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D3.1 Online educational materials for transplant centre physicians on SEAR reporting

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Abbreviations

- APBMT = Asia Pacific Blood and Marrow Transplantation
- EBMT = European Society for Blood and Marrow Transplantation (EBMT)
- S(P)EAR = Serious (Product) Events and Adverse Reactions
- WMDA = World Marrow Donor Association

Introduction

In 2019, the WMDA has set up a central global reporting system to report Serious (Product) Events and Adverse Reactions (S(P)EARs) to gain insight in the occurrence of serious events and adverse effects in relation to blood stem cell donation, collection and processing. The WMDA collects and analyses information on S(P)EARs that affect donors and/or products from all WMDA stem cell donor registries and cord blood banks to ensure donor health and safety. This online reporting system has been previously described in EU deliverable reports D4.1 'Launch an online reporting system to report Serious(Product) Events and Adverse Reactions -S(P)EARs-(unrelated donors)' and D4.2 'User guide for new Serious (Product) Events and Adverse Reactions S(P)EAR –reporting system' in 2019.

This Deliverable D3.1 publication about the online educational materials for transplant centre physicians on S(P)EAR reporting is part of the 2020 work programme of the World Marrow Donor Association for the EU Third Health Programme (2014-2020). It is based on the various educational materials the WMDA has released or co-produced throughout the year. This report will be used as a resource to support the development of further educational materials in the future for member registries to implement good and best reporting practices that serve to improve donor care.

To increase the awareness of the existence of the reporting tool and improve the knowledge and understanding of the importance of adverse event reporting to the WMDA, as well as increase the general understanding of the working of the online reporting tool, various educational products have been released throughout the year. Firstly, a new and improved user guide for S(P)EAR reporters has been published. Secondly, webinars have been given to inform WMDA members and new S(P)EAR reporters. Thirdly, two scientific publications showcase S(P)EAR to a broader audience. And fourthly, two posters were presented at the virtual 46th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT).

1. User guide for S(P)EAR reporters

1.1. Introduction to S(P)EAR

In July of 2019, the World Marrow Donor Association (WMDA) launched a new global online reporting tool for WMDA member organisations to report Serious (Product) Events and Adverse Reactions – S(P)EARs – to the WMDA. With this global online reporting tool, the WMDA collects and analyses information on recipient and donor S(P)EARs which affect donors and/or products from the WMDA stem cell donor registries and cord blood banks. Trends and patterns can be identified and if necessary, rapid communication on severe incidents can be disseminated to the global community.

1.1.1. Definition of adverse events

WMDA member organisations and their affiliated organisations are obliged to report to WMDA any unexpected donor and/or patient issue or product quality issue in a timely manner. If necessary, urgent measures can then be implemented to protect donors and/or patients, such as a recall of one or more defective batch(es) from the market or change in policies and procedures.

Any adverse event or reaction, or risk thereof, that occurs during any step in the stem cell donation process can and should be reported in the online reporting tool: S(P)EAR. This includes adverse events or reactions that occur to patients and donors, related and unrelated. The WMDA follows the EU definitions of a serious adverse event or reaction:

EU definition of a serious adverse event DIRECTIVE 2004/23/EC, article 3 (m)	**EU definition of a serious adverse reaction** DIRECTIVE 2004/23/EC, article 3 (n)
'serious adverse event' means any 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, hospitalisation or morbidity.	***'serious adverse reaction' means an 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, hospitalisation or morbidity***
WMDA classification*: Harm to a Donor / Recipient*	*WMDA classification: Risk of Harm*

1.1.2. The user guide

This user guide to the S(P)EAR online reporting tool is designed to provide background information on the S(P)EAR reporting tool. It outlines how to submit a S(P)EAR report and provides answers to commonly asked questions. If any information is missing or something is unclear to you, please do not hesitate to contact us at: sear-spear@wmda.info.

To get access to this online reporting tool (as a S(P)EAR reporter), to send us your feedback or if you have any questions, please let us know. You can contact us via e-mail on: sear-spear@wmda.info

1.2. Quick start

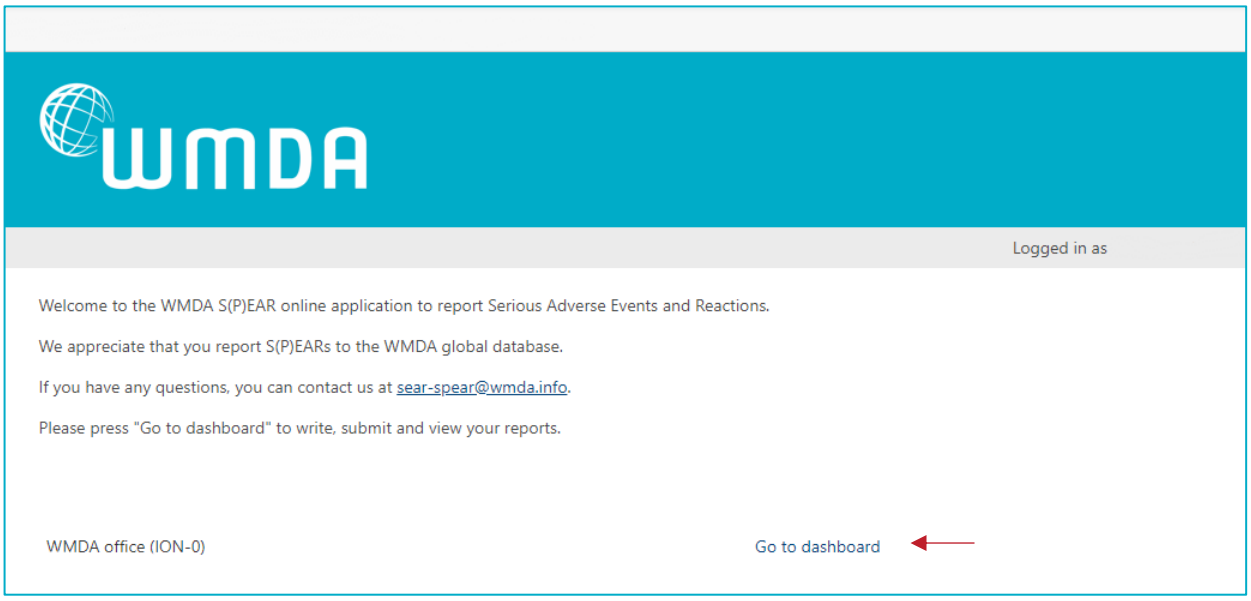
1.2.1. Log in

In your browser, go to https://wmda.knack.com/spear and login with your user name and password.

> No account yet? Send an email to sear-spear@wmda.info to request login credentials and to receive further instructions
>
> !

1.2.2. Create/submit/view reports

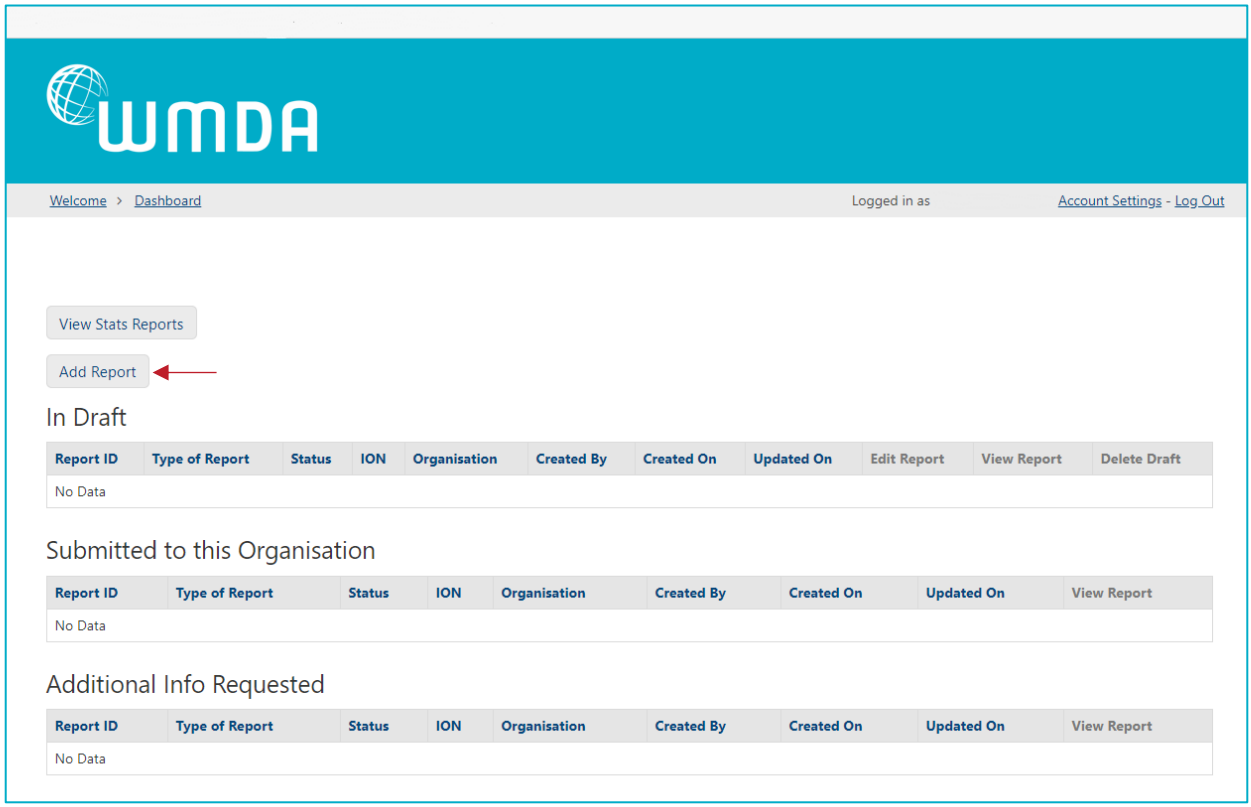
Once you're logged in, click on "Go to dashboard". Here you can write, submit and view your reports. Some reporters will be affiliated to multiple organisations. Please select the dashboard you currently want to use.



1.2.3. Create a report

In the dashboard you can add a new report or view the reports you've previously submitted. To add a new report click the "Add report" button at the top of the page.

