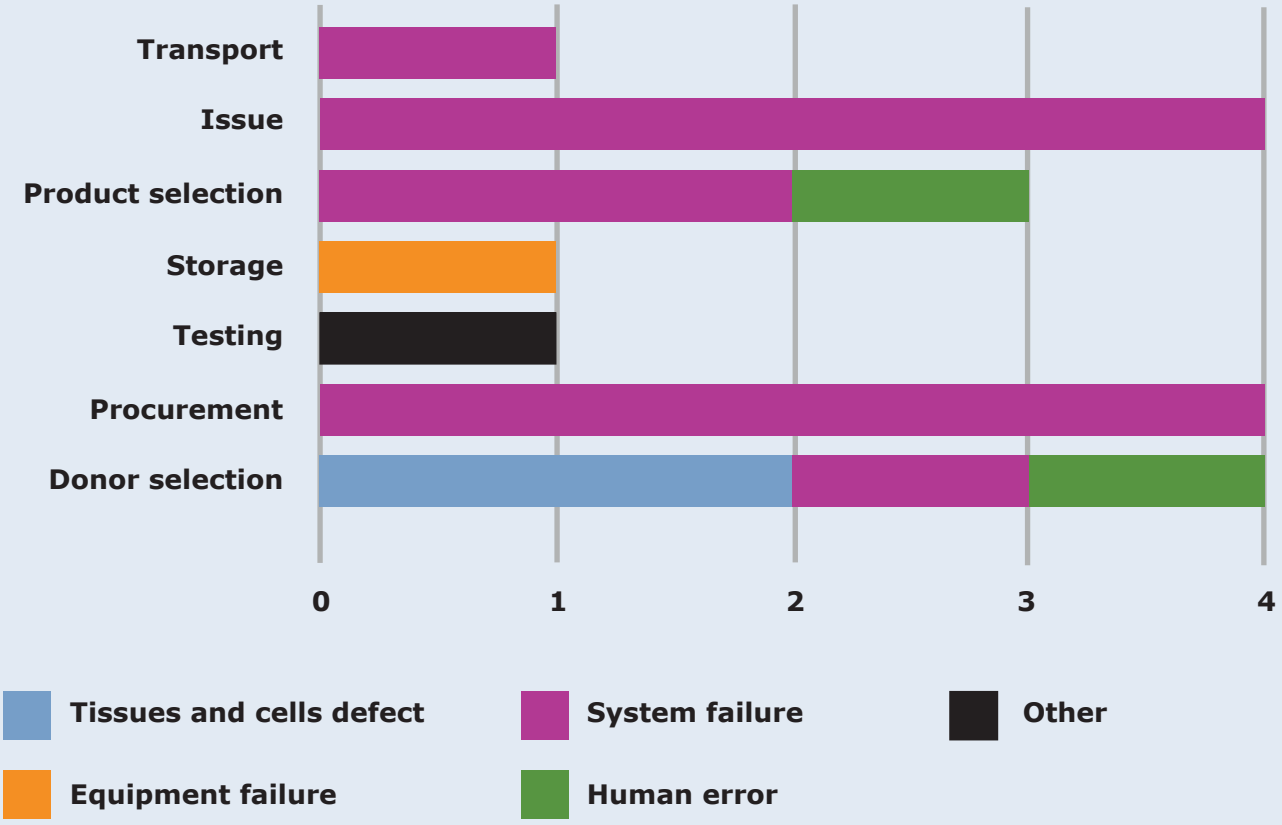
[1] With 49 SAE due to Rapid Alert notifications + 2 SAE due to Belgian SAR (not notified to EU).

NON REPRO

Classification of SAE NON REPRO by HBM category and subcategory (n = 18)

HBM category	HBM subcategory	Number	%
Bone and other musculoskeletal tissue	Bone	4	22 %
Cardiovascular tissue	**Heart valve, blood vessel**	**9**	**50 %**
Skin		1	6 %
Ocular tissue	Cornea, other	2	11 %
Other tissues and cells	Amniotic membrane, other	2	11 %
Total		18	100 %

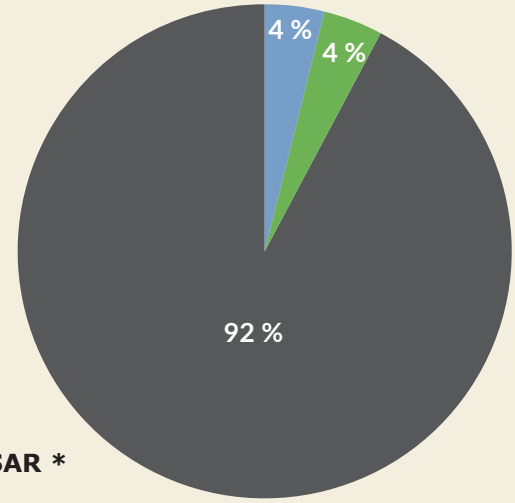
Classification of SAE NON REPRO by activity and category (n = 18)



Hematopoietic stem cells (HSCs) and cells for therapeutic purposes

Hematopoietic stem cells (HSCs) are multipotent primitive cells that can develop into all types of blood cells, including myeloid-lineage and lymphoid-lineage cells. HSCs can be found in several organs, such as peripheral blood, bone marrow, and umbilical cord blood.

