FDA NOTIFICATION PROCESS for TRANSFUSION RELATED FATALITIES and DONATION RELATED DEATHS BLOODBOOK.COM

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Blood Transfusion Related Fatalities and Blood Donation Related Incidents and Deaths - FDA Notification Process and Complete Blood Transfusion Problem Contact Information.

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When the average person goes to the hospital to get a Blood transfusion they are most concerned with getting AIDS or hepatitis. The Blood center physician who is accountable for the transfusion process has a whole list of other concerns. That very long list starts with Acute Hemolytic Transfusion Reaction, a very real, all too common, and potentially very serious problem.

Acute Hemolytic Transfusion Reaction or HTR occurs when incompatible Blood is transfused into a patient that should have been given Blood of a different Blood type.

Acute hemolytic transfusion reactions (HTRs or AHTRs) account for the vast majority of fatalities related to Blood transfusion. Most of these fatal reactions are positively preventable. According to a 1997 paper by P. J. DeChristopher and R. R. Anderson ("Risks of Transfusion and Organ and Tissue Transplantation: Practical concerns that drive practical policies." *American Journal of Clinical Pathology*) in 1997, this preventable tragedy caused by Blood type incompatibility occurs in one in 6,000 to one in 33,000 Blood transfusions. It is fatal in about one in 500,000. The reported number of these incidents, over the years, is not going down.

Deaths After Transfusion - When is this reported; when is it investigated?

In the United States and Canada there is no hard and fast rule from state to state or province to province in Canada! One would think that this type of thing would be a big deal.

For a taste of the dilemma from an industry perspective, click HERE.

Blood Transfusion Reaction

Following here, below the red line is the process protocol and points of contact for notification of transfusion related

fatalities and donation related deaths.

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Initial notification of transfusion related fatalities and donation related deaths should be made to FDA's Center for Biologics Evaluation and Research (CBER) 24 hours per day, seven days per week.

1-301-827-6220 (Voice mail)

1-301-827-6748 (FAX)

e-mail: fatalities2@cber.fda.gov

Follow-up contact by CBER will be made as soon as possible to obtain more detailed information. This does not replace the seven-day written report regarding the fatality and all related information that is required by 21 CFR 606.170(b).

The seven-day written report should be sent to:

Center for Biologics Evaluation and Research (CBER)
Director, Office of Compliance and Biologics Quality
Attn: Fatality Program Manager (HFM-650)
1401 Rockville Pike
Suite 200 N
Rockville, MD 20852-1448

1-800-835-4709 (Voice - Toll-free)
1-301-827-2000 (Voice)
1-301-827-3843 (FAX)
1-888-223-7329 (FAXBACK)

During regular business hours, transfusion related fatalities and donation related deaths should be reported to CBER's fatality program contact within the Division of Inspections and Surveillance at 1-301-827-6220 ■

http://www.fda.gov/cber/transfusion.htm

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Center for Biologics Evaluation and Research (CBER) - cber_info@a1.cber.fda.gov

U. S. Food and Drug Administration (FDA) - www.fda.gov/cber/

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