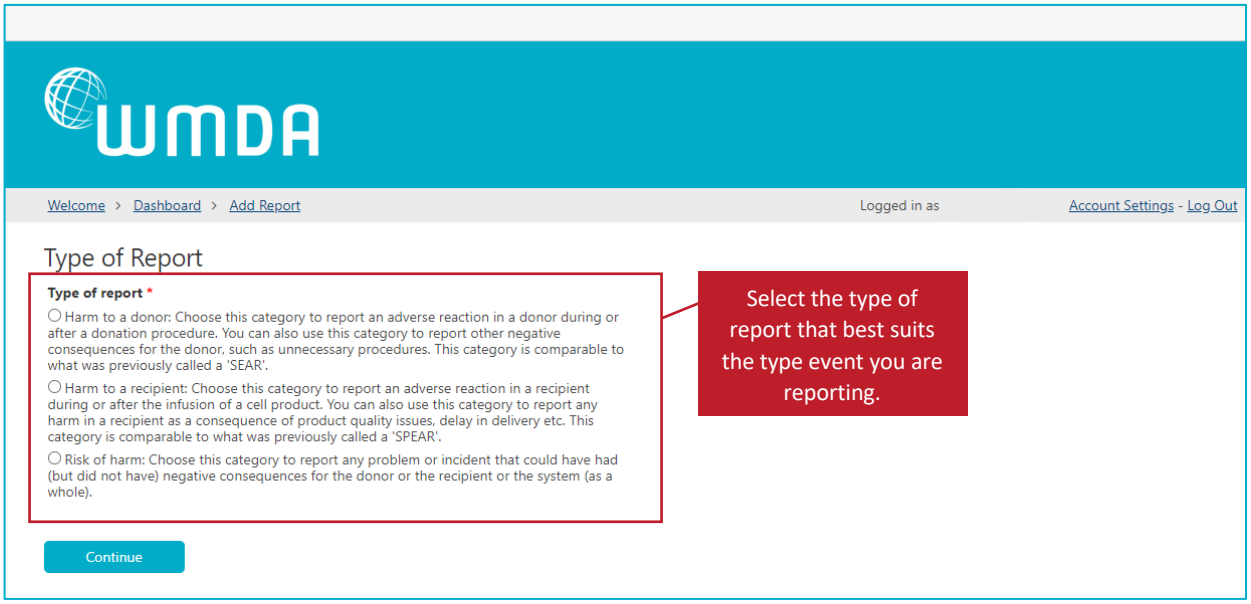
> Reports are automatically saved to allow to continue editing at a later time. Previously started reports can be found in the "In draft" table in the dashboard.
>
> ?



1.2.4. Selecting the type of report

There are three types of report to choose from: Harm to a donor, harm to recipient or risk of harm. Depending on the type of harm you choose, the tool will display different relevant questions.

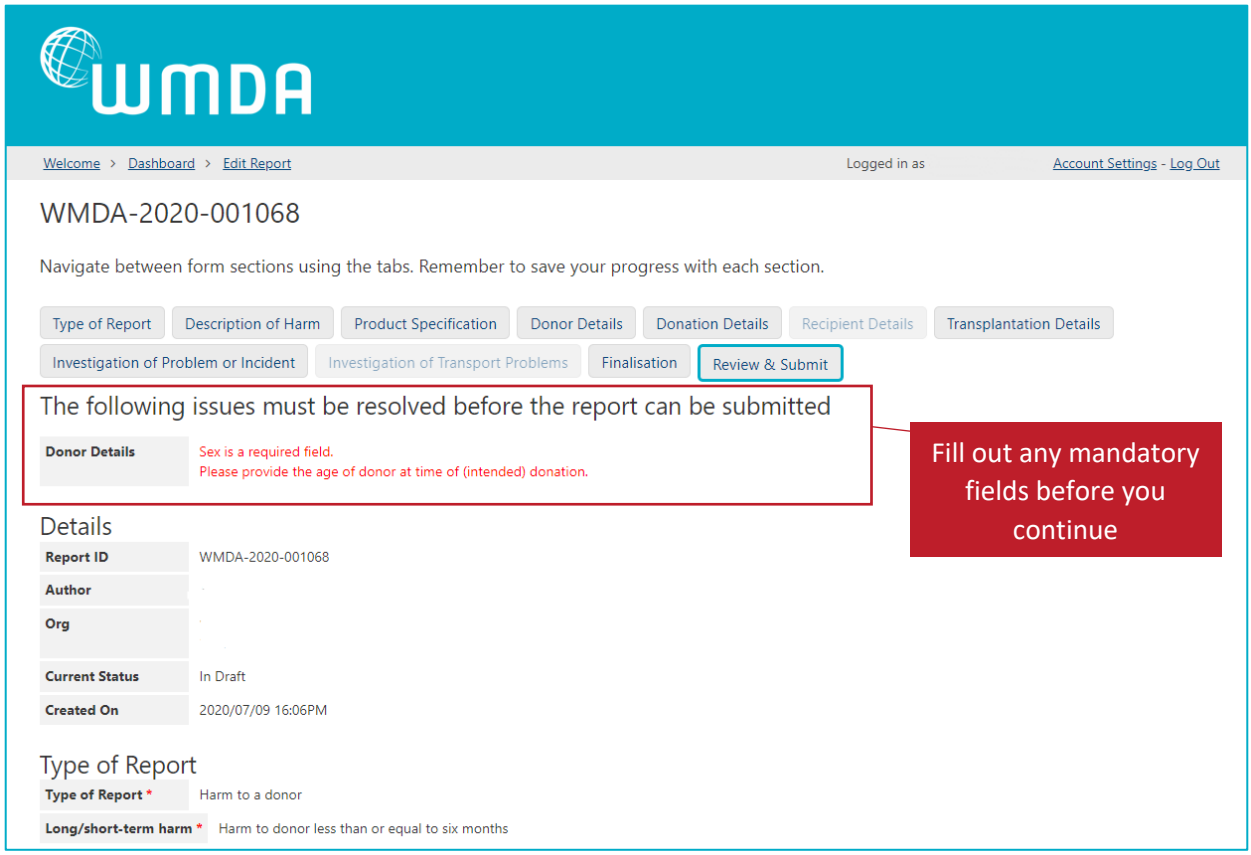
A brief decsription of each category can be found on the “Type of report” page (see image below).



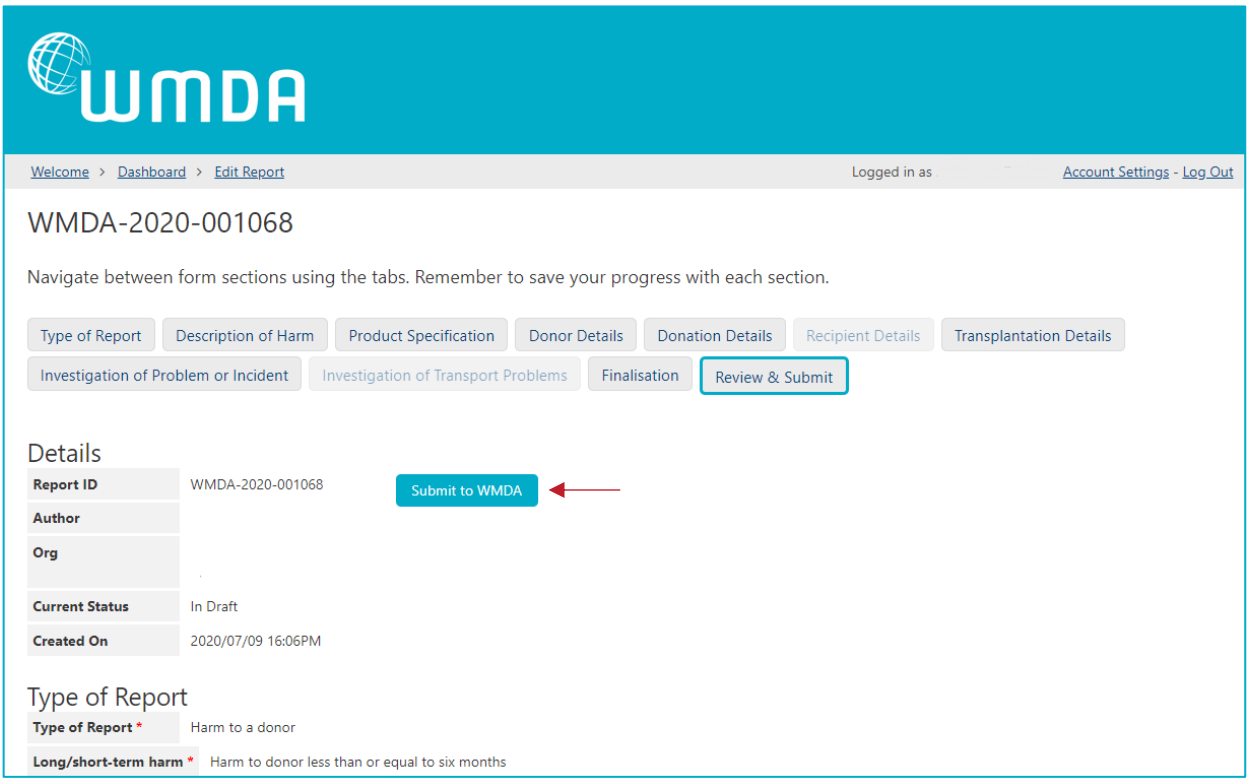
1.2.5. Finalizing the report

Once you've filled out all the necessary information, your report is ready to be submitted. The final tab, titled "Review and submit", will display any issues that need to be solved before the report can be submitted. To submit the report, please click the "submit to WMDA" button that can be found next to the report ID at the top of the page.

1. Click on the tab "Review and Submit".
2. Double check all your data.
3. Make sure to fill in all mandatory questions



4. Remove any confidential patient/donor related data
5. Click on the button "Submit to WMDA"



To view the reports you've submitted, you can find them on your dashboard. Here you can also view other reports with different statuses (e.g. draft reports, additional information requested and the reports that have been reviewed by the S(P)EAR committee.

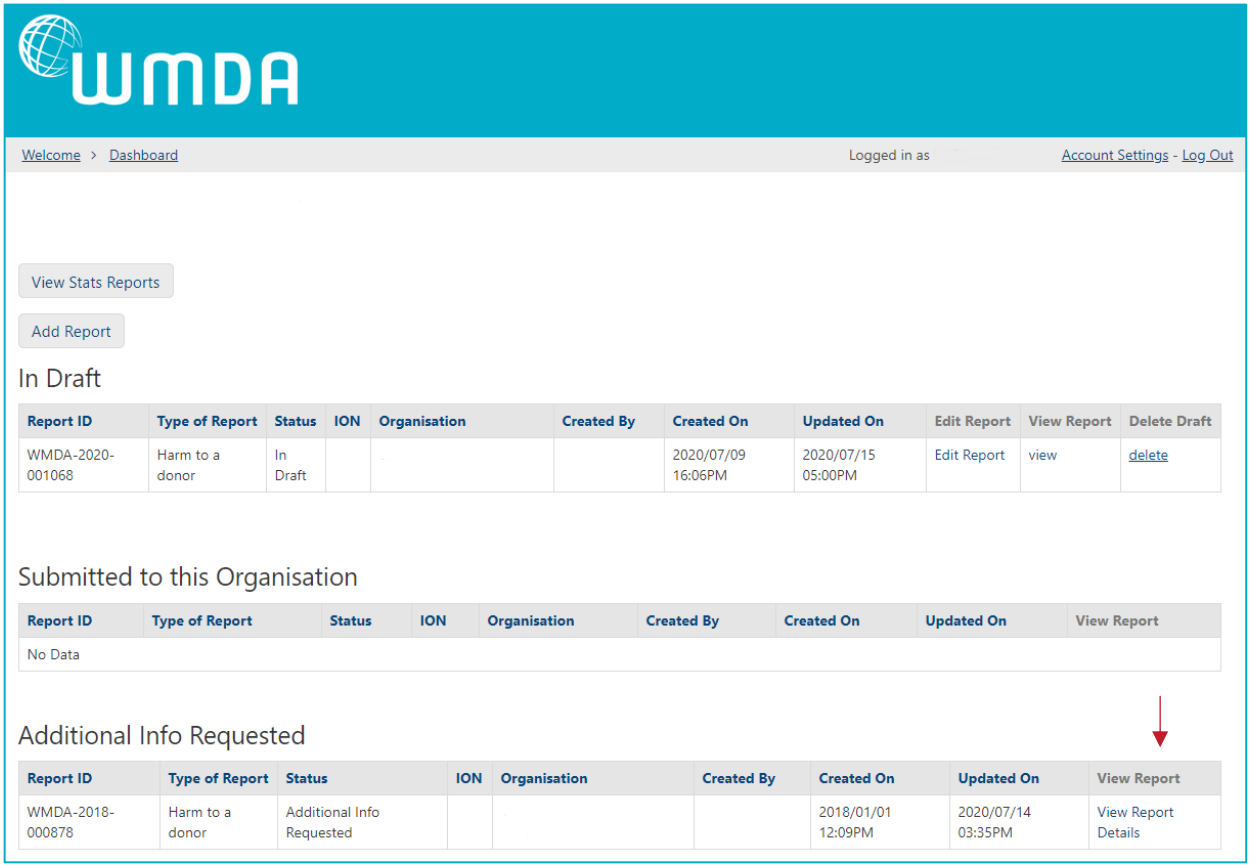
?

