Vigilantie stamceldonaties wereldwijde rapportage en analyse

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Medisch adviseur World Marrow Donor Association

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World Marrow Donor Association

- **Optimising 'Search, Match & Connect'**: Provide a global platform that facilitates access to the most suitable stem cell source for a transplant patient;
- **Supporting global development**: Support members to develop and grow, so that more transplant patients find the most suitable match;
- **Promoting donor care**: Assure that the rights and safety of stem cell donors are promoted and protected;
- **Ensuring quality**: Promote product quality and global collaboration through accreditation and standardisation.

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S(P)EAR

- Serious (Product) Events and Adverse Reactions

https://wmda.info/professionals/promoting-donor-care/adverse-events-searspear/

  - Mandatory for accredited registries, open for transplant centers
  - Donor harm, patient harm, risk of harm
- Online reporting tool https://spear.wmda.info/login?returnUrl=%2Freports
- Assessment of reports within 7 working days and by peer committee
- Support by the office (medical consultant)
- Annual report + presentation at WMDA meeting
  - https://wmda.info/professionals/promoting-donor-care/adverse-events-searspear/
- (rapid) alert system

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BIC: ABNANL2A
CC: 40448326

S(P)EAR alert: December 2019

Description of the serious events

The S(P)EAR Committee of WMDA has recently been notified of a serious event in which a bone marrow product was completely lost, as described in more detail below. A subsequent donation was necessary. Both donor and patient are progressing as expected.

The bone marrow product was lost because transfer bags from a bone marrow collection system were ruptured during centrifugation for plasma separation at the transplant centre.

This is the second time that an incident of this sort was reported to WMDA. In the previous case, a sufficient portion of the product could be salvaged and used for a successful transplant. In both cases, the manipulation step was consistent with standard operating procedure, and not the result of error.

Root cause analysis

These frequently-used transfer bags are generally not certified or validated for centrifugation, storage, or cryopreservation.

S(P)EAR alert: August 2011

For the attention of the S(P)EAR designated contact individual(s) at each WMDA member registry

Dear Colleagues,

The S(P)EAR committee have recently been informed of a donor death due to a tension haemo/pneumothorax related to the insertion of a central venous catheter (CVC).

Since 2002, the WMDA has been notified of 5 other CVC related SEAR:

- 3 episodes of bleeding/bruising (+/- hospitalisation) following insertion/removal of a femoral CVC
- 1 episode of a supraventricular tachycardia during CVC insertion
- 1 Horner syndrome following CVC insertion

RECOMMENDATIONS of the WMDA S(P)EAR COMMITTEE:

- We urge all stem cell donor registries to review their policies concerning the placement of CVCs.
- If a stem cell donor registry does not have a policy concerning CVC placement, one should be written.
- Insertion of a CVC for PBSC collection should only be used in exceptional circumstances i.e. only when peripheral venous access is not deemed feasible after skilled assessment or cannot be obtained or has failed.

ents

Reporting tool

- Donor harm: adverse reactions
  - Short term: < 6 months
  - Long term: > 6 months
- Imputability
  - Excluded – Definite
- Categorization
- Root cause analysis

spear.wmda.info/login?returnUrl=%2Freports

WMDA matching donors • serving patients SPEAR

Welcome to the SPEAR Reporting Tool

Email Address *
mirjam.fechter@matchis.nl

Password *
••••••••••••••••••

Log in | Forgot password

Select Role
reporter (Matchis Foundation)

