International Society of Blood Transfusion

WORKING PARTY ON HAEMOVIGILANCE

PROPOSED STANDARD DEFINITIONS FOR SURVEILLANCE OF SENTINEL TYPES OF ERRORS AND INCIDENTS

Adopted 2015

in collaboration with

IHN International Haemovigilance Network

INTRODUCTION

This document forms a companion document to the surveillance definitions for non-infectious adverse transfusion reactions. The definitions proposed in this document were prepared by members of the ISBT Working Party on Haemovigilance and have been submitted for consultation to all members. Definitions 1-3 were agreed in 2011, definition 4 in 2013 and definition 5 in 2014.

These definitions are for the sole purpose of surveillance of adverse events related to the transfusion of blood components in haemovigilance systems. The working party is aware that numerous classifications of errors and incidents are in use. The purpose of this document is to provide definitions for a small number of types of event which are serious and important, so-called sentinel events. It also proposes criteria for when it shall be deemed that transfusion has taken place.

In future further types of sentinel event may be included.

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SENTINEL TYPES OF ERRORS AND INCIDENTS

1 Incorrect blood component transfused (IBCT)

All reported episodes where a patient was transfused with a blood component that did not meet the appropriate requirements or that was intended for another patient. Include even if

- the component was ABO compatible and/or
- even if only a small quantity of blood was transfused and/or
- there was no adverse reaction.

2 ABO incompatible transfusion

All cases where a blood component was transfused which was (unintentionally) ABO incompatible. Include all such events

- even if only a small quantity of blood was transfused, and/or
- if no adverse reaction occurred.

All cases are to be included, whether the first error occurred in the blood establishment, in the blood transfusion laboratory or in clinical areas.

Note that these are a subgroup of the IBCT category.

3 Wrong name on tube (WNOT)

All cases where it was found (in the reporting year) that a blood sample submitted for blood group determination, irregular antibody screen and/or compatibility testing was labelled with the identification details of a different patient. This is a problem which is ubiquitous and serious. Include all such events

- even if the error was detected by routine checks such as repeat blood group determination;
- even if the error did not lead to an incorrect transfusion (for whatever reason);
- even if the patient sampled was not (imminently) scheduled for transfusion.

Note that there can be overlap between WNOT and ABO incompatible transfusion or other IBCT subgroups, as well as near miss.

4 Distribution of inappropiate/unsafe blood component(s)

All events where a blood component is distributed that at that time did not fulfil the release requirements for a suitable transfusion.

Examples of this are

- Distribution of a component from a donor deferred, or who should have been deferred, for reasons related to patient safety.
- Distribution of a rejected component
- Distribution of an expired component, a non-released component, or a component showing signs of deterioration.
- Distribution of a component after detection of a safety risk or serious quality deviation (not destroyed or recalled)
- Transport under inappropriate conditions
- Distribution of a special requirements blood component to the wrong hospital
- Failure to recall after post-donation information.

5 Hospital blood bank sentinel event(s)

All events where a blood component is issued for transfusion that, at that time, did not fulfil the issuing requirements and might lead to the provision of inappropriate blood component, e.g.

- Component labelling, handling and storage errors
- Component selection errors (including specific requirements not met)
- Testing errors (including transcription, interpretation errors and specific requirements not met).

ADDITIONAL MATERIAL

1 The patient was transfused…

Transfusion shall be deemed to have started when the final pretransfusion checks have taken place and the next step (according to local SOP or national guidelines) has been performed. In many countries this will be at the moment of spiking the unit.