1.2.6. Additional info requested

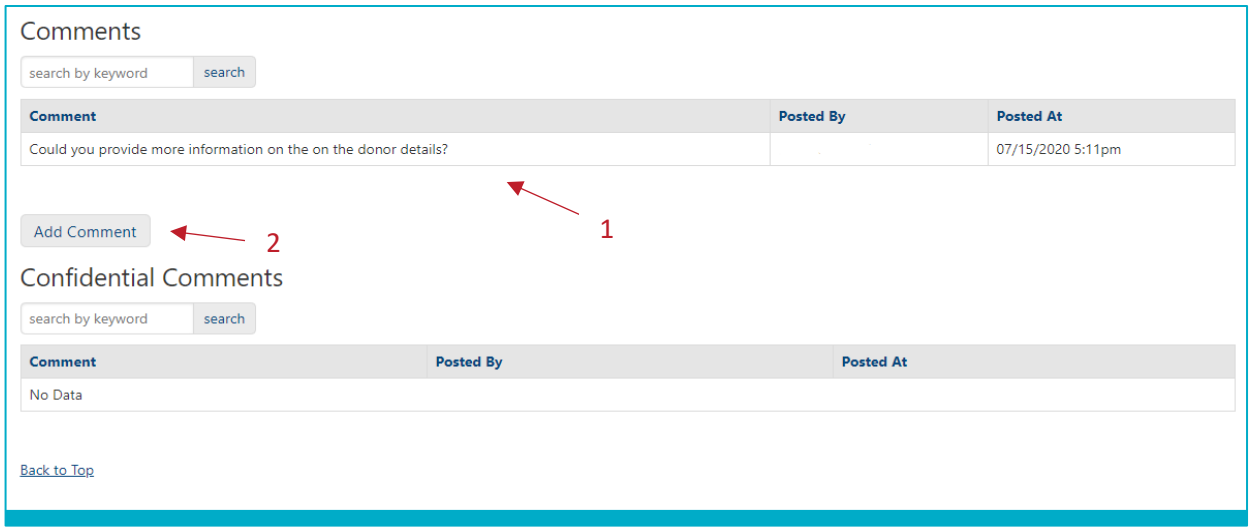
Once you submit a report, it will be reviewed by the medical advisor. If there are any additional questions or a request for more information, the report will be sent back to you. You can find the report in the "additional info requested" box on your dashboard.

To answer a request for additional information:

1. Go to your dashboard.
2. Open the report by clicking on ‘View Report Details’.



3. Scroll down to read the question in the Comments section.
4. Provide you answer or additional information via the “Add comment” button.



5. Once you've filled out all the requested information, scroll to the top of the page .
6. Click "Submit to WMDA" to re-submit your report including the additional information.

Please make sure you click the **submit to WMDA** button when you're finished writing your comment to the additional information that was requested. If not, the report will not be sent back to the medical advisor and your input is not submitted.

!

Reporting a rapid alert

In case of recall or big risks for future donations or transfusions a report can be submitted as a rapid alert. This includes, but is 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;

Please **flag** your report as a rapid alert after submitting it by contacting WMDA the by telephone (+31-(0)88 5057900) or e-mail (sear-spear@wmda.info). If the report qualifies as a rapid alert and for dissemination to the international community, it will always be shared without any traceable information on the reporting agency, donor, patient or reporter.

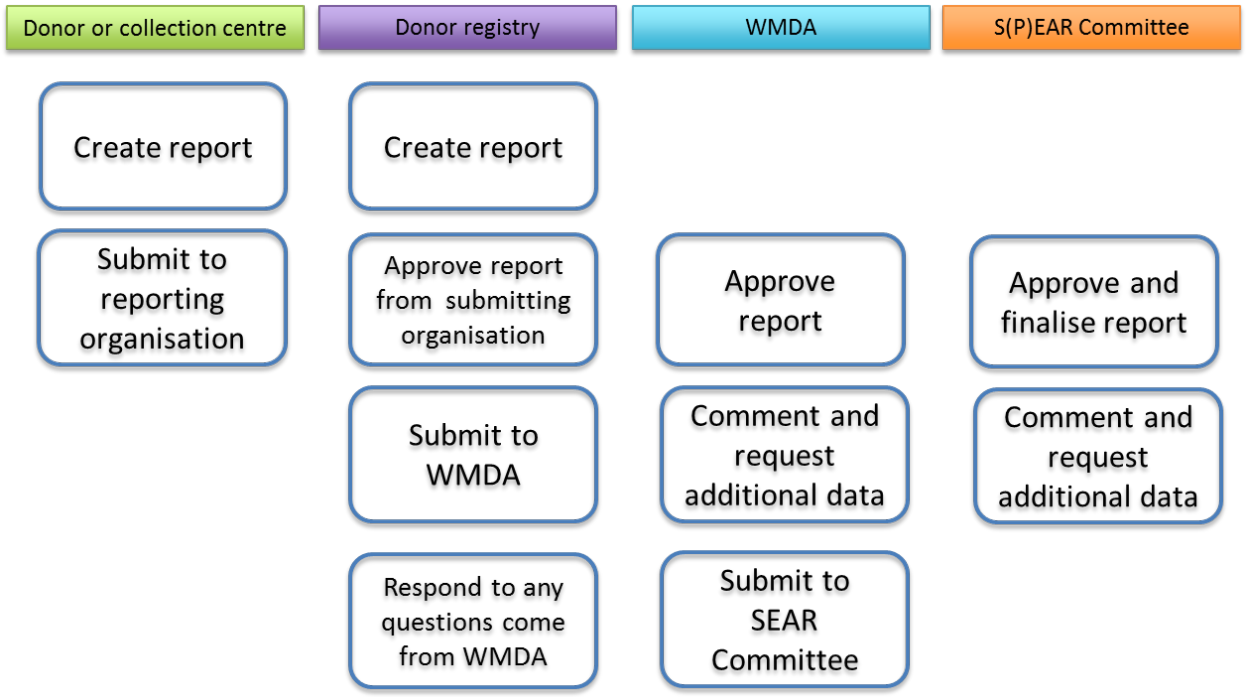
In addition, reporters should notify their competent authorities/health where incident has occurred.

1.4. Process flow

Donor, transplant or collection centres are affiliated with donor registries have the possibility to create reports and submit them to the reporting organisation/donor registry. The further handling of the report will go via the donor registry. The donor registry can approve and submit reports from submitting organisations as well as their own incident reports.

When submitted, all reports are available to the WMDA office and the S(P)EAR Committee. The WMDA office team for S(P)EAR reporting consists of a medical advisor and a project coordinator. The medical advisor reviews all reported incidents at least once a week and checks for rapid alerts. If necessary, the medical advisor can request the reporting organization for additional information. If the report is approved by the medical advisor, it will be turned over to the S(P)EAR Committee.

The S(P)EAR Committee consists of 11 medical experts from worldwide WMDA member organisations. Their main task is to review and finalise the reports every month. If necessary, they can request additional information. In case of a Rapid Alert, they will ad-hoc schedule a meeting to discuss the issue, followed by sending out the Rapid Alert to the WMDA community if required.



1.5. Frequently asked questions

1.5.1 How can I become a S(P)EAR reporter?

To become a S(P)EAR reporter, you can contact the WMDA office to receive login details and further instructions on how to access the system. Please contact the S(P)EAR project coordinator by e-mail: sear-spear@wmda.info

1.5.2 How do I login?

Login on https://wmda.knack.com/spear#welcome/ with your email address and password. If you do not have a password yet, please see question 5.1.

1.5.3 I forgot my user name/password

When you go to the **login page** you will find the login module where you can enter your email address and password. Click on "forgot?" next to Password. Enter your email address in the designated field and press the "Submit" button. You will then receive a link to reset your password.

1.5.4 What to report and what not to report?

Check the document S(P)EAR examples of what to report and what not to report.
In addition, see the Standard Operating Procedure for reporting SEAR/SPEAR on WMDA Share.

1.5.5 How do I assess the imputability?

To perform an imputability assessment, WMDA created the Imputability Assessment Tool.

1.5.6 How do I assess the severity of the reaction?

More information on assessing the severity of a reaction can be found on the page of the Imputability assessment tool (see above).

1.5.7 What ICD-10 refence can I use?

The WHO online ICD-10 reference tool is used for assigning ICD-10 codes to S(P)EAR reports.

1.5.8 I made a mistake in a submitted report, can I change this?

Once you have submitted a report to the WMDA, you can no longer make changes yourself. If it is an important change or update that needs to be made before the report is reviewed by the medical advisor and or committee, please contact sear-spear@wmda.info and outline the report ID and details of the change request to the WMDA office.

1.5.9 How can I withdraw a submitted report?

Once a report has been submitted, you can not withdraw the report. If withdrawal is necessary, please contact the WDMA office at sear-spear@wmda.info with the Report ID number and the details outlining why the report should be withdrawn. The WMDA office and the medical advisor will then assess if your request for withdrawal will be honored or not.

1.5.10 Will I receive feedback on the report and in what time frame?

In general, you will not receive any feedback. WMDA and/or the S(P)EAR Committee could ask for additional information, visible via comments under the report. Once a report has been reviewed by the committee, you can see the committee's final assessment in the Dashboard.

1.5.11 What happens with the reported incident?

All reported incidents are collected in the system and will be analysed. They will be shared anonymously with the WMDA community in annual S(P)EAR reports.

1.5.12 What is the annual report?

Annually, the WMDA office analyses and summarises all provided S(P)EAR data. This is then published in annual S(P)EAR reports which are published on WMDA Share, available for the WMDA community.

1.5.13 What does a Rapid Alert mean?

A Rapid Alert can be sent out in the rare case of a donor death, or if the chair of the S(P)EAR Committee deems a S(P)EAR report to require expedited reporting. An ad-hoc meeting of the S(P)EAR Committee will then be called within 5 working days to review the event. Rapid alerts consist of a brief description of the event that has occurred (without any information that can trace back to the reporting registry, reporter, patient or donor) and recommendations based on the event that has occurred. The recommendations can be used as a guideline for best practice.