Select

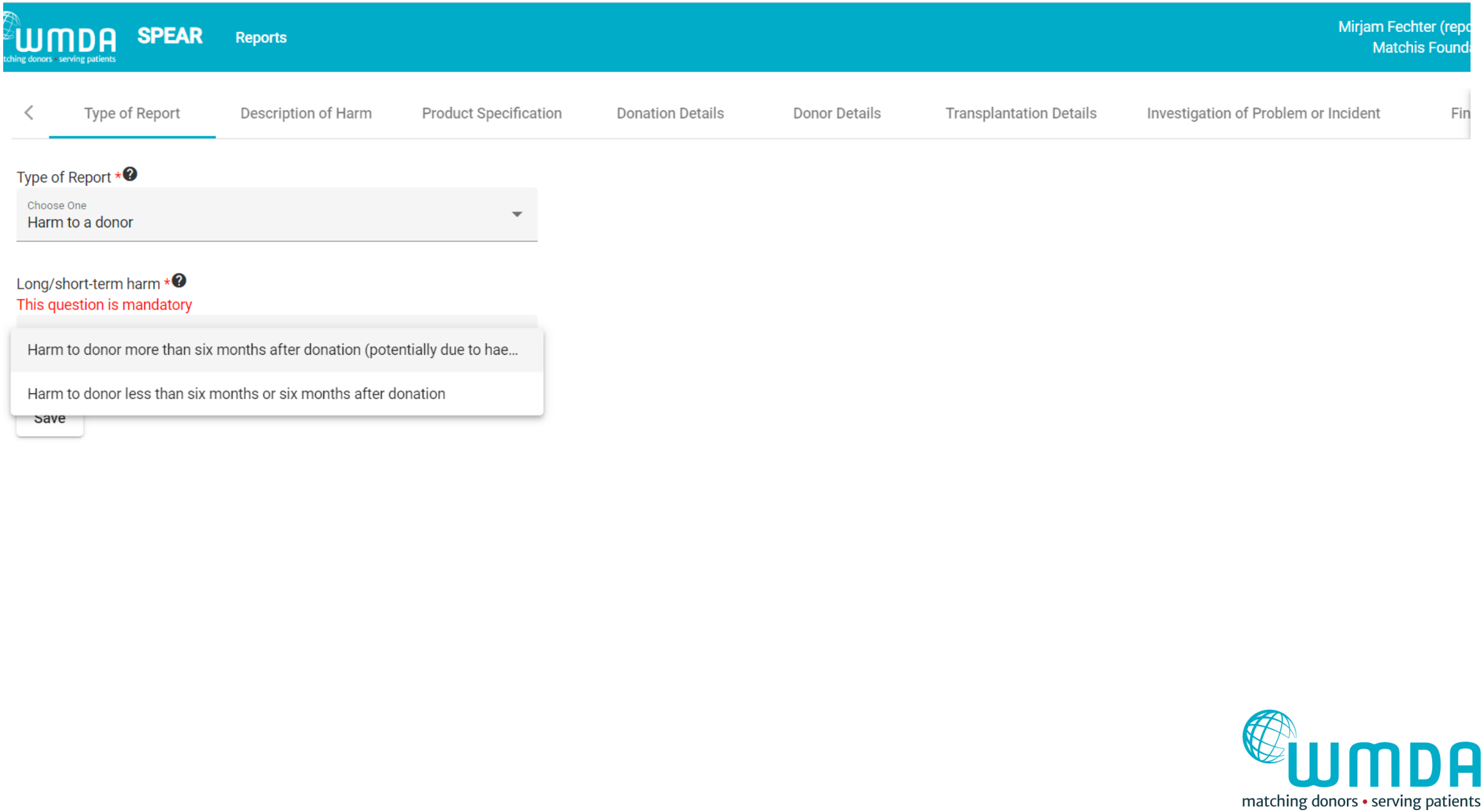
Notifications

Dear SPEAR reporter,
Welcome to the SPEAR reporting tool of the World Marrow Donor Association (WMDA). This online reporting tool allows you to report Serious Adverse Events and Reactions (SPEARs). Please login to access the SPEAR dashboard.

Terms of Use
By logging in to the SPEAR reporting tool, you agree to the term: Terms of Use

Rapid alert
If you have an incident that requires quick dissemination as a **rapid alert** in our community, please contact the WMDA office directly by sending an e-mail at sear-spear@wmda.info and by phone on: **+31 (0)88 505 7900**. Rapid alert cases include, but are not limited to:

- Any prohibition or restriction imposed by the competent authority/health authorities of any country in which the stem cell product is provided or transplanted;
- Donor death;



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Type of reports

- Donor harm
  - <6 months e.g.
    - Allergic reactions, Auto immune disease, Mechanical damage, Acute toxicity, Infections, Unnecessary donation
  - >6 months
    - Malignancies, Auto-immune disease
- Patient harm e.g.
  - Infusion reactions, Engraftment failure (product quality), Transmission of disease (infection)
- Risk of harm
  - Incorrect donation, incorrect donor health screening, unnecessary donation

SPEAR Annual Report 2021

Curtosy Thilo Mengeling, Rachel Pawson,
Lydia Foeken (WMDA)

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349 reports accepted

-26% compared to 2020

+66% compared to 2019

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Key Facts 2021

- The committee accepted **349** SPEAR reports down from 474
- Reports were received from **35** different organisations up from 32
- Much improved analysis due to online reporting system
- **55** reports were classified as COVID-related 54
- No **Rapid Alert** notification was sent in 2021; one critical incident still under investigation 2 Rapid Alerts

