FAMHP ANNUAL REPORT 2022
BIOVIGILANCE

Symposium 2024

famhp
federal agency for medicines and health products

.be

ANNUAL REPORT 2022

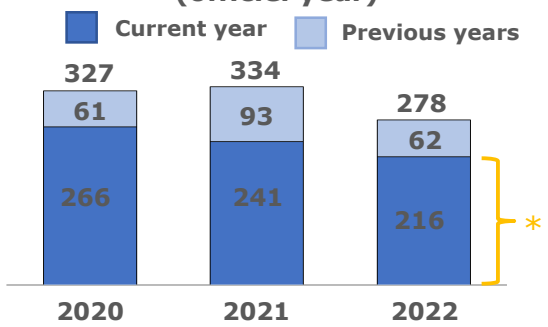
Biovigilance

Biovigilance is the systematic monitoring (alerting, managing and preventing) of 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 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 Unit of the FAMHP in 2022 by 45 (23 REPRO + 22* NON REPRO) Belgian tissue establishments and hospitals.

GENERAL INFORMATION

Number of notifications (officiel year)



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

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

	Received	
Occurence	Number	%
SAR	72/250	29 %
SAE	**157/250**	**63 %**
SAR DONOR	21/250	8 %
TOTAL	250	100 %

Type of notifiers

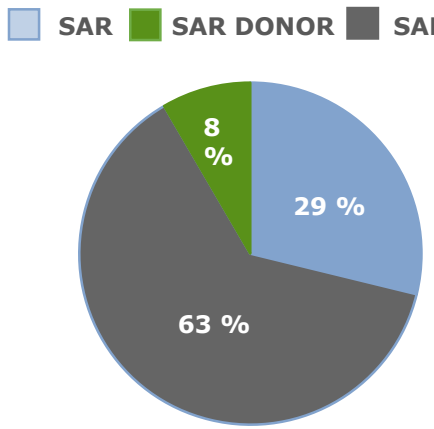
44/112 tissue establishments

222/250 notifications = 89 %

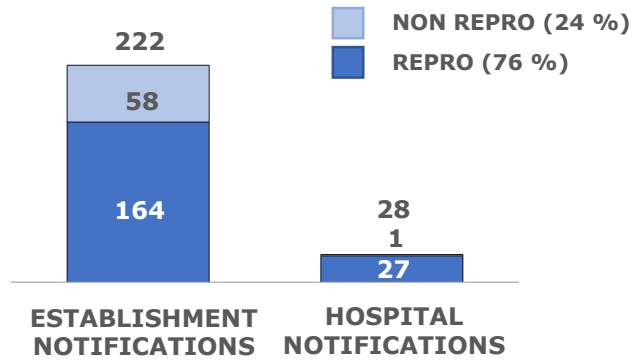
1/103 hospitals

28/250 notifications = 11 %

Number of notifications in function of the type of notifiers. 12 different types of HBM in Belgium: reproductive system, stem cells and musculoskeletal system are the largest in number.



Type of HBM



Number of notifications by establishments and hospitals in function of the type of HBM (REPRO, NON REPRO). In total, 76% of REPRO notifications and 24% of NON REPRO notifications.

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

	Received	
Occurence	**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 %

ANNUAL REPORT 2022

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 consist to analyze all investigation results received in the investigation form and to determinate if a link exists between the occurence and the quality and safety of tissues and cells. If this link exist, the occurence will be classified into SAR, SAR DONOR of SAE.

OCCURENCES

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

	Evaluated			
	REPRO		NON REPRO	
SAR	5/191	3 %	3/59	5 %
SAE	***75/191**	**39%**	**40/59**	**68 %**
SAR DONOR	19/191	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 %

