



Appendix C. Adverse Reaction Severity and Imputability Definitions

Severity

An assessment of the degree to which the patient developed symptoms as a result of the adverse event.

Grade 1: Non-Severe

Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.

Grade 2: Severe

Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function.

Grade 3: Life-threatening

Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.

***Grade 4: Death**

The recipient died **as a result of the adverse transfusion reaction**.

*Grade 4 should be used only if death is **possibly, probably** or **definitely** related to transfusion. If the patient died of a cause other than the transfusion, the severity of the reaction should be graded as 1, 2 or 3 as appropriate given the clinical circumstances related to the reaction.

Imputability

An assessment of the relationship between the transfusion and the adverse event.

Definite: Conclusive evidence exists that the adverse event can be attributed to the transfusion.

Probable: Evidence is clearly in favor of attributing the adverse event to the transfusion.

Possible: Evidence is indeterminate for attributing the adverse event to the transfusion or an alternate cause.

***Doubtful:** Evidence is clearly in favor of attributing the adverse event to a cause other than the transfusion.

***Ruled Out:** Conclusive evidence beyond reasonable doubt that the adverse event can be attributed to a cause other than the transfusion.

Not Determined: The relationship between the adverse event and the transfusion is unknown or not stated.

*Adverse reactions for which imputability is doubtful or ruled out need not be routinely reported. These categories are intended to be used when a reaction was initially thought to be transfusion-related but additional information revealed a non-transfusion related cause. However, facilities may use these categories for their own purposes. For example, they can be used to keep an inventory of suspected transfusion reaction investigations.