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Number of Reports

	HARM TO DONOR	HARM TO RECIPIENT	RISK OF HARM	TOTAL
TOTAL REPORTED 2021 2020	228 367	16 36	89 55	333* 458*
- Short term harm (<= 6 months)	126 151			126 151
- Long term harm (> 6 months)	102 216			102 216
TYPE OF (INTENDED) PRODUCT				
- HPC-Apheresis	196 296	15 29	72 40	283 365
- HPC-Marrow	27 68	1 7	6 10	34 85
- MNC-Apheresis	5 3		3 2	8 5
- HPC-Cord	-	-	8 3	8 3

*15 reports were *accepted*, but categorized as **NOT A SEAR** according to the definitions by the Committee, and are excluded from further analysis, as well as one duplicate report (see AR for details)

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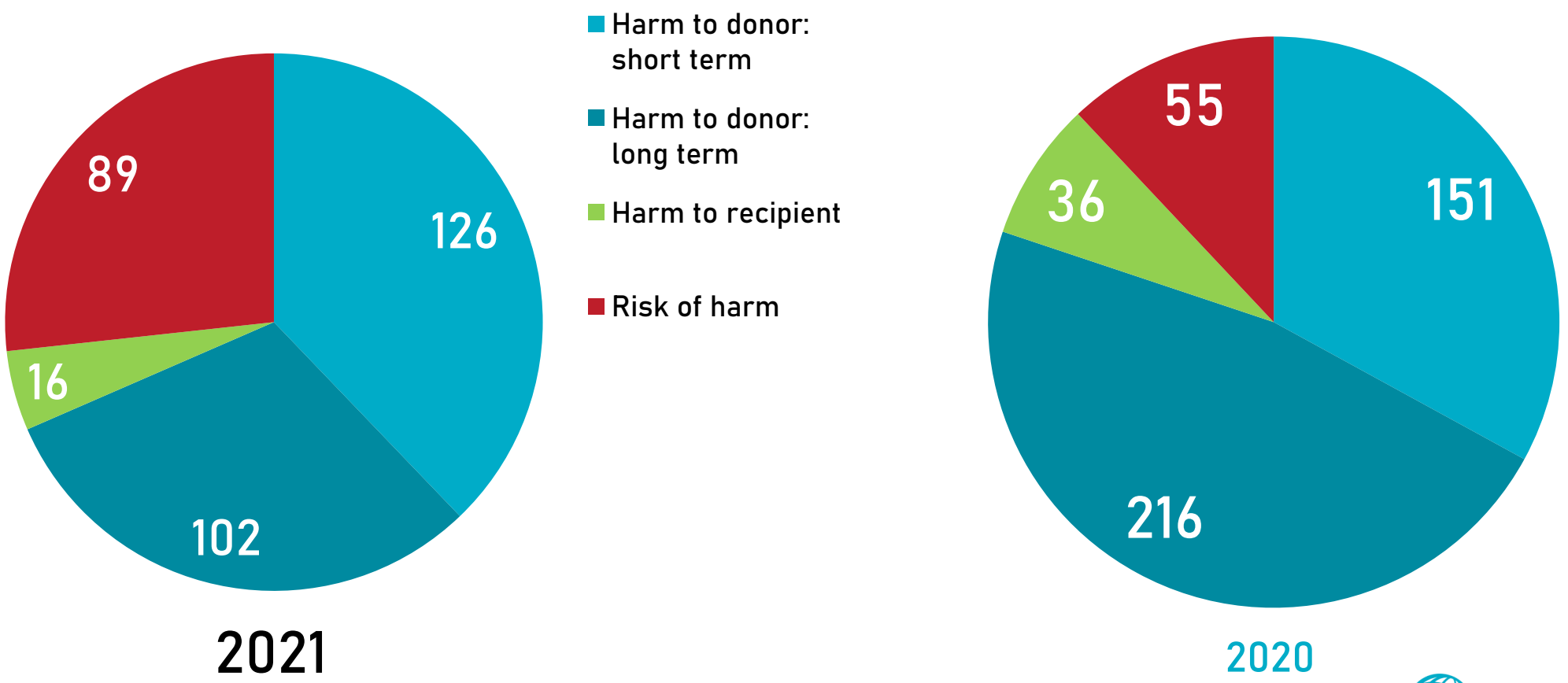

2021

2020

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"Benchmarking" – How many Incidents should be expected?