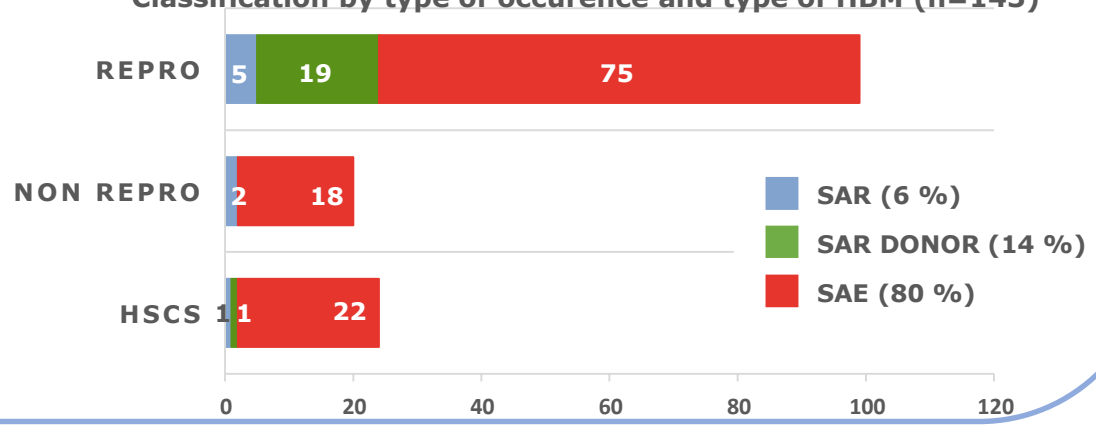
n = 143

SAE/SAR/SAR DONOR: when the investigat ion proves that it was a SAE/SAR/SAR DONOR. No SAR/no SAE/no SAR DONOR: when the investigation proves that it was not a SAE/SAR/SAR DONOR of when the investigation did not confirm the SAE/SAR/SAR DONOR. Open files: when the investigation form has not been received.

Notifications classified after evaluation (n=143)

Occurence type	HBM type	Number	%
SAR	REPRO	5	3.5
	NON REPRO	2	1.5
	HSCs	1	1
SAE	**REPRO**	**75 ***	**52**
	NON REPRO	18	13
	HSCs	22	15
SAR DONOR	REPRO	19	13
	HSCs	1	1
TOTAL		**143**	**100**

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



* + 49 SAE due to Rapid Alert notifications + 2 SAE due to Belgian SAR (not notified to EU)

ANNUAL REPORT 2022

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 tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalization 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 (non partner)	Transmitted genetic conditions	Cryos	No	1	60
		Belgian banks	/	2	
TOTAL				5	100

NON REPRO

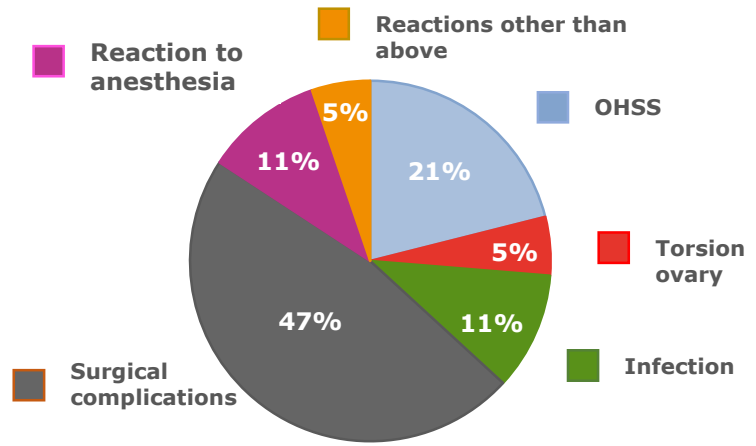
Classification of SAR NON REPRO by HBM category and reaction type (n=2)

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
	Torsion of the ovary	1	5
	Infection	2	11
	Surgical complications	**9**	**47**
	Reaction to anesthesia	2	11
	Reactions other than above	1	5
TOTAL		19	100



ANNUAL REPORT 2022

Serious adverse events (SAE)

Untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalization or morbidity

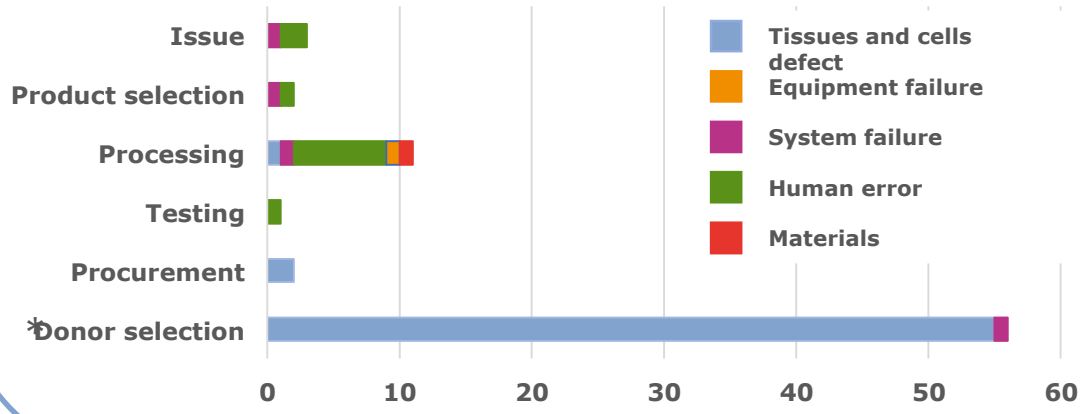
REPRO

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

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

54 foreign donors, 1 Belgian bank, 20 NA

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

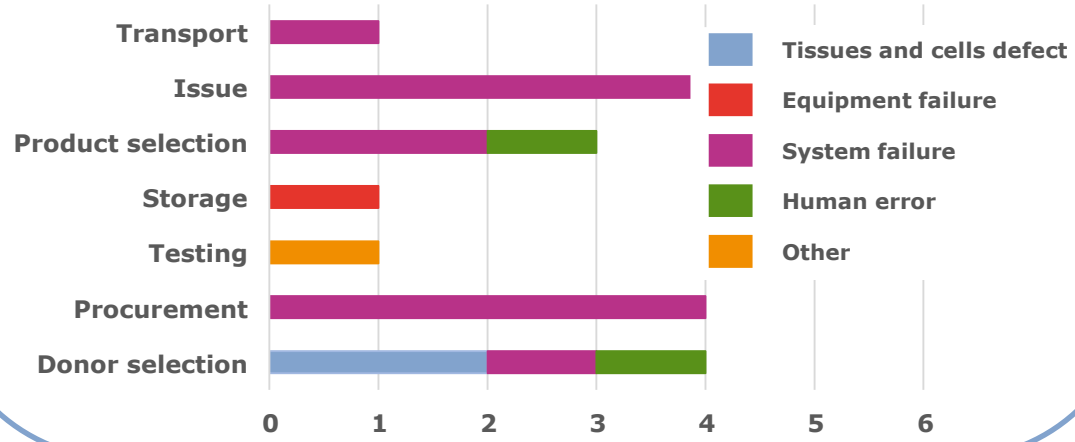


NON REPRO

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)



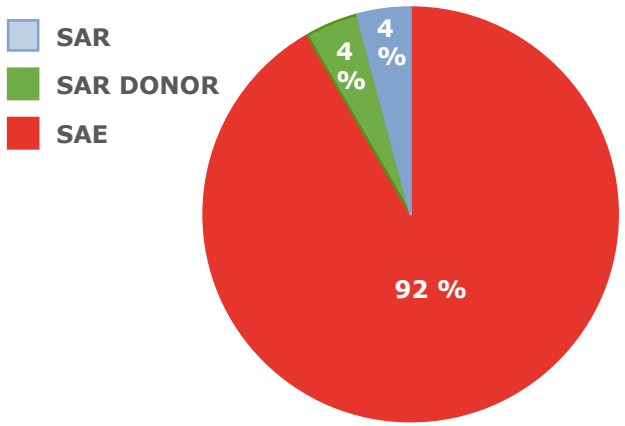
* + 49 SAE due to Rapid Alert notifications + 2 SAE due to Belgian SAR (not notified to EU)

