Oral Presentation
CBER Blood Products Advisory Committee Meeting
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Sickle Cell Disease Advisory Committee

At it's June 4, 2001 meeting, the NIH Division of Blood Diseases and Resources Sickle Cell Disease Advisory Committee considered the recently proposed revisions to the FDA guidance document on pre-storage leucocyte reduction of Whole Blood and blood components intended for transfusion. The guidance document contains seven recommendations. The seventh of which reads: "to consider donor screening for sickle cell trait". The recommendation appears to be based on reports in the literature and abstracts from scientific meetings that blood components from individuals with sickle cell trait may not filter properly. The sample size of all of these reports is small, precluding accurate estimation of the frequency with which failure occurs, and the contribution of such failures to the overall failure rate for attempted leucoreduction of donated units of blood.

In a presentation at the meeting by Dr. Rebecca Haley of the American Red Cross it was noted that of 2,917,136 units of red cells filtered, 25,917 failed for a failure rate of 0.9%. 360 of these units were from individuals with sickle cell trait. The major causes of failure were clots n=11,019, unknown cause n= 9264, user error n= 2680, and cold agglutinins n=1009. The failure rate was well below the FDA maximum failure rate of 5%.

After careful consideration the Advisory Committee determined that there were several issues raised by the proposed FDA guidance document which were of great concern:

Most importantly, since many individuals with sickle cell trait are African American, the implication that donations of blood from African Americans could be deemed undesirable would undercut current efforts to increase African American donations not just of blood, but of bone marrow and other organs as well!

Additional concerns were also discussed:

- Screening for sickle cell trait would have to be universal. If it were not, and were based on criteria such as appearance or query as to racial origins, it would be discriminatory.

- Screening for sickle cell trait could only be done with informed consent. e.g.: the individual would have to be advised of the reasons why screening was deemed necessary. This might well lead individuals to conclude that sickle cell trait was a health problem, thus undercutting years of teaching efforts as to the difference between the trait and disease.

- Individuals would have to be educated re sickle cell trait in order to give informed consent and would require genetic counseling if found to have the trait. Providing these

activities would be the responsibility of the Blood Center.

· The chances of finding compatible donors for alloimmunized African American patients would be reduced.

It was also observed that given the relative infrequency of sickle cell trait as a cause of filtration failure, a screening program would not be cost effective.

The Sickle Cell Advisory Committee therefore recommends that the proposal to screen for sickle cell trait be abandoned and that efforts be undertaken to determine the reason for failures.