



GENERAL

The Serious Product Events and Adverse Effects Registry of WMDA "SPEAR" is a central reporting system of the WMDA member organisations to the WMDA Clinical Working Group. Its goal is to obtain insight into the occurrence of serious events and adverse effects in relation to stem cell harvest and processing from unrelated donors. Comprehensive and confidential reporting is fundamental to success of this scheme.

WMDA Member organisations participate in this project. If WMDA member organisations do not want to participate they have to inform the WMDA Office. All participating member organisations receive a monthly reminder by e-mail.

For WMDA Accreditation participation is requested.

To relate the total number of serious events to the total harvests of each type from participating registries, relevant general information will be extracted from the annual report and reported as total accumulated data of the donor registries.

The chair of the Clinical Working Group will present the SPEAR data annually in anonymous form to the WMDA Board. The WMDA Board will report the results in anonymous form to the members of WMDA.

Each member organisation/registry will be provided with SPEAR-forms. The current version can be downloaded from the WMDA website (www.worldmarrow.org). A completed form is mailed to the WMDA Office.

WMDA Office, 6th floor
Chief Operating Officer
Plesmanlaan 1b
2333 BZ Leiden,
The Netherlands

The WMDA Chief Operating Officer will document the receipt of the report and send it to the chair of the Clinical Working Group.

DOUBLE REPORTING

To avoid double reporting in case a follow up report is sent on the same event, a copy of the previous report must be included.

WHEN TO REPORT

When a serious event or adverse effect relating to a stem cell product collected from an unrelated volunteer donor has occurred, a report should be submitted. In case of long lasting, uncertain outcome, the report should be completed and a follow up report is then submitted later.

The senior medical officer of the registry is responsible for the report to SPEAR. Through annual confirmation of participation in the scheme, the director of the organisation confirms that all eligible events were reported.



WHAT TO REPORT

Although the interpretation of what should be considered a serious event is subjective, some categories of events are clearly important to report.

The WMDA Standards, JACIE/FACT standards and the European Union Directive on Tissues and Cells (2004/23/EC) have been used to develop this form and instructions.

GENERAL ISSUES

The general principles are that events likely to result from a defect in the stem cell product should be reported if they lead to one or more of the following outcomes in the recipient:

1. Death
2. Life-threatening disease
3. Unexpected hospitalisation or considerable prolongation of existing hospitalisation
4. Persistent or significant disability/incapacity

In addition to these general principles, the following specific events are given as indicators what should be reported:

SPECIFIC ISSUES RELATING TO PRODUCTS (BM, PBSC) THAT SHOULD TRIGGER A REPORT TO SPEAR

Inadequate cell dose in the stem cell product

Any serious impairment of the quality of the stem cell product including coagulation and contamination

Serious problems in transportation

Wrong stem cell product transfused

Any serious unpredicted transmissible infection
e.g. HIV, Hepatitis B, Hepatitis C

Any serious unpredicted non-infectious transmissible disease
e.g. hematologic/oncologic diseases discovered in the donor BM or PBSC after administration of the product

The listing of course is not considered to be complete and every effort to prevent underreporting should be avoided. The Clinical Working Group is responsible for analysis and presentation of the annual data collection.

DESIGN OF THE REPORT

The report consists of a general part (page 1 and 2, question G1 to G15) to be completed in all reported cases.



WHO REPORTS

- The Chief Medical Officer of the Registry/Organisation is responsible for the contents of the SPEAR report.
- The Chief Medical Officer of the Registry/Organisation is responsible for the decision what to report to the SPEAR.
- The director of the Registry/organisation confirms annually in the WMDA annual report that all eligible events were reported to the best of the registry's ability and knowledge.

CORRESPONDENCE

The director of the organisation/registry will receive all correspondence from the WMDA Office or Clinical Working Group concerning SPEAR.

CHANGES IN PROCEDURES OR FORMS

Changes in procedures or forms will be initiated by the Chair of the WMDA Clinical Working Group, approved by the WMDA Board and will take effect not earlier than 1st of January of the year following the approval. These instructions are also available on the WMDA website under the information of the Clinical Working Group. (www.worldmarrow.org)

COMMENTS, CORRESPONDENCE TO SPEAR

Members are welcomed to send suggestions and comments. These comments as well as correspondence on policy should be directed to the Chair of the WMDA Clinical Working Group.

PARTICIPATING REGISTRIES

A list of participating WMDA members in SPEAR will be published annually.