ANNUAL REPORT 2022

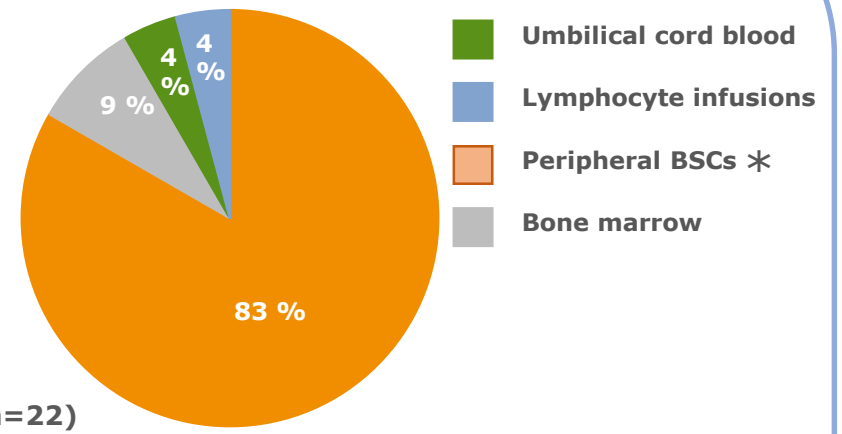
Hematopoietic stem cells (HSCs) and cells for therapeutic purposes

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.

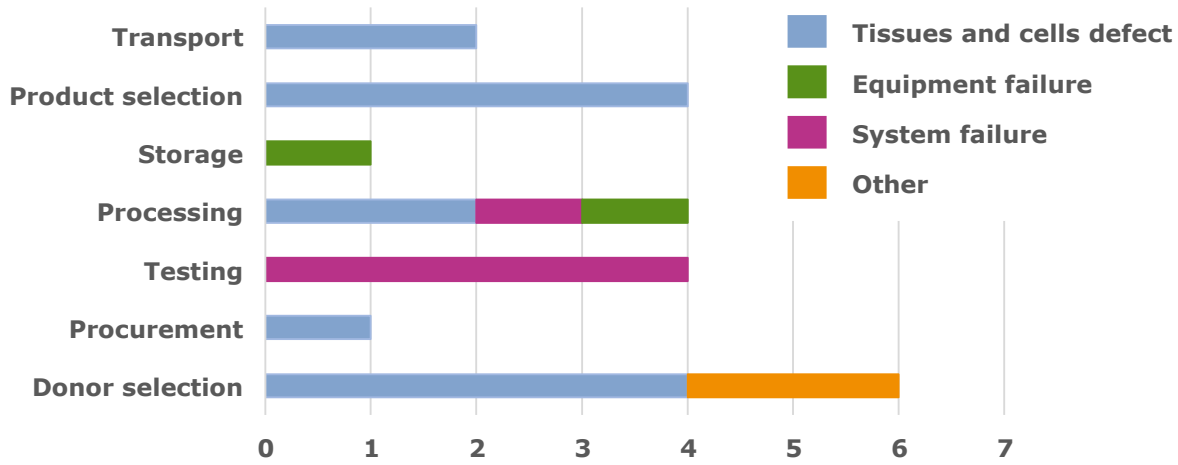
Classification by type of occurrence (n=24)



Classification by cell origin (n=24)



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



* Including 1 SAR (Other SAR: Immunological reactions) + 1 SAR DONOR (Mechanical damage - from apheresis or bone marrow collection)

ANNUAL REPORT 2022

Conclusions and take-home messages

Raise awareness among all stakeholders about biovigilance so that events and reactions are correctly reported with the aim of improving the safety and quality of the use of human body material.

Ensure that events and reactions are reported more quickly and that a complete and adequate analysis of the cause and circumstances is possible.

Ensure good timing of notifications/acquire rigor with the aim of improvement:

1. **Notify with notification form (with maximum information available + direct actions taken);**
2. **Investigation + results + follow-up;**
3. **Confirm with investigation form (the investigation results which made it possible to confirm/exclude the link between the event/reaction and the quality/safety defect).**

The quality and robustness of the investigation will allow evaluators to have sufficient information to correctly assess the risk to public health, to possibly take adequate/corrective measures (e.g. RATC, information notes …), to communicate in order to reduce the risk of recurrence of the incident.

Don't be left alone with your questions. Communicate – ask – discuss with the Biovigilance cell.

If in doubt, it is always better to notify!

Avoid no notification.

Reporting cases/SARE to FAMHP benefits all: patients, professionals, tissue establishments and the health system.