If you have a **rapid alert** that needs to be shared with the community quickly, we urge you to send a separate e-mail to the WMDA office (sear-spear@wmda.info) or call us on: +31 88 505 7900.

1.6. Terminology

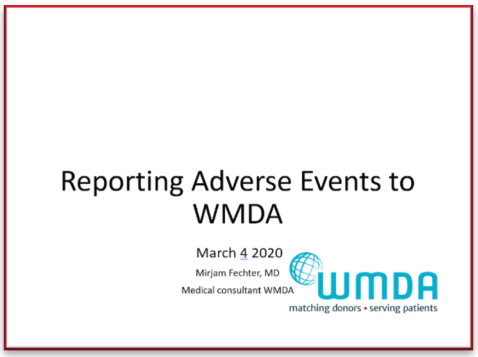
TERM	DEFINITION
IMPUTABILITY	An assessment of the likelihood that an adverse event / reaction in a donor or recipient is related to the process of donation or to a safety or quality defect in the transplanted tissue or cells. Defined as: Definite, Probable, Possible, Unlikely, Excluded, or Not Assessable.
IMPUTABILITY ASSESMENT TOOL	A online tool developed by the WMDA to help identify the likelihood an event is attributed to the donation or transplantation process.
MEDICAL CONSULTANT	The medical consultant is part of the WMDA committee and works is a medical doctor that works in the field of hematopoietic stem cell transplantation.
REPORT ID	The report ID is a uniquely identifying code that is specific to each report. It is automatically generated when a new report is created.
REPORTER	The reporter is the author of the report and the person that submits the report to the WMDA on behalf of the reporting registry or donor, transplant or collection centre

2. Webinars

During 2019 various webinars have been held to inform the blood stem cell community on S(P)EAR-related topics.

2.1 WMDA Educational Webinar: Definition of Serious Adverse Events and Examples by Mirjam Fechter

In this webinar (Appendix I), Mirjam Fechter (WMDA medical consultant/member of the S(P)EAR committee) talks about what (not) to report, root cause analysis and how to assess the imputability of an adverse event, amongst other topics. The webinar since then has become a standard item included in the welcome package to new S(P)EAR reporters. The webinar is freely accessible to anyone that visits the WMDA website and via the WMDA YouTube channel. The webinar can be viewed here: https://youtu.be/wLzWbcHYoCQ

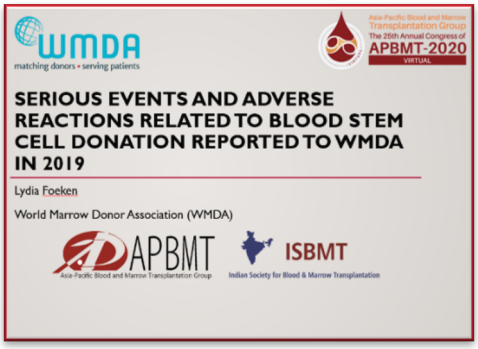


2.2 WMDA Virtual Week 8: SEAR Annual Report by Thilo Mengling and Mirjam Fechter

During the WMDA Virtual Week, an event hosted by the WMDA as a digital conference for WMDA members, Thilo Mengling (Chair of the WMDA S(P)EAR Committee) and Mirjam Fechter (WMDA medical consultant/member of the S(P)EAR committee) gave a webinar to elaborate upon the 2019 S(P)EAR annual report (Appendix II). In this webinar, the most important numbers and graphs of the 2019 report were presented and notable cases were discussed. The webinar can be viewed here: https://youtu.be/HZChQ2jLepk

2.3 APBMT-2020: Serious Events and Adverse Reactions Related to Blood Stem Cell Donation Reported to WMDA in 2019 by Lydia Foeken

At the Asia Pacific Blood and Marrow Transplantation (APBMT) 2020, Lydia Foeken (CEO of the WMDA) was invited to speak on serious and adverse reactions related to blood stem cell donations reported to the WMDA. In this talk, she highlighted the importance of S(P)EAR reporting and the usage of the reporting tool as well as the main results of the 2019 annual report (Appendix III).



3. Publications

Two publications were published in 2020, communicating the importance of S(P)EAR reporting to a broader audience.

3.1 "New global reporting system for serious (product) events and adverse reactions in hematopoietic stem cell donation and transplantation", Jöris et al.

On September 9th 2020, Jöris et al. published an article in Cell and Tissue Banking on the new global reporting system S(P)EAR. In this article they describe the development process of the system, as well as provide an analysis of the collected data about S(P)EARs occurring in donors to provide statistics on the type of reports being submitted and to put in place best practices to mitigate such effects and occurrences.

Reference to full article: Jöris M, Pustjens E, Mengling T, et al. New global reporting system for serious (product) events and adverse reactions in hematopoietic stem cell donation and transplantation. Cell and Tissue Banking. 2020 Sep. DOI: 10.1007/s10561-020-09863-y.

3.2 "Adverse event reporting for cellular therapy products: Current status and future directions", Loper et al.

On October 16th 2020, Loper et al. published an article on adverse event (AE) and adverse reaction (AR) reporting. They discuss the importance of review and analysis of this data for process improvement, product information and interventions. This review article, authored by experts from various organizations, serves to summarize the current state of reporting and offers opportunities for streamlining and coordination, as well as key reference for professionals in this field.

Reference to full article: Loper, K., Sugrue, M., Raval, J., Schwartz, J., Land, K., Koh, M., Mengling, T., Greinix, H., Halter, J., Celluzzi, C., & Chaudhri, M. (2020). Adverse event reporting for cellular therapy products: Current status and future directions. *Transfusion*. https://doi.org/10.1111/trf.16062

4. Other

4.1 EBMT Poster presentation

EBMT
European Society
for Blood and Marrow Transplantation

SERIOUS EVENTS AND ADVERSE REACTIONS IN RELATION TO BLOOD STEM CELL DONATION

Data from 2018 and 2019

Mirjam Fechter (Matchis, Leiden, the Netherlands), Thilo Mengling (DKMS gGmbH, Tübingen, Germany), Monique Jöris (WMDA, Leiden, the Netherlands), Eefke van Eerden (WMDA, Leiden, the Netherlands), Lydia Foeken (WMDA, Leiden, the Netherlands).

BACKGROUND

The World Marrow Donor Association (WMDA) has set up a unique central global adverse events reporting system with the aim to collect data on adverse reactions and serious events in relation to (un)related blood stem cell donations and the provision of these blood stem cell products. This Serious (Product) Events and Adverse Reactions (S(P)EARs) system is characterized by easy accessibility for WMDA member organization and their affiliations, a rapid analysis of incoming reports and a regular, and if necessary rapid, feed-back to the community. In this poster we present the data from 2018 and also those from 2019, the year in which we introduced a new online reporting tool with improved user friendliness.

METHODS

WMDA member organisations are encouraged to report their S(P)EARs to WMDA by regular communications and by education, explaining the importance of reporting and providing instructions on how to report. In 2018, the data collection was done through the online questionnaire platform SurveyGizmo, followed by a data analysis using Excel. In July 2019 WMDA introduced a new online reporting tool. All reported S(P)EARs were evaluated by the WMDA medical consultant on a weekly basis, unclear or incomplete data were checked and a final review was done by the S(P)EAR committee consisting of acknowledged experts on all relevant fields including, but not limited to donation, transplantation, transport and cord blood units.

RESULTS

In 2018, the S(P)EAR committee received and considered 206 reports of which 24 were considered not to be a S(P)EAR which leaves a total of 182 S(P)EAR incident reports from 18 organisations in 14 countries, compared to 210 S(P)EAR incident reports from 27 different registries in 2019. The type of (SP)EARs reported were as follows: 151 harm to donor in 2018, 155 harm to donor in 2019, 15 harm to recipient in 2018, 23 in 2019 and 16 risk of harm in 2018 and 32 in 2019. The majority involved reports associated with HPC-Apheresis donations (75% in 2018 and 70% in 2019). See table 1 for the details.

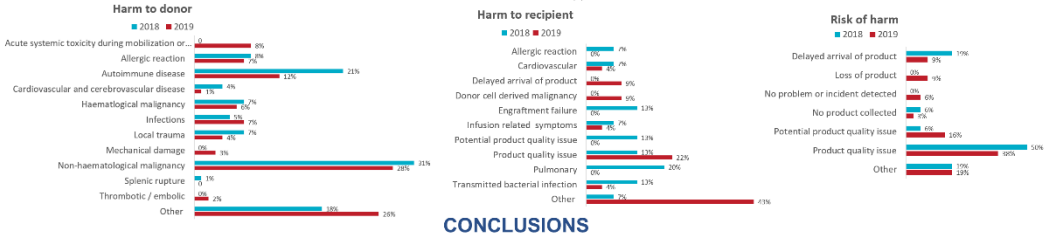
In graph 1 the types of reports are listed. The majority of the harm to donor reports were malignancies and autoimmune disorders, mainly reported as long term donor harm. A pulmonary disorder or symptom was the most common harm to recipient reported in 2018 and in 2019 product quality issue was the most reported as recipient harm. Half (2018) to 38% (2019) of the reported risk of harm incidents involved a product quality issues.

The committee assessed each report for causation using the imputability tool[1]. This tool is used to assess the likelihood that an adverse event/reaction in a donor or recipient is related to the process of donation or to a safety or quality defect in the transplanted tissue or cells. In 2018, 21% (n=38) of reports were assessed as having definite, 12% (n=21) probable, 7% (n=13) possible, 44% (n=80) unlikely and 11% (n=20) excluded imputability. Five percent (n=10) of reports were not assessable. Since 2019 imputability is no longer assigned to long term donor harm or to risk of harm. Of the 88 donor harm reports that included the assessment, donation and short term after donation, 37 (42%) were assessed as definite/certain, 13 (15%) as probable, 12 (14%) as possible, 21 (24%) as unlikely, 2 (2%) as excluded and 3 (3%) as not assessable. During 2018, 21,745 and during 2019 24,627unrelated blood stem cell donations took place worldwide[2]. This means that for 0,25%-0,28% of the HPC-Cord donations, for 0,90%-0,91% of the HPC-Apheresis donations and for 0,86%-1,1% of the HPC-Marrow donations a S(P)EAR has been reported (Table 1). In 2019 two rapid alerts were disseminated, one regarding a fatal event in an unrelated bone marrow donor and one regarding the loss of a because of incorrect use of transfer collection system bags[3].

