Evaluation of a new classification process for reports to the Norwegian Haemovigilance System.

Øystein Flesland,

Division of Surgery, Akershus University Hospital, Norway

Introduction

In January 2021 we introduced a new electronic form for reports to the Norwegian Haemovigilance System. In an attempt to make reporting easier we decided to use the same general classification as already used by the compulsory reporting and learning system in all Norwegian hospitals. In addition, we have several specific classifications, like type of blood component, infectious agents, antibodies etc. In addition to the classification the reporter must include a text describing the event.

The general classification used include location, type of event, preventability, outcome (seriousness), worst possible outcome in similar cases and frequency of

similar events in the reporter's department (blood bank). For each of these only one choice is possible.

When received by the National Haemovigilance Group the report is evaluated by a specialist in transfusion medicine. The report can be accepted as submitted, reclassified and/or discussed with two other transfusion medicine specialists before inclusion in the haemovigilance database. Reclassification is primarily based on information in the text describing the event, but if necessary additional information is requested from the reporter.

Materials and methods

To evaluate the new electronic form and the general classification done by the reporters, the need for reclassification and/or discussion by the National Haemovigilance Group were studied. The database contains both the original and the final classification as well as administrative information such as time to status change, if the report were discussed, if further information was received

etc. All reports received between January 14th 2021 and January 21st 2022 that had been included in the haemovigilance database were examined.

Results

We received 476 reports from 17 different hospitals. The reports were evaluated by at least one of four transfusion medicine specialists.

We received 177 reports of blood donor complications/reactions. 156 (88%) of these had been reclassified and 41 of these had been discussed in the group. In addition, three of the 21 reports not reclassified had been discussed.

We received 142 reports of adverse events/near misses. 106 (75%) had been reclassified and 59 of these had been discussed. In addition, seven of the 36 reports not reclassified had been discussed.

We received 157 reports of transfusion reactions/complications. 110 (70%) had been reclassified and 49 of these had been discussed. In addition, seven of the 47 reports not reclassified had been discussed.

Discussion

Classification of serious adverse reactions and serious adverse events is important for data analysis of haemovigilance reports.

Classification is difficult for the person reporting to the National Haemovigilance Group, but also for transfusion medicine specialists working there. The introduction of the classification already used by the compulsory reporting and learning system in all Norwegian hospitals could make it easier for the reporters.

The results show that between 70 and 88 % of the reports had been reclassified by experienced specialists. This is an indication that the new classification is complicated for the reporters.

Of the 476 reports, 166 (35%) had been discussed among the specialist working in the National Haemovigilance Group before being added to the data base. This is another indication that the new classification is complicated.

A new evaluation should ideally be performed after some time to see if primary classification has improved and to see if the specialists have become more confident so that the need for discussion is reduced.

A purpose-built IKT system and a database that is designed to allow this kind of studies is an advantage when looking for process indicators that can be valuable in monitoring the haemovigilance system.