

WORKING PARTY ON HAEMOVIGILANCE

Definitions and tools for haemovigilance

Need for standardised definitions

Standard definitions are essential if comparisons from different haemovigilance systems are to be made. These definitions should be simple yet precise enough to be able to classify most adverse transfusion events for purposes of surveillance of adverse events related to the transfusion of blood components in haemovigilance systems. Surveillance definitions are not intended as strict diagnostic criteria.

What needs to be defined?

According to state of the art haemovigilance practice, definitions are needed for all the main types of adverse transfusion reaction and adverse reactions in donors as well as for levels of severity and imputability. In the area of adverse incidents (errors) currently a small number of sentinel events have been defined as being appropriate for comparisons between haemovigilance systems.

Further work is proposed in the following areas:

1. In collaboration with the ISBT working party on transfusion-transmitted infections, to define criteria for assessment of suspected transfusion-transmitted bacterial and other infections
2. To enable countries where fewer diagnostic methods are available to classify haemovigilance reports as well as possible according to clinical features
3. To pursue the exercise of classification of errors and incidents, taking account of existent classifications
4. To develop one or more flow charts to facilitate the application of the definitions
5. To examine available listings of recommended investigations and develop guidance.

Process of developing or revising definitions

The core stages of developing or revising definitions are as follows:

Agreement within drafting group on purpose and category

Drafting, incorporating available material

Consultation of relevant groups / organisations

Validation, may lead to final corrections (may be omitted if minor revision or correction only)

Final consultation (may be omitted if minor revision only)

Publication and information of relevant organisations

Process of validation

The present definitions for non-infectious transfusion reactions and for donor complications were validated (tested) prior to adoption. Case scenarios from actual haemovigilance reports were developed and volunteers from various haemovigilance systems agreed to classify the

cases using the standard definitions. Good agreement was obtained for the case definitions but a less good agreement was obtained for imputability grading. It was decided to keep imputability grading as developed because already in use in multiple haemovigilance systems. A step of validation is recommended for extensively modified or new definitions.

Revisiting or revising definitions

When definitions are adopted, a date should be set for review. In most cases this will be 3-5 years later; new findings from research or practice can lead to earlier reassessment. Revisions should not be frequent; be limited to the minimum necessary to facilitate organisations which adopt the definitions to upgrade to new versions in a controlled fashion. The old versions will remain publicly available (with dates and status clearly marked).

Consultation of relevant experts and organisations

The widest possible consultation should be undertaken, involving experts who may be but are not necessarily members of ISBT or IHN, WHO and international organisations in the domain of blood transfusion. As a minimum this will be performed by sending the draft to the individuals or organisations in question. A reasonable term will be set, after which the drafting group will review the comments received and move to the next stage. Consultation will in any case include submission of the final draft to working party members at least two weeks before a meeting (which will be in the setting of an ISBT congress) and final opportunity for comment before adoption.

Ownership and commitment to updating

It is essential for definitions to be owned by a group of professionals who are committed to keeping them fit for use. The commitment to this task by the ISBT working party on haemovigilance ensures:

- Definitions and experts within an international organisation (ISBT)
- Continuity of experts professionally involved in all areas of haemovigilance
- Accessibility of expert group for queries or proposals for new definitions
- Clear procedures describing the way in which definitions and tools are to be kept up-to-date.

(Adopted June 2013)