TABLE 1: OVERVIEW OF REPORTED INCIDENTS

Total reported (considered not a S(P)EAR)	Harm to donor 2018 151 (83%)	Harm to donor 2019 155 (74%)	Harm to recipient 2018 15 (8%)	Harm to recipient 2019 23 (11%)	Risk of harm 2018 16 (9%)	Risk of harm 2019 32 (15%)	Total 2018 182	Total 2019 210
Timeframe, total	151	155	15	23	16	32	182	210
- Donor assessment/ search and selection/ distribution / processing / transport/ unknown/unspecified	-	7	3	11	7	16	10	34
- Mobilisation/ collection (transplant)	30	8	2	3 (9)	8	16	40	36
- Short term <30 days (Long term >=30 days)	27 (94)	73 (67)	- (-)	-(-)	- (-)	-(-)	27 (94)	73(67)
Product type, total	151	155	15	23	16	32	182	210
- Pre-collection samples / DLI/unknown/unspecified	2	3	-	3	2	3	4	9
- HPC-Marrow	26	33	4	6	4	5	34	44
- HPC-Apheresis	123	119	7	11	7	19	137	149
- HPC-Cord	-	-	4	3	3	5	7	8

GRAPH 1: TYPE OF PROBLEM PER S(P)EAR TYPE



CONCLUSIONS

The report rate of S(P)EARs is between 0.25-1.1% per all cell types. However, we do believe there is a certain degree of underreporting of S(P)EARs to the WMDA. In the past year a new reporting system was developed and implemented which should increase the user friendliness for reporters as well as improve communication about the reports. It is important to emphasize that in addition to events and reactions in connection to a donation, any malignancy, severe autoimmune disorder, and donor death should be reported.

REFERENCES

1. WMDA. (2018, June 7). *WMDA Share online collaboration tool -member's access only-*. For more information see the User Guide S(P)EAR p. 11
2. WMDA. (2019). *WMDA Global Trend Report 2018*. Leiden: WMDA.
   WMDA. (2020). *WMDA Global Trend Report 2019*. Leiden: WMDA.
3. https://wmda.info/professionals/promoting-donor-care/adverse-events-searspear/

WMDA
matching donors • serving patients

4.2 EBMT Virtual Booth poster

S(P)EAR Annual Report 2019

matching donors • serving patients

Serious (Product) Events and Adverse Reactions – S(P)EARs – in relation to blood stem cell donation and blood stem cell collection/processing are collected via the WMDA online reporting tool. The aim of this systematic collection is to gain insight in the occurrence of serious events and adverse effects in relation to blood stem cell donation and blood stem cell collection/processing.

210

reports were received in 2019.

27 different registries filed S(P)EAR reports.

149

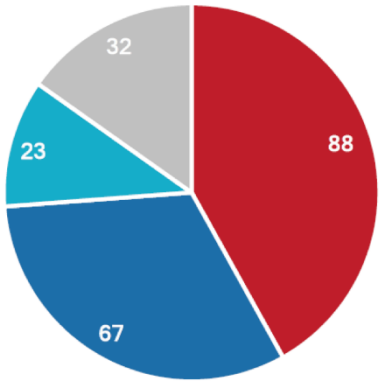
incidents occurred with HPC-Apharesis.

53 malignancies were reported.

50%

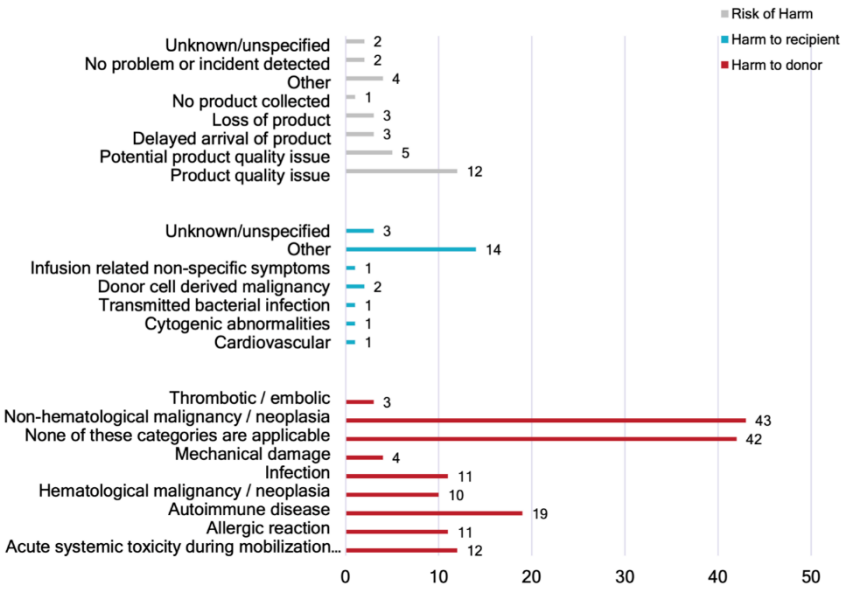
of all outcomes were mild to severe in reaction

Type of Report



- Harm to donor: short term
- Harm to donor: long term
- Harm to recipient
- Risk of harm

Type of Problem



Read the full report on WMDA Share

5. Plans for the 2021

The focus of WMDA for 2020 was to educate healthcare professions, who are reporting incidents occurring after unrelated stem cell donation, on how to accurately report adverse events and incidents via the S(P)EAR online report. The various educational materials described in the previous chapters, outline how the WDMA has done this in 2020 and which audiences were targeted.

In 2021, the WMDA plans to further improve the quality and occurrence of S(P)EAR reporting. In addition to the standard educational materials such as webinars, publications and user guides, the WMDA plans to fortify the S(P)EAR documentation base and to deploy an educational course for S(P)EAR reporters.

The documentation base surrounding S(P)EAR needs to be reviewed and revised where necessary to make sure it is complete, accessible, up to date and easy to use. By providing more and accurate documentation, the S(P)EAR set-up and process will become more transparent to the reporting centres. This will aid reporters in becoming more knowledgeable on S(P)EAR and hopefully will facilitate the registration of more reporting members and non-member organizations.

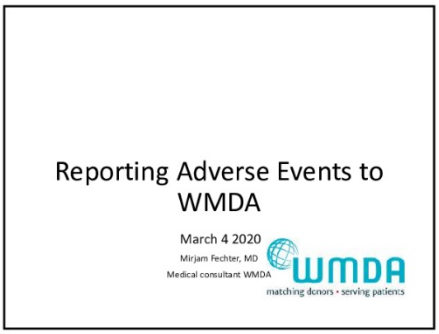
Another main focus in 2021 will be education of new reporters. For this, the WMDA can use the improved Educational platform. New S(P)EAR reporters will be required to complete a brief course before becoming a S(P)EAR reporter. By doing so, the WMDA can ensure all S(P)EAR reporters are aware of the rules and regulations regarding privacy and sensitive information in S(P)EAR reports, as well as become more knowledgeable on the workings of the S(P)EAR online reporting tool as well as the S(P)EAR reporting process.

An important step forward in this era of a growing demand on family donors will be to include transplant centres to submit their S(P)EARs regarding stem cell donations of family members. Therefore, in 2021 there will be a focus on targeting these transplant centres via the educational materials to be released.

6. Appendices

I. WMDA Educational Webinar: Definition of Serious Adverse Events and Examples by Mirjam Fechter

08/12/2020



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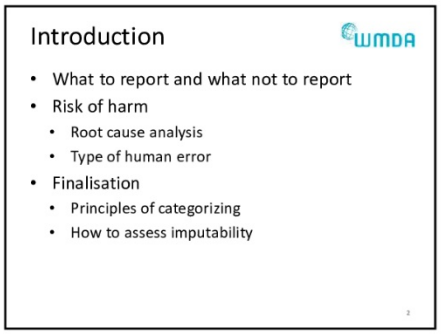

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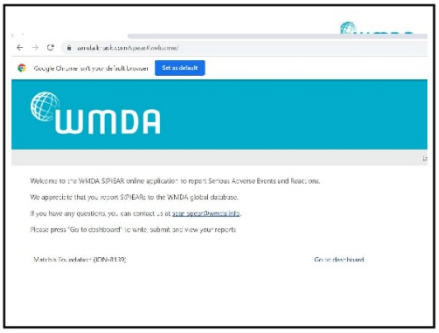

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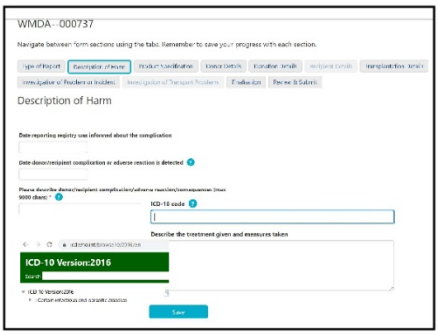

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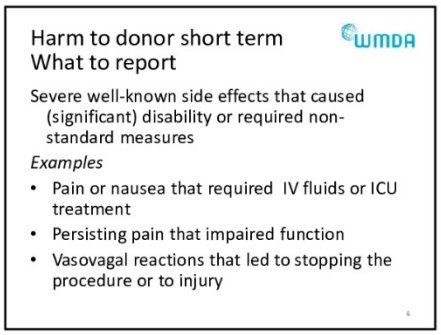

6

Harm to donor short term What to report

Rare, but well-known side effects or complications

Examples

- Thrombosis (in CVC),
- Splenic rupture,
- Skin disorders during G-CSF,
- Local damage to bone,
- Anaphylactic reaction on G-CSF

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Harm to donor short term What to report

Disease of which it is suspected to be exacerbated or worsened due to donation

Examples

- (Flare of) auto-immune disease
  - Single organ: thyroid disease
  - Skin disorders: eczema, psoriasis
- Reactivation of herpes especially if closely linked to donation (<30 days post)
- Aggravation of pre-existing back pain
- Aggravation of fatigue in chronic fatigue syndrome

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Harm to donor short term What to report

Disease with that could theoretically be linked to the donation

Examples

- First symptoms of auto-immune disease,
- Thrombosis
- Cardiovascular disease
- Persistent back pain after bone marrow collection

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Harm to donor What to report

Unnecessary procedures

Examples

- Donation was canceled by TC, but did take place due to communication incident (also problem or incident)
- Also for mobilization procedures

10

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Harm to donor short term What not to report –*per se*

Well-known side effects, that could be well controlled.

Examples

- Short term use of opiates to control pain
- IV Calcium for hypocalciaemia during apheresis
- Iron suppletion for mild iron-deficiency after bone marrow collection

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Harm to donor short term What not to report- *per se*

Disease with a clear cause that is excluded to be related to donation and no consequences or substantial risk of harm for the donation or the recipient

Examples

- Uncomplicated flu during the flu season
- Minor injuries after full recovery

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Harm to donor short term
What not to report –*per se*

Uncomplicated use of rare but standard measures

Examples

- Uncomplicated CVC
- Emergency bone marrow collection in non-mobilizers

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But note:

- If there was an incident e.g. human error that contributed, or
- a contributory finding during pre-donation examination, or
- impact on the donation procedure which led to an insufficient product
- Etc.