Calculation based on

- Count of accepted reports 2021 (2020) on Donor Harm from start of procedure until 6 months after donation (N = 131) (N = 157)
- Count of HPC shipments in 2021 by the registries with at least one such report (N = 14,654) (N = 13,020), representing 67% of total shipments (w/o CBU)

Indicator

Count of reports per shipments: 0.9 reports per 100 shipments

Including all SPEAR reporters, thus representing 69% of shipments, has only marginal impact (0.87 instead of 0.89 per 100)

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Notable reports 2021

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CMV Status Change

WMDA-2021-001489

Transplant coordinator noted that recipient CMV status has changed from negative to positive after the donation took place although the results were available beforehand. Results were not checked during staff member's absence. Cells cannot be transfused due to risk of developing CMV viraemia.
Donor underwent unnecessary PBSC collection that was avoidable
⇒ Unnecessary Donor Burden

Decoupling of donation from transplantation due to cryopreservation of the product let to

multiple reports of unnecessary donation where the root cause was

full recipient assessment or even donor selection after donation

CMV status of recipient is part of this full assessment.

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Mixed-up Products

WMDA-2021-001640

The recipient was infused with incorrect unrelated donor stem cells. Institution SOP details a process to **relabel** (using ISBT-128 labels) any hematopoietic progenitor cell, apheresis product received from unrelated donors not already labelled with an ISBT donation ID label at the collection centre. The ISBT labels generated for this product and a 2nd product were switched and applied to the incorrect products.
The stem cells were HLA-mismatched. Recipient developed GVHD grade 4 and passed away one month after transplantation.

(The recipient of the other product developed no symptoms and was re-transplanted with a different donor)

Ongoing investigation about root causes. Qualifies as **Alert**

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Granulomatosis with polyangiitis (GPA)

previously known as Wegener's granulomatosis

WMDA-2021-001570

HPC-A August 2019 without complications. May 2021 requested for MNC. At PE, in the chest X-ray the radiologist described post-inflammatory (?) compaction / shadowing at the apex of both lungs not present in the previous X-ray. Later in May, developed dyspnoe, dry cough, haemoptysis, fever and join pain. He was hospitalized and ultimately diagnosed with Granulomatosis with polyangiitis

WMDA-2021-001512

HPC-A February 2020 without complications. After COVID-19 in April 2021, in May 2021 admitted to a hospital with fever, fatigue, joint pain, haemoptysis. Diagnosed with Granulomatosis with polyangiitis, glomerulonephritis, autoimmune thyroiditis, vitamin B12 deficiency

1 case in 2020, otherwise rarely reported, now 2 cases diagnosed within one month and reported by the same registry

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Covid-19 Related Reports

- *Fifty-five (55)* reports were classified as COVID-related reports: an incident was either effect of an infection (suspected / confirmed) with SARS-CoV-2, or directly caused by mitigation measures such as travel restrictions, quarantine, or cryopreservation of HSC products.
- The majority of these reports involve confirmed or suspected SARS-CoV-2 infections in donors, and the subsequent delays, unused products and similar consequences
- No serious COVID-19 case among donors was reported
- No transmission of SARS-CoV-2 (or any other agent) was reported
- Unneccessary Donor Burden / Unneccessary collection was reported less frequently than in 2020 (8 clear cases, down from 18). However, substantial underreporting is expected as the main reasons for unused products shifted from processing or donor selection issues to recipient-related reasons
- In-depth analysis of the COVID-19 related cases is outside the scope of this Annual Report, but is currently in preparation with the intention to publish together with the COVID survey results.

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MEETINGS DONATE JOIN US

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Adverse events (SPEAR)

Home > Professionals > Promoting Donor Care > Adverse events (SPEAR)

Adverse events (SPEAR)

Every year, close to 30.000 volunteer donors are asked to donate blood stem cells to a patient they do not know. To

PROMOTING DONOR CARE

WMDA sends out Rapid Alerts in case a (series of) Serious (Product) Events and Adverse Reactions must be brought to the attention of the public at once to avoid this type of incident for the future.

Find the Rapid Alerts that were sent out in the past below:

- 2020
- 2020
- 2019
- 2019
- 2013
- 2013
- 2011

Useful documentation

- Log in to SPEAR global online reporting tool
- Examples of SEAR/SPEAR report
- SPEAR Committee standard operating procedure
- Standard Operating Procedure reporting to the WMDA
- Imputability assessment tool

External links

- Common Terminology Criteria for Adverse Events
- International Statistical Classification of Diseases (ICD) 10th revision
- Notify Library