G49 Autopsy Performance in Transfusion Recipient Fatalities Reported to the United States Food and Drug Administration (FDA) During Fiscal Year 2008

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After attending this presentation, attendees will learn recent updates regarding the classification of fatal transfusion reactions, review recent transfusion-recipient fatality data relevant to forensic practice, especially regarding autopsy performance and medical errors, consider approaches to the investigation of deaths potentially related to transfusion of blood products, and learn how to contribute to the national investigation of transfusion-associated fatalities through the FDA transfusion fatality program.

This presentation will impact the forensic science community by sharing how findings suggest that ME/C systems can provide important contributions to the investigation of transfusion-related fatalities through increased awareness, vigilance, autopsy performance, and reporting.

This presentation will inform attendees of something they do not know: (1) classification of fatal transfusion reactions; and, (2) recent

transfusion-recipient fatality data relevant to forensic practice, especially regarding autopsy performance and medical errors. This presentation will inform attendees of something they do not know/do: (1) how to approach the investigation of deaths potentially related to transfusion of blood products; and, (2) how to contribute to the national investigation of transfusion-associated fatalities by the FDA transfusion fatality program through increased awareness, vigilance, autopsy performance, and reporting.

Background: Many deaths investigated by medical examiner/coroner (ME/C) systems are associated with a blood transfusion shortly before death. Complications of transfusion may occur and are occasionally fatal. The transfusion service is required to report fatal complications of transfusions to the FDA Center for Biologics Evaluation and Research (CBER). A CBER Medical Officer (CMO) reviews submitted information and determines to what extent, if any, the transfusion may have contributed to death. CBER publishes an annual summary of the reported fatalities. As part of its investigation, FDA requests the reporting facility to provide information on whether or not an autopsy was performed, but autopsy data have never been published in the annual summary.

Hypotheses: (1) Transfusion-associated fatalities reported to the FDA are under-reported to ME/C systems, despite the fact that several of these deaths are due to medical errors and therefore likely be certified as Accidental in manner of death; (2) a significant number of these cases would also otherwise typically fall under ME/C jurisdiction, such as cases involving transfusion for traumatic injuries; (3) there is a very low autopsy rate in these cases; and, (4) for the group of fatalities in which the FDA could not rule out transfusion as contributing to the death, a higher autopsy rate could have potentially helped to determine the cause of death with a higher degree of certainty and therefore allowed more definitive classification of some of these cases as either transfusion- related or not.

Methods: After review of the 2008 U.S. FDA Annual Summary report of fatalities following transfusion, the most recent year for which data had been published at the initiation of the project, a Freedom of Information Act request was submitted to CBER for the "Table of Final Conclusions" prepared by a CMO for each of the 72 reported transfusion-recipient deaths. Sixty-nine individual reports with some data redacted were received, as three cases had been withdrawn prior to CMO review. Available documents were mined for data that would address the hypotheses and potentially be of interest to participants of death investigation systems.

Results: Of the transfusion-recipient deaths reported (N=69), there were 35 males (51%), 33 females (48%), and 1 sex unspecified. Age ranged from 6 weeks to 97 years (median=66 years). The overall reported autopsy rate was 26% (18/69). Performance of an autopsy was reported in 24% (11/46) of cases in which transfusion was determined by the CMO to have contributed to the death and in 43% (6/14) of cases in which transfusion was determined to be unrelated to the death, but in only 11% (1/9) of cases in which transfusion could not be ruled out or confirmed as contributing to the death. Human errors in pre-transfusion specimen collection, compatibility testing or blood administration accounted for 30% (14/46) of transfusion-related deaths; all of these were due to hemolytic transfusion reactions (HTRs). Ninety percent (90%, 9/10) of the deaths due to ABO incompatibility (ABO HTRs) occurred when Type A donor red blood cells were erroneously transfused to non-A recipients, 89% (8/9) of whom were Type O. Of the deaths due to incompatibility of non-ABO red blood cell antigens (non-ABO HTRs), 71% (5/7) were due to errors that occurred in the blood bank during compatibility testing. Autopsy performance was reported in only 14% (2/14) of the deaths due to human error. Trauma patients accounted for 6% (four cases) of all reported deaths, and for each of these a transfusion complication was determined to contribute to the death (three cases) or could not be ruled out

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(one case). For five of the eight deaths without an autopsy in which transfusion could not be ruled out or confirmed as a contributing factor, the CMO listed a differential

diagnosis that suggested autopsy findings may have helped with further classification.

Conclusions: In this study, a significant number of reported transfusion-related deaths were due to human error. Transfusion complications may cause or contribute to death in cases that would typically otherwise fall under ME/C jurisdiction, including trauma cases. Lack of autopsy findings may impede the determination of whether or not a transfusion contributed to death and thereby prevent definitive classification.

Transfusion, Fatal, Autopsy

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