→ **DO REPORT**

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Type of harm to donor
causality - pathophysiology

No.	Type of harm	Examples/clarification
1	Allergic reaction	
2	Autoimmune/ immune related disease	including asthma and eczema exacerbation during GCSF, multiple sclerosis
3	Mechanical damage	including bone or nerve damage and infections as a result of such damage
4	Thrombotic / embolic event	including pulmonary embolism or stroke as a result of
5	Acute systemic toxicity during mobilization or collection	this also includes severe pain, fainting, citrate toxicity
6	Hematological malignancy /neoplasia	
7	Non-hematological malignancy /neoplasia	
8	(Systemic) Infections	not as a direct result of mechanical damage

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Type of harm to donor
Organ systems/other

No.	Type of harm	Clarification
9	Cardiovascular and cerebrovascular disease	
10	Neurological disease	not auto-immune or as a consequence of mechanical damage
11	Musculoskeletal / joint affection	not auto-immune or as a consequence of mechanical damage
12	Psychiatric / psychogenic disorder	
13	Respiratory disorder	
14	Unnecessary donor burden	
15	To be classified by WMDA/SEAR committee	
16	Other, please specify (free text)	

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Imputability - harm

Imputability	Description
Not Assessable	Insufficient data for imputability assessment
Excluded	Conclusive evidence beyond reasonable doubt for attributing adverse reaction to alternative causes
Unlikely	Evidence clearly in favour of attribution to alternative causes
Possible	Evidence is indeterminate
Probable	Evidence in favour of attribution to the tissues/cells
Definite	Conclusive evidence beyond reasonable doubt for attribution to the tissues/cells

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Imputability
Current "rules" of the committee

- Malignancy
  After marrow = excluded; after PBSC = unlikely
- Auto-immune disease
  ≤6 m post donation = possible
  >6m post donation = unlikely
  If condition already there but exacerbated = possible
- Cardiovascular ≤6m
  Soon after collection (esp. PBSC) possible
  > 30 days after collection = unlikely

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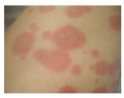
Case 1

- Female donor (36) developed rash two days after donation.
- GP: erythema multiforme
- After 8 day complete recovery, only skin involvement
- No treatment
  - Donation date: 12/02/2018
  - Registry informed 08/03/2018



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Question 1
Would you report and how?

A. No, not a well-know side effect, probably other cause
B. No, not serious, no consequences for recipient or other donor.
C. Yes, as donor harm. Type of harm: acute toxicitiy
D. Yes as donor harm. Type of harm: auto-immune

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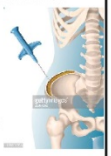
Test case 2

- Mechanical trauma in donor (43) after bone marrow collection.
- Donor incapacitated for 6 months.
  - Incomplete recovery
- Investigation reveals puncture holes not at the height of iliac crest
  - Donation date 18/03/2018
  - Registry informed on 1/12/2018



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Question 2
Would you report and how?

A. No, serious, but common side effect
B. No, individual registry incident, not educational for community
C. Yes, as donor harm, mechanical damage
D. Yes, as donor harm, musculoskeletal

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Harm to donor long term
What to report

- Late events are defined as **Harm to a Donor more than 6 months after collection** (= typically everything occurring later than the Follow-up questionnaire or interview after 6 months)
- Dynamic and user friendly to fill for a late SEAR compared to a critical Risk of Harm (RoH) assessment, where donor or collection **details** mater
- Less than **10** mandatory questions (preliminary)

Question	Data type
What is the type of report?	Radio button
In case of harm to donor long term or short term?	Drop down
Please describe donor complication /adverse reaction /consequences	Alphanumeric
Type of harm to donor	**Multiple options may be selected**
ICD-code	Alphanumeric
Type of (intended) cell product	Drop down
(Intended) date of collection	Date Finder
Were mobilising agents given to this donor?	Drop down
Which mobilisation agent was used? (conditionallymandatory only)	Multiple choices possible if 29 answer is not No
Which filgrastim? (conditionallymandatory only)	Drop down
Which lenograstim? (conditionallymandatory only)	Drop down
Did a problem or incident occur which may have resulted in or contributed to harm to donor/recipient?	Drop down
Please describe problem or incident	Alphanumeric
Type of problem or incident - risk of harm to donor (conditionallymandatory only)	Drop down

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Harm to donor long term
What to report

Up to 10 years after both types of donation

- All auto-immune disease
- All malignancies (hematological and solid
- Disorder that could possibly be linked to donation (e.g. psychiatric disease after learning that recipient has died)
- Unusual/ unexpected deaths

> 10 years after donation

Disorder that is definitely (probably) related to donation.

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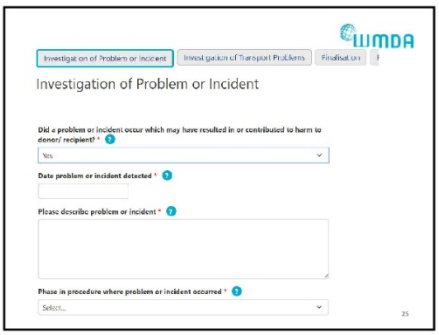

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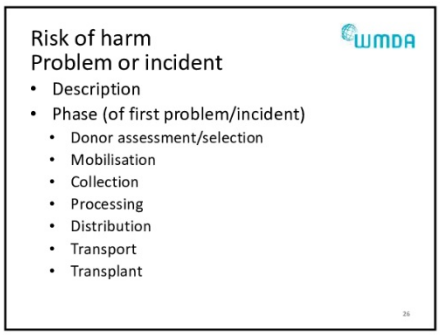

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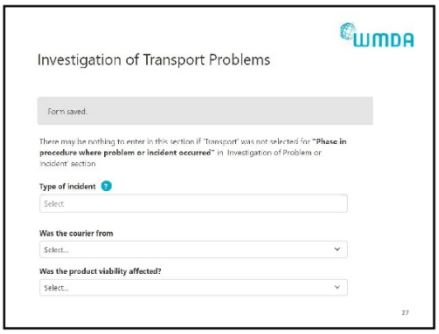

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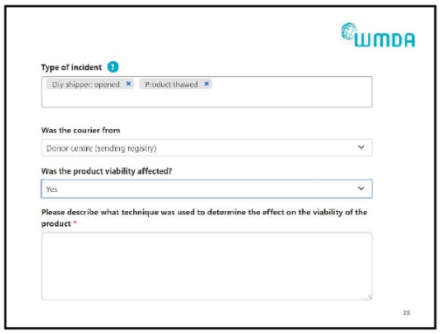

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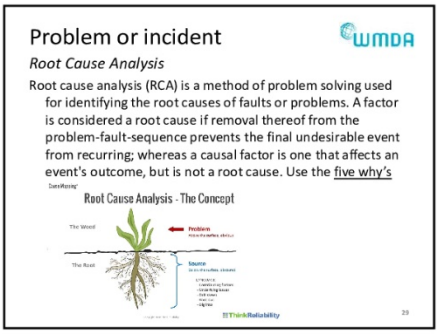

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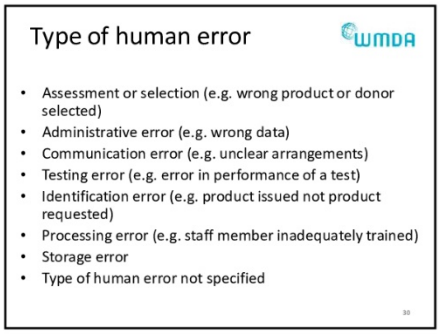

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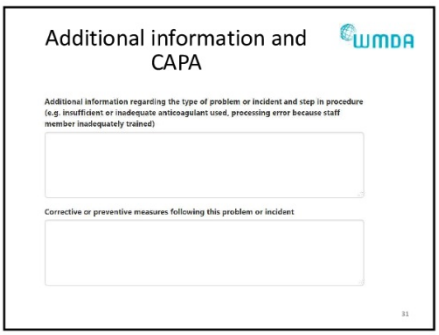

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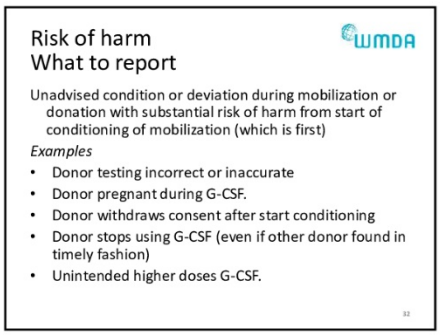

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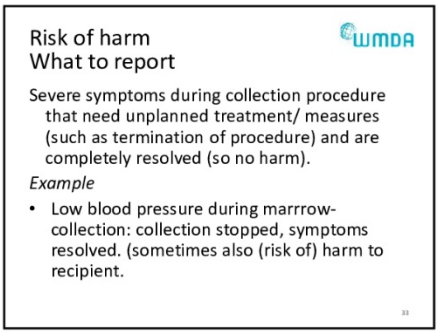

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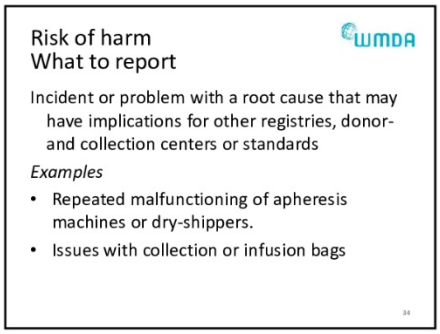

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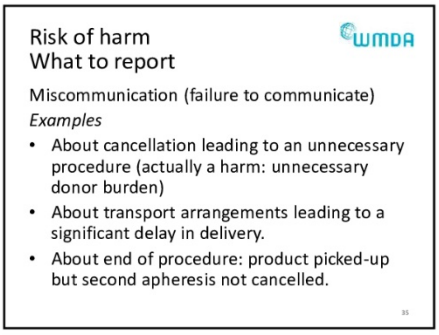

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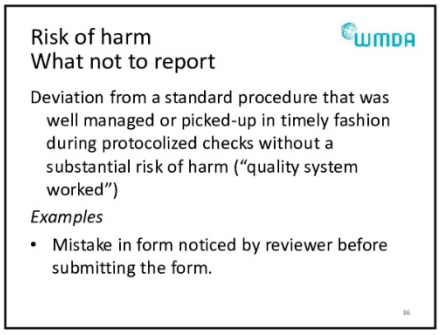

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Risk of harm
What not to report

Deviations from arrangements (or standard procedures) with or in other centers or organizations that were well managed or picked-up in timely fashion without a substantial risk of harm.

Examples

- Lower than requested number of TNC/CD34+ cells but patient engrafted.
- Lower than requested number of precollection samples, but all testing could be performed.

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Risk of harm
What not to report

Late cancellations by the TC (after start G-CSF, before collection) if it can be considered a calculated risk and every measure was taken to minimize harm.

Examples

- Acute unforeseen fatal complication in patient.

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Risk of harm
What not to report

Positive results of routine tests on product *without* evidence of transmission to recipient

Examples

- Positive bone marrow culture
- Positive test results of hepatitis E

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Test case 3

- Recipient not transplanted due to loss of cells
- Transport of dry shipper took longer than the shipper was validated to maintain temperature

- It was communicated by CBB, but itinerary was not changed by courier company.
  - Planned transplantation date 24/05/2012

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Question 3
Would you report and how?

A. Yes, as transport incident

B. Yes, as recipient harm and transport incident

C. No, because recipient was transplanted at later date and recovered well.

D. No, because this is well-known issue with transport of dryshipper and the reason why conditioning may only start after arrival of CBU.

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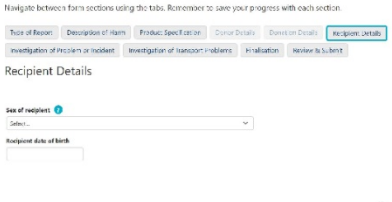
Harm to recipient



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Harm to recipient
What to report

Report an adverse reaction in a recipient during or after the infusion of a cell product

Examples from type of harm

- Infusion related non specific symptoms
- Allergic reaction
- Cardiovascular
- Pulmonary
- Renal/ urinary

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Harm to recipient
What to report

Harm to recipient as a consequence of product quality isues or delay in delivery etc.

