SPEAR CHEAT SHEET

FOR COMMITTEE MEMBERS

The SPEAR committee is responsible for the analysis of the Serious (Product) Events and Adverse Reactions (S(P)EAR) reports submitted to the WMDA and evaluation of their imputability and impact. On a monthly basis, notable reports are discussed. Findings are periodically made available to the public and if there's an urgent need, they will issue a rapid alert notification.

SPEAR REPORT LIFE CYCLE

After the report is submitted to WMDA, the medical advisor checks it for accuracy and completeness. If necessary, the reporter may be asked follow-up questions. When complete, reports are assigned to a committee member for review. Some reports are discussed at the monthly committee meeting. After review, WMDA office finalizes the report in the SPEAR tool. Reviewed reports stay accessible for analysis. This process ensures that serious events and adverse reactions are properly and promptly addressed through thorough analysis.

QUESTIONS?

Find additional documentation on WMDA Share or contact sear-spear@wmda.info

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REPORT ASSESSMENT PROCESS

Committee members are assigned reports to assess based on their expertise (eg. CBU, transport etc.). It is the responsibility of the committee member to review these reports in a timely manner and assess the completeness, accuracy, importance and impact of a report. This review is then used to determine the required follow up (if applicable) and used in analysis of the data. The steps below detail an example work flow.

1. Review the content of the report assigned to you

When logged in, choose *Committee member* as your Role to review reports. You will find the reports for your reviewal in the *Assigned to me* table. Click on a report to view its content.

1.1 **Do you have all the necessary information to assess the report and fill out the review notes section?***

- **Yes**: continue to step 2 to fill out your assessment in the Review Notes section.
- **No**: write down your questions/comments in Review Notes. Under *Review stage* select "Needs internal discussion" to discuss with the SPEAR committee at monthly meeting, or select "Needs more details from reporter" if a request for more details should go to the reporter. Specify the exact question(s) for the reporter in text area.

1.2 Do you have any changes you'd like to propose to the report?*

- **Yes:** fill out the proposed changes in the text area of the *Review Notes* and update the *Review Stage* to "Needs internal discussion" to discuss during the monthly meeting. If committee agrees, the WMDA office or medical advisor will reach out to the reporter to request a change.
- **No:** continue to step 2 to fill out your assessment in the Review Notes section.

**Note that the report has already been reviewed by the medical advisor at this stage. They may have already asked the reporter additional questions. Look at the Comments section of the report to verify.*

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2. Classify the report for finalization

Once you've established that you have sufficient information to complete the assessment of a report, the following details should be added:

2.1 **Do you propose to accept or reject this report as a legitimate, accurate and complete SPEAR report?** See below for more information on accepting/rejecting of a report.
2.2 **What type of report would fit best, based on your assessment of the report content?** Select Harm to Donor, Harm to Recipient or Risk of Harm. This can diverge from the report details entered by the reporter.
2.3 **Indicate the Reason to accept or reject this report to determine if follow up is required.** See below for more information on possible classifications. You can select multiple categories.
2.3 **Do you have comments or questions about this report?** Please use the text area (Review notes) to add notes, comments or questions for yourself or to discuss with others. Review notes are not visible to the reporter.
2.4 **Select the Review Stage to communicate that no next steps are needed**: Select 'Ready to be finalized' at Review Stage to indicate that this report is complete, accurate and reviewed by you and may now be finalized by the WMDA office.

ACCEPT OR REJECT A REPORT

During assessment, the committee member rejects or accepts a SPEAR report. Accepted reports are included in the data analysis for (annual) reports, rejected reports are not. Almost all reports are accepted.

Accept if: the report provides a complete and accurate description of a SAE/SAR. **Reject if**: the report is empty, duplicate or in conflict with the WMDA terms of use.

TYPE OF REPORT

Harm to donor

An **adverse reaction in a donor** during or after a donation procedure, including unnecessary procedures.

Harm to recipient

An **adverse reaction in a recipient** during or after the infusion of a cell product, including any harm in a recipient as a consequence of product quality issues, delay in delivery etc.

Risk of harm

Any problem or incident that **could have had (but did not have) negative consequences for the donor or the recipient** or the system (as a whole).

REPORT FOLLOW UP (REASON)

When completing the assessment of a report, choose one or more of the following categorisations. Select the category(-ies) that fit the impact of the report best.

Type of report and follow up:

- **Collect and forward to other WMDA committee/working group**
- **COVID-related report:** to track all reports that are (possibly) COVID-related
- **Educational report:** to create educational material eg. a written piece in our newsletter
- **Not a SEAR:** report is accepted but not event is considered to classify as a SEAR
- **Rapid alert:** requires expedited reporting to notify community
- **Reason for a survey:** request (other) reporters for similar reports
- **Regular report**
- **Possible change of WMDA standards or recommendation**
- **Possible trend**

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3. **Join the monthly SPEAR committee meeting to discuss notable reports**

Please prepare by reviewing your reports before each meeting and adding comments or questions where applicable. During this meeting, notable reports are discussed. This is a collaborative environment where you are encouraged to ask questions and share your thoughts without fear of judgment or reprisal; reviewing reports is, after all, greatly dependent on sharing knowledge and learning by doing. Your attendance is vital to this process.

FREQUENTLY ASKED QUESTIONS

- **How do I make a change to the content of the report?**

WMDA may only edit the ICD code field and the "type of problem or incident - (risk of) harm to donor/recipient" if "to be classified by SPEAR committee" is chosen. Any other changes to a report must be approved by the reporter, who can approve or reject them. To request a change, write the proposal for change in the review notes. The WMDA office or medical advisor will contact the reporter with a request to implement the requested change.

- **What if the SPEAR committee disagrees with the reporter on report details?**

If the committee concludes that a different outcome should be considered for, for example, imputability, severity, type of report, then the reporter will always be approached first to request a change (see above). If the reporter disagrees to the committee's assessment and does not agree with the proposed change, the committee can decide to use their own report classification. The report details will then not be changed, but the review notes will reflect the committee's decision.

- **Why do not all reports have an imputability score?**

Imputability assessment is only required if report is a Harm to Recipient report or a Harm to Donor report where harm occurred <6 months after donation. The WMDA Imputability Assessment tool is available on WMDA Share

- **What severity grading system is followed to determine severity?**

The WMDA follows the Common Terminology Criteria for Adverse Events (CTCAE) guide for severity assessment. Severity grading is only mandatory for Harm to Recipient reports and Harm to Donor reports where harm occurred <6 months after donation.

- **What is a notable report?**

Any report that the committee as a whole should be aware of. This can be, for example, a report on a rare or unique occurrence, a report that holds educational value to the community to ensure best practices, or a report that on a regular occurrence but with follow-up actions that differ from international standards.

to be completed

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