Guideline for collection from High risk donors (4/17/91)

Date: April 17, 1991

From: Director, Center for Biologics Evaluation and Research

Subject: Revision to 26 October 1989 Guideline for Collection of Blood or Blood Products from Donors with Positive Tests for Infectious Disease Markers ("High Risk" Donors)

To: All Registered Blood Establishments

For approximately 10 years blood establishments have applied certain FDA recommended precautions when collecting blood or blood components from persons known to have positive tests for infectious disease markers. The most recent FDA recommendation (26 October 1989) includes a statement limiting the use of an automated collection device to one specific program; this would require, for example, that different equipment be used for HBsAg reactive donors and anti-HIV-1 positive donors.

Although labeling for the equipment has never included such limitations, this very conservative approach was initially adopted because of the lack of information about the potential for transmitting disease from one donor to another. This recommendation for limiting use is now being withdrawn because over this ten year period we have been unable to find in reviewing the literature, consulting with the Centers for Disease Control and other experts responsible for large apheresis programs, any instance of disease transmission attributable to use of these devices. Nor have we learned of operational-problems that would support the limitation. Complaint files at the Center for Devices and Radiological Health were also reviewed.

Even in the past, before all portions of the fluid pathway were completely disposable, there were no reported problems that would indicate a potential for disease transmission. These devices are also used clinically in many situations where the presence of disease markers in patients is unknown and therefore, no similar consideration is given to patients. Likewise, this same equipment is widely used in routine Source Plasma collection and cytapheresis, and first-time donors may also have positive tests for disease markers. No extra precautions in lieu of dedicated machines have been applied for either patients or first-time donors,

The burden created by equipment restrictions has also escalated over time because the number of special programs has increased from the HBsAg program in 1981 to ten or more programs currently, as well as having a potential impact on autologous donor programs.

Therefore, effective immediately, the "Manner of Collection" paragraph on page 2 of the 26 October 1989 memorandum is amended by deletion of the phrase "...if these devices are dedicated to use only for the one specific program..." Please note that all other precautions outlined in the 26 October 1989 memorandum, including immediate clean-up and disinfection of any spill and disinfection of equipment between donors should remain in place.

Licensed establishments may implement this change concurrently with submission of notification that the less stringent procedure will be implemented.

Questions may be addressed to the Laboratory of Blood Bank Practices, 301-443-8483.

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