Examples from type of harm

- Engraftment failure
- Transmitted bacterial infection
- Transmitted viral infection
- Transmitted parasitic infection

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Harm to recipient
What to report

Possible consequences for donor or related to predonation examination findings

Examples

- Malignancies
- Genetic disease (in hematopoietic gene pool)
- Auto-immuun disease/allergies

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Harm to recipient
What not to report

Standard, anticipated complications of (scheduling) an HSC transplantation

Examples

- Graft versus Host disease
- Infectious complications not related to product
- Unavailability of donors

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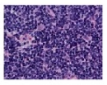
Test case 4



- Male donor (56) develops mantle cell lymphoma
- 5 years post PBSC donation
- Treatment: autologous TX, then allogeneic TX
- Doing fairly well under maintenance treatment
  - Donation date: 15/05/2012
  - Registry informed: 05/02/2018

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Question 4
Would you report and how?

A. Yes, donor harm long term, as hematological malignancy
B. Yes, donor harm short term, as hematological malignancy
C. No, still well controlled, no relation to donation.
D. No, only report to recipient center is important.

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Test case 5

- Nut allergy in recipient (45) 6 months post donation.
- DC informed: indeed donor (34) also has nut allergy.
- Not on clearance documents, unclear why
  - PBSC donation on 23/01/2017
  - Registry informed on 01/07/2017

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Question 5
Would you report and how?

A. Yes, as recipient harm: allergy
B. Yes, as recipient harm and problem/incident
C. No, the donor center should report, not me
D. No, not serious enough.

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Question 6

1. What combinations do you think are possible?

A. Donor harm and problem/incident
B. Recipient harm and problem/incident
C. Donor harm and recipient harm
D. All of the above

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Question 7

How would you report the following case?

Shortly before donation donor returned from Mexico, symptoms of Dengue started during mobilization and worsened and there was evidence of transmitting the disease to the recipient.

A. As recipient harm
B. As donor harm with a description of recipient harm
C. As recipient harm with a description of donor harm
D. As a recipient harm and problem/incident.

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S(P)EAR Committee

- Thilo Mengling – DKMS ***Chair***
- Ann Woolfrey - Fred Hutchinson Cancer Research Center
- Brian Lindberg – NMDP
- Chloe Anthias - Anthony Nolan
- Danielli Cristina Muniz de Oliveira - REDOME - Registro Nacional de Doadores Voluntarios de Medula Ossea
- Diane Fournier - Banque Publique de Sang de Cordon Héma-Québec
- Elizabeth O'Flaherty - Australian Bone Marrow Donor Registry
- Jeff Szer - Australian Bone Marrow Donor Registry
- John Miller – NMDP
- Lydia Foeken – WMDA
- Mirjam Fechter – Matchis, WMDA medical consultant
- Monique Jöris – WMDA
- Rachel Pawson - NHS Blood and Transplant
- Tigran Torosian – DKMS Poland

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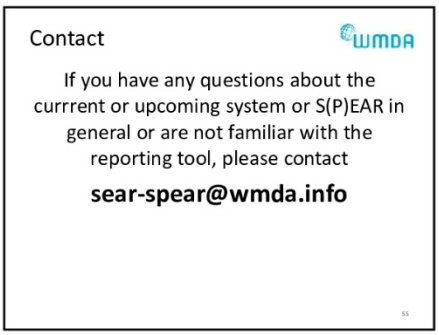
Contact
If you have any questions about the currrent or upcoming system or S(P)EAR in general or are not familiar with the reporting tool, please contact
sear-spear@wmda.info
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II. WMDA Virtual Week 8: SEAR Annual Report by Thilo Mengling and Mirjam Fechter

08/12/2020

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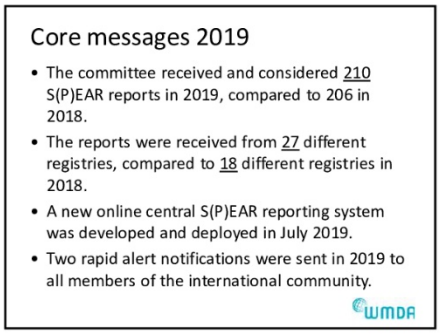

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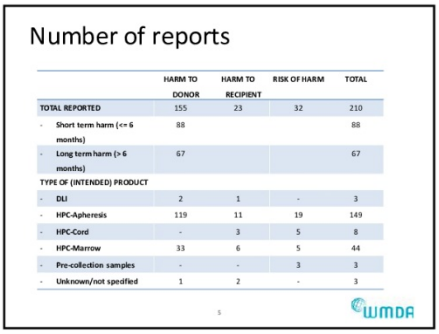

	HARM TO DONOR	HARM TO RECIPIENT	RISK OF HARM	TOTAL
TOTAL REPORTED	155	23	32	210
- Short term harm (<= 6 months)	88			88
- Long term harm (> 6 months)	67			67
TYPE OF (INTENDED) PRODUCT				
- DLI	2	1	-	3
- HPC-Apheresis	119	11	19	149
- HPC-Cord	-	3	5	8
- HPC-Marrow	33	6	5	44
- Pre-collection samples	-	-	3	3
- Unknown/not spedfied	1	2	-	3

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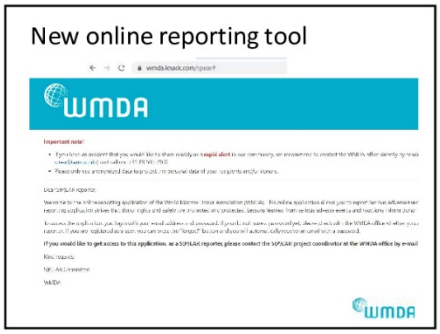

6

Type of report

- The new system now clearly defines the type of report being submitted. These are now listed as :
  - Harm to recipient
  - Harm to Donor
  - Risk of Harm

7

Late reactions

- Late reactions are defined as **Harm to a Donor more than 6 months after collection** (= typically everything occurring later than the Follow-up questionnaire or interview after 6 months)
- Less than **10** mandatory questions (preliminary)

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Reporting process

1. A report is drafted by a member organization or an affiliated organization
2. The report is submitted to WMDA by the member organization
3. The report is reviewed for missing or inconsistent data by the WMDA medical consultant
4. The report is reviewed by the SPEAR committee to decide on further actions and to finalize imputability and classification

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Rapid alerts

In April

A fatal event in an unrelated Bone Marrow donor

Summarizing published data on the incidence of serious adverse events associated with BM donation as to help you in addressing questions.

In December

Bone marrow product was lost because of incorrect use of transfer collection system bags

Listing recommendations for use of those type of bags

10

Overview

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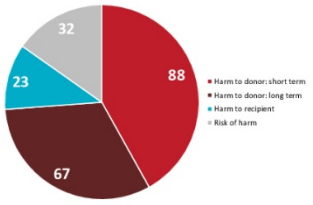
Type of reports



12

Type of harm to donor

	N	TIME AFTER DONATION IN DAYS [MEDIAN(RANGE)]
Acute systemic toxicity during mobilization or collection	12	5(1-1)
Allergic reaction	11	1(1-21)
Autoimmune disease	19	731 (2-2769)
- Long term (> 6 months)	11	1096 (371 – 2769)
- Short term	8	153 (2-415)
Mechanical damage	4	1 (1-5)
Thrombotic / embolic	3	34 (14-42)
Infection	11	6 (3-366)
Haematological malignancy / neoplasia	10	1078 (92-4687)
- Long term	8	1344 (647-4687)
- Short term	2	109 (92-126)
Non-haematological malignancy / neoplasia	43	1642 (33-4017)
- Long term	29	1461 (87-4017)
- Short term	4	54 (33-92)
- Other	10	-
- Musculoskeletal / joint affection	2	-
- Cardiovascular and cerebrovascular disease	2	-
- Unnecessary donor burden	2	-
- Psychiatric / psychogenic disorder	2	-
- Neurological disease	4	-
TOTAL	155	

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Malignancies

	N	time after donation in days [median(range)]
Breast cancer	18	1552 (92-2556)
Haematological malignancy / neoplasia	10	1078 (92-4687)
Intracranial neoplasia	4	1661 (643-2557)
Nasopharynx cancer	4	1203 (16-3514)
Testicular cancer	4	2055 (37-3411)
Colorectal cancer	3	1943 (1943-3652)
Melanoma	3	92 (92)
Other	7	1970 (365-4017)
TOTAL	53	

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Malignancies 2018

	N	Time after donation in years [median (range)]
Breast cancer	17	4 (1 – 8)
Haematological malignancy / neoplasia	6	4 (1 – 7)
Renal cancer	6	4 (3 – 6)
Testicular cancer	6	2 (1 – 4)
Colorectal cancer	4	3 (1 – 6)
Ovarial cancer	3	1 (1 – 1)
Melanoma	2	4 (3 – 5)
Bone cancer	2	7 (6 – 7)
Other	7	6 (1 – 7)
TOTAL	57	4 (1 – 8)

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Hematological malignancies

	Type of product	time after donation
Essential Thrombocythaemia	PBSC	3 months
Hodgkin's Lymphoma	PBSC	4 months
Hodgkin's Lymphoma	PBSC	2.5 years
Diffuse Large B-Cell Lymphoma	BM	2.5 years
Polycythemia vera	PBSC	4 years
Diffuse Large B-Cell Lymphoma	PBSC	4 years
Mantle Cell Lymphoma	PBSC	5 years
Hodgkin's Lymphoma	BM	5 years
AML	PBSC	8 years
CML	*PBSC*	*13 years**

* Technically not a SLAR (>10 years)

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Autoimmune disorders

	N	TIME AFTER DONATION IN DAYS [MEDIAN(RANGE)]
Alopecia areata	3	53 (32-415)
Ankylosing spondylitis	1	2191
Crohn's disease	1	123
Multiple sclerosis	3	1461 (814-1836)
Rheumatoid arthritis	3	373 (60-730)
Sarcoidosis	1	2769
Other	7	731 (2-1827)
TOTAL	19	

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Other types of harm to donor

	N	TIME AFTER DONATION IN DAYS [MEDIAN(RANGE)]
Cardiovascular and cerebrovascular disease	2	1 (1)
Musculoskeletal / joint affection	2	204 (204)
Neurological disease	4	2 (0-254)
Psychiatric / psychogenic disorder	2	5(5)
Unnecessary donor burden	2	18.5 (14-23)
Other	30	2.5 (-121-2542)
TOTAL	42	

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Type of harm to recipient

	N
Cardiovascular	1
Cytogenic abnormalities	1
Donor cell derived malignancy	2
Infusion related non-specific symptoms	1
Transmitted bacterial infection	1
Delayed arrival of product	2
Loss of product	1
No product collected	1
No problem or incident detected	1
Product quality issue	5
Other	5
Unknown/unspecified	3
TOTAL	23

A total of 23 harm to recipient incidents were reported. The majority of incidents followed after HPC-Apheresis (47,8% (n=11)) and after HPC-Marrow transplants (26% (n=6)). Three (3) reported on incidents of HPC-Cord transplant and 1 after DLI. In two cases graft type was not specified.

