

The CBER Division of Epidemiology will present a preliminary analysis of donor fatalities among U.S. blood/blood component donors reported to FDA between 1983 and October 31, 2003. This analysis will include information on patient characteristics and trends in surveillance practices over time.

The 52 reported deaths over the years 1983 – 2003 included 29 donors of source plasma, 20 donors of whole blood, and three donors of platelets. Reported deaths occurred minutes to days following donation. When the 21-year time period was divided into three seven-year intervals (1983-89, 1990-96 and 1997-2003), the reported numbers of deaths in each interval were 2, 6, and 12 for whole blood and 6, 5, and 18 for source plasma. However, changes in surveillance practices and/or the number of blood donations may account for apparent increases; these factors will be discussed.

Given the hundreds of millions of donations over the past 21 years, these small numbers of donor fatality reports must be interpreted very cautiously. The most common reported cause of death in these patients was cardiovascular heart disease, the leading cause of death in the United States. The prevalence of underlying cardiac disease in people who donate blood is unknown. Data are being gathered to estimate how many deaths in blood component donors might be expected based on background rates alone.

An increase in reported deaths could result, in part, from improved surveillance without a true increased risk over time. This possibility is supported by our finding increases in the proportion of reports in which the death occurred more than 24 hours after donation: 1983-96 3/18 [16.7%] of deaths were >24hr after donation, 1997-2003 9/27 [33.3%] of deaths were >24hr after donation. Other possible explanations for increases in reports include higher rates of sudden cardiac death in the general population<sup>1</sup>, risk factors for

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<sup>1</sup> For example, according to the American Heart Association Heart Disease and Stroke Statistics 2003 Update, the sudden cardiac death rate in young women increased by 30% between 1989 and 1996.

cardiac death that may have become more prevalent among blood product donors, or chance (especially given the small numbers involved). Alternatively, the increase may be due to a change in the donation procedure. Of particular interest is the practical application of the nomogram for determining the amount of plasma withdrawn and how this determination has changed over time.

The number of donor fatality reports received by FDA over the past 21 years indicates that these are very rare events, reported less frequently than one per million donations. Regardless of whether the apparent increase in reports is biologically-based, due to changes in surveillance, or due to chance, it is important to understand why donor fatalities occur. Additional analyses are in progress, and the feasibility of a case-control study is being explored.