Classification by type of occurrence (n = 24)



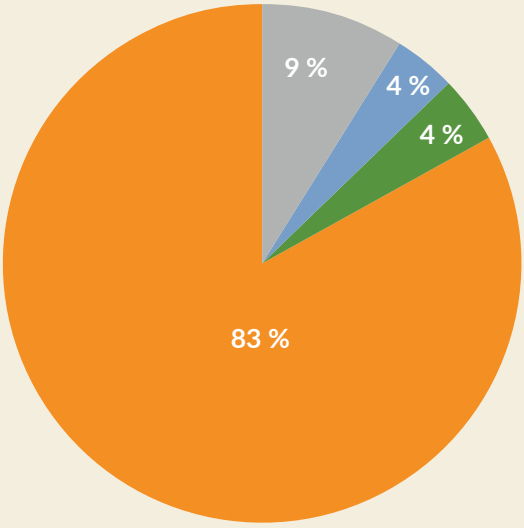
SAR *

SAR DONOR *

SAE

Including 1 SAR (other SAR: immunological reactions) + 1 SAR DONOR (mechanical damage - from apheresis or bone marrow collection).

Classification by cellular origin (n = 24)



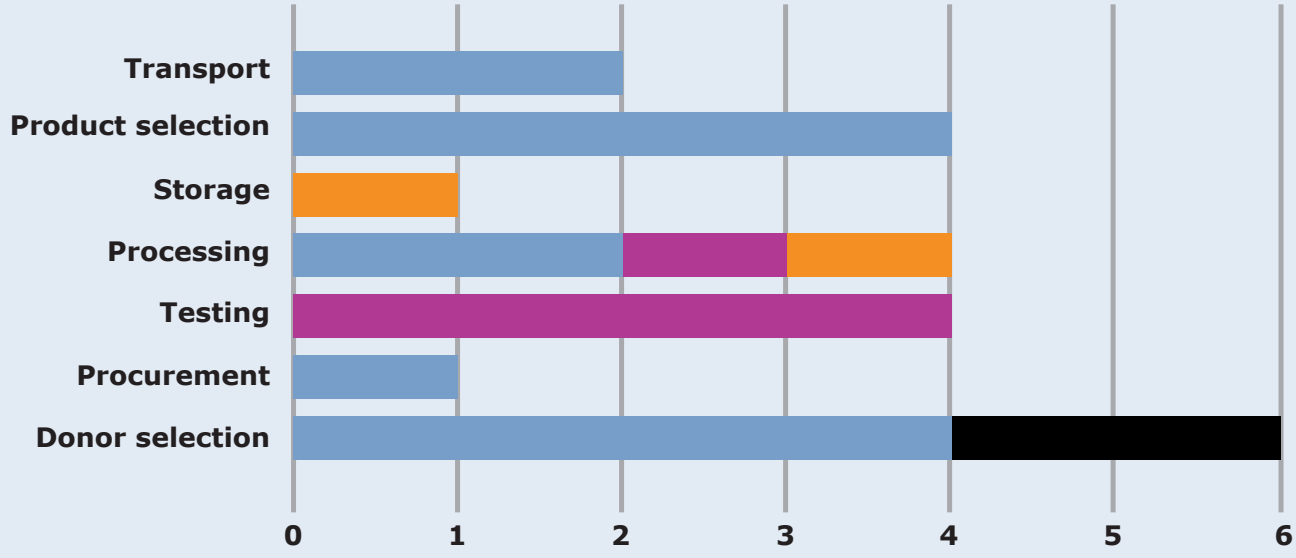
Umbilical cord blood

Lymphocyte infusions

Peripheral BSCs

Bone marrow

Classification of SAE by activity and category (n = 22)



Tissues and cells defect

Equipment failure

System failure

Other

Conclusion

The FAMHP Biovigilance Entity works to raise awareness among all stakeholders about biovigilance with the purpose to improve the quality of reporting of events and serious adverse reactions. The aim is to make the use of various substances of human origin safer and more effective.

It is important for all the persons involved in an efficient biovigilance network to report incidents and serious adverse reactions as quickly as possible, providing a full and adequate analysis of the cause and circumstances.

Events and reactions are reported by healthcare professionals in two successive stages:

1. reporting with a dedicated notification form containing as much relevant information as possible, and information on the actions taken directly;
2. confirmation with a dedicated investigation form, including the results of a thorough investigation that confirms or excludes the link between the event/reaction and any quality or safety deficiencies which may impact on patients' quality of life. It also includes the corrective and preventive actions taken to minimise the probability of recurrence of serious situations that have already occurred.

Thanks to the relevance and quality of the information provided, the employees of the FAMHP Biovigilance Entity will be able to conduct a robust scientific assessment and ensure the most appropriate communication with regard to the situations notified/reported.

The reporting of events and serious adverse reactions to FAMHP benefits all: patients, professionals, tissue establishments and the health system.

Read the full report at
www.famhp.be

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Avenue Galilée - Galileelaan 5/03
1210 BRUSSELS
T + 32 2 528 40 00
www.famhp.be

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