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Risk of harm

	N	TIME AFTER DONATION IN DAYS [MEDIAN(RANGE)]
Delayed arrival of product	3	n/a
Loss of product	3	n/a
No problem or incident detected	2	2 (1-3)
No product collected	1	n/a
Potential product quality issue	5	2 (0-1840)
Product quality issue	12	1.5 (0-35)
Other	4	1.5 (-4-36)
Unknown/unspecified	2	

Thirty-two (32) risk of harm incidents were reported. Nineteen (19) incidents took place after HPC-Apheresis, 5 following HPC-Cord, 5 following HPC-Marrow and 3 after pre-collection. Risk of harm incidents occurred during various phases of the procedure, but mainly during transplant (n=7), transport (n=5) and transport (n=5).

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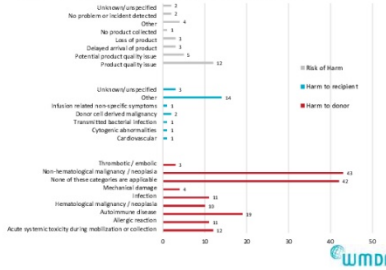
Type of problem, summary



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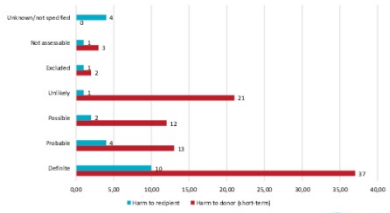
Imputability

only mandatory for harm to donor (=< 6 months) and harm to recipient reports



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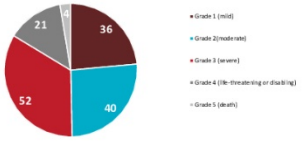
Severity of reaction

only mandatory for harm to honor (<6 months) and harm to recipient reports



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Notable Reports

matching donors • serving patients

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BM transfer bags ruptured during centrifugation

Two 600 ml Transfer Bags from BM collection system ruptured (both at the lower side margin) during 30 minute CENTRIFUGATION for plasma separation at the TC.

The entire product (580 mL undiluted + 100mL plasma) was lost.

- ⇨ Transfer bags are not certified for centrifugation, nor storage or freezing.
- ⇨ WMDA Rapid Alert December 2019

Recommendations of the WMDA S(P)EAR Committee

- Transplant centres should be aware that those transfer bags are generally unsuitable for centrifugation. Before any processing steps are undertaken, it is recommended that stem cell products be transferred to a bag which is validated by the manufacturer and any appropriate regulatory agency for the purpose intended. WMDA further recommends that transplant centres and processing stem cell laboratories check the specifications of all bags to ensure consistency with any intended use, including but not limited to manipulation (e.g., centrifugation), storage, and infusion.
- WMDA recommends that the transplant centre be provided with any necessary documentation and/or statements regarding type and specification of transfer bags no later than at hand-over of the stem cell product.

https://share.wmda.info/download/attachments/29710727/20191125-SEAR-Rapid%20Alert.pdf?version=1&modificationDate=1582129907038&api=v2

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Patient CT after donor selection

International donor, medical check and collection had to be postponed multiple times by the TC. Before collection, patient registry informed the DC that patient's confirmation typing was only performed recently (AFTER final donor selection) and revealed MM between patient and donor: Donor was no longer best match, TC cancelled WU.

- ⇨ According to patient registry's policy, verification typing of patient is not mandatory BEFORE final donor selection. Verification typing must be performed prior to collection only.
- ⇨ For most registries /DC verification typing of patient has to be performed BEFORE final donor selection (before start WU) since a specific matching grade between patient and donor has to be met
- ⇨ See "wrong donor incident" ***Inadvertent completely HLA-mismatched allogeneic unrelated bone marrow transplant,*** *Sorensen et al, BMT 2016*

CAVE AT: COVID Cryopreservation and late hospital admission of recipient – typing before collection ensured?

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Cryopreserved BM not infused

- On a Friday, 4d before planned BM collection, TC decided to postpone TX due to personal reasons of the recipient.
- Because of to the weekend and 3 different time zones for TC, hub and DC, this information reached CC and donor only on Monday afternoon, when the donor was already admitted to collection unit.
- Donor did not agree to postponement, but to cryopreservation.
- BM collection without abnormalities, though requested TNC total count was unrealistic (50% achieved, sufficient dose/kg). Product was not washed or erythrocyte-depleted.
- One week after donation, TC informed about cell count not sufficient, and all 3 bags coagulated. Courier stated no abnormalities on handover.
- 2nd donation was requested from the same donor. This request was refused by DC as long as the BM product was not used
- TC confirmed to infuse 6 weeks later, but was unresponsive after that announcement.
- 10 months later, the hub was informed about TX with an alternative donor and the BM product would be discarded

Categorized as **Harm to donor:** Unnecessary donor burden

- ⇨ If deviation from regular processes results in several incidents, the *donor* harm should take precedence

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Appendicitis – Cluster of 4 cases?

- F, 33 yrs, 09/2019 – Mobilisation ended after the first 3 doses of Filgrastim because of appendicitis, requiring hospitalization and urgent appendectomy.
- M, 35 yrs, 05/2019 - Acute phlegmonous appendicitis during mobilisation day 4 (Lenograstim)
- M, 27 yrs, 09/2018 - Abdominal and back pain for 5+ days after PBSC; 3 weeks later similar symptoms, acute appendicitis, appendectomy (Lenograstim)
- M, 33 yrs, 07/2018 - Acute appendicitis ICD10 K35.8 on d4 GCSF, no donation. Surgery, no further complications (Lenograstim)

⇨ One report on appendicitis before (in 2017)

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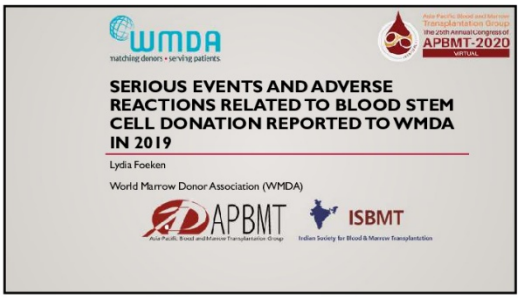
III. APBMT-2020: Serious Events and Adverse Reactions Related to Blood Stem Cell Donation Reported to WMDA in 2019 by Lydia Foeken

08/12/2020



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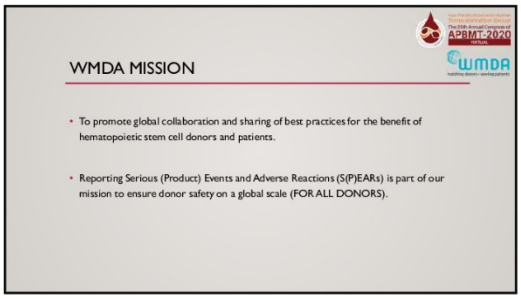

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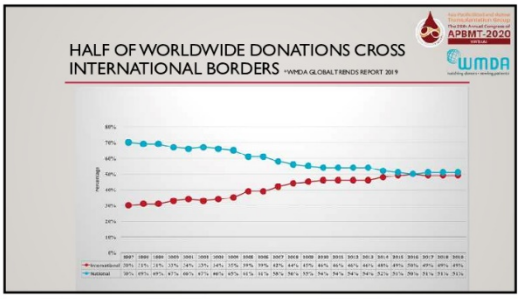

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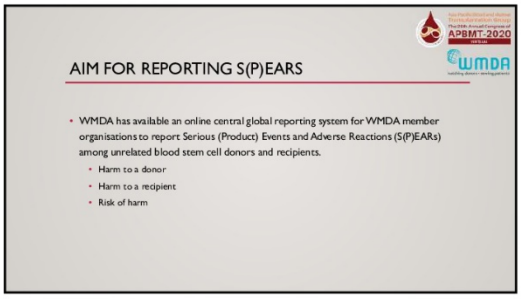

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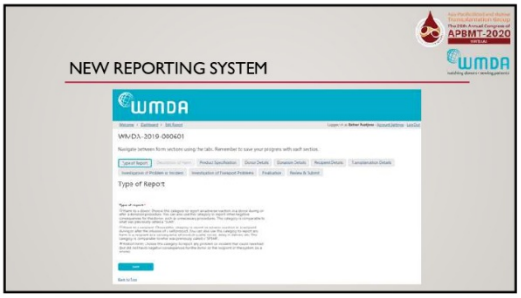

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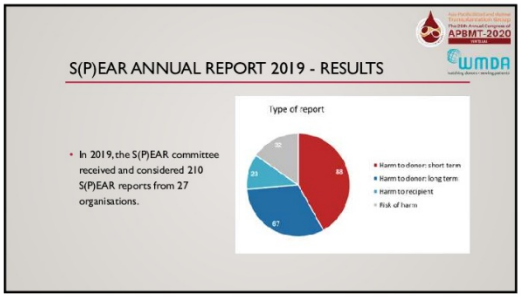

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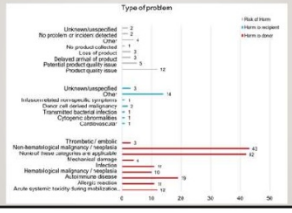
S(P)EAR ANNUAL REPORT 2019 - RESULTS



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S(P)EAR ANNUAL REPORT 2019 - RESULTS

- During 2019, 23,181 unrelated blood stem cell donations have taken place worldwide*
  - 2,851 HPC-Cord donations
  - 16,406 HPC-Apheresis donations
  - 3,924 HPC-Marrow donations
- This means that for the following percentage a S(P)EAR has been reported:
  - 0,07% (N=2) of the HPC-Cord donations
  - 0,49% (N=81) of the HPC-Apheresis donations
  - 0,87% (N=34) of the HPC-Marrow donations
  - For this calculation we only taken the short term incidents into account.

*WMDA Global Trends Report 2019

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S(P)EAR ANNUAL REPORT 2019 - RESULTS

Table 1. Overview of reported incidents.

	Harm to donor	Harm to recipient	Risk of harm	Total
Total reported	195	23	32	212
Timeframe				
Short term (<6 months)	88	11	24	125
Long term (>=6 months)	107	12 (6 UNK*)	8 (1 UNK*)	87 (7 UNK*)
Product type				
HPC-Marrow	33 (28 ST*)	6 (5 ST*)	5 (4 ST*)	44 (34 ST*)
HPC-Apheresis	120 (58 ST*)	11 (7 ST*)	15 (13 ST*)	150 (71 ST*)
HPC-Cord	-	3 (1 ST*)	5 (1 ST*)	8 (2 ST*)
DLI	3 (1 ST*)	1	-	3 (2 ST*)
Pre-collection samples	-	-	3 (3 ST*)	3 (3 ST*)
UNK	-	2 (1 ST*)	-	2 (2 ST*)

*ST: Short Term; *UNK: Unknown

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S(P)EAR ANNUAL REPORT 2019 - CONCLUSION

- The report rate of S(P)EARs in unrelated blood stem cell donation is below 1% for all cell types.
- However, we do believe there is a certain degree of underreporting of S(P)EARs to the WMDA.
- If your organisation wishes to start reporting your S(P)EARs and get your own account, contact us at sear-spear@wmda.info

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TRIP and WMDA office team
Members S(P)EAR Committee
WMDA member organisations

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