

Mississippi Blood Service

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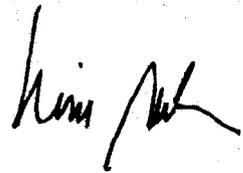
To: Martin Ruta From: Nina Salamon
Fax: 301-827-3533 Pages: 19 (including this one)
Date: 5/8/01

Dear Mr. Ruta,

Attached is the abstract I presented at the AABB meeting last year. Take a look at it and call me if you have any questions. I will try to put our most recent data together on no flow and slow flow units and fax it to you sometime this week.

Sincerely,

Nina Salamon



**(SLIDE 1) IMPACT OF SICKLE CELL TRAIT BLOOD DONATIONS FOR A
COMMUNITY BLOOD CENTER AFTER UNIVERSAL
LEUKOREDUCTION**

(Slide 2) Mississippi Blood Services, located in Jackson, Mississippi, collects approximately 50,000 units per year. Over the past several years we have increased our collections from the African American community. This year approximately 30% of the donors we collect will be African American. Our blood center relies heavily on African American donors to meet the community blood requirements. In October 1999, as a response to the FDA's recommendation for universal leukoreduction, and at the request of our major hospitals, we implemented 100% leukoreduction of red cells.

(Slide 3) Anecdotal reports suggest that sickle cell trait donors will cause leukoreduction filter failures. Sickle cell disease is an inherited blood disease that affects approximately 1 in 400 African Americans. Sickle trait is not a disease, and affects approximately 1 in 7 African Americans. In Mississippi, newborn testing has been performed since 1988 to detect sickle cell disease, however no centralized data base exists and many individuals do not know their sickle trait status. Because we rely heavily on our African American donors to meet our blood needs we encourage sickle trait positive donors to donate. We estimate that approximately 2% of our collections would come from sickle trait positive individuals, which would cause filter failures and lost products.

(Slide 6) 485 donors were tested using this protocol. 228 donors representing 47% of the donors tested were African American. 255 donors; 52%; were Caucasian. 15 donors, screened sickle trait positive.

(Slide 7) Of the donors tested who screened positive for sickle cell trait, 14 donors did pass through the filter but failed the residual white cell count. One donor passed the residual white cell count after filtration. Donors sickle trait status was confirmed by hemoglobin electrophoresis.

(Slide 8) Evaluation of the residual white cell count of all 485 donors revealed that 93% passed the residual white cell count, while 7% failed the residual white count. The failures were comprised of 14 donors who screened positive for sickle trait; however, there were 19 sickle trait negative donors who also failed the residual white cell count.

This study was designed to include 2000 donors, however after 485 donors were evaluated, Becton Dickinson placed a ship hold on their Imagn reagents and the study was discontinued. Concurrent with the Becton Dickinson hold, Baxter recalled their Sepacell filter and we began using Pall filters.

(Slide 9) A second study was begun to look at the residual white cell count using the Pall filters. During the course of a few weeks, African American donor units were selected for sickle trait screening and residual white cell counts. The

Institute for Transfusion Medicine performed the residual white cell counts within 48 hours of collection.

(Slide 10) In this study, 67 African American donors were screened for sickle cell trait. None screened positive. All units were tested for residual white count. 59 units, 88%, passed and 8 units, 12% failed.

Recently the FDA has issued a concept paper suggesting that they will lower the residual white cell count from 5×10^6 to 1×10^6 . Using the European standard of 1×10^6 there was a 52% failure rate with the Sepacell filter and a 70% failure rate with the Pall filter. The Pall filter was in use for several weeks when the second study was begun suggesting perhaps tech training and familiarity with the product might have caused a higher failure rate.

(Slide 11) In our center, faced with increased requirements for QC after universal leukoreduction, we continue to Nageotte count our QC units. Mid size centers should consider automating their residual white cell counting methods; however it is not feasible in our center, even if reagents were available, to perform residual white cell counts using the Imagn machine. Imagn reagents are costly and throughput is slow. The machine requires very precise pipetting, and operator errors occur frequently necessitating repeat sample runs. We are currently considering third party flow cytometry for our leukoreduction QC.

(Slide 12) In summary, we are currently meeting the FDA requirements for leukoreduction of red blood cells. Units drawn from donors who screen positive for sickle cell trait will not flow or will not adequately leukoreduce, however sickle trait negative units also failed to adequately leukoreduce. Because many sickle trait negative donors did not adequately leukoreduce and because sickle cell trait in our population is not confined to individuals recognized as African American, we elected not to screen all of our donors for sickle trait. Currently we are evaluating all units which do not flow or which exceed 60 minutes to filter, for residual white cell count and sickle trait status. In this process we hope to capture all units that do not adequately leukoreduce.

(Slide 13) After one full year of 100% red cell leukoreduction, Mississippi Blood Services has lost 1.3% of units collected due to filter flow problems. Due to the complexity and community perceptions associated with sickle trait screening in our population we have decided at this time not to screen our donors for sickle cell trait. In order to meet the challenge of providing adequately leukoreduced red cell units we are continuing to study this problem. In addition we are investigating sickle trait positive donors on subsequent donations to determine if they adequately leukoreduce or not. Routine donors who do not adequately leukoreduce will be redirected to non red cell collection procedures.

**IMPACT OF SICKLE CELL TRAIT
BLOOD DONATIONS FOR A
COMMUNITY BLOOD CENTER
AFTER UNIVERSAL
LEUKOREDUCTION**

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JK Anderson, Baxter Healthcare Corp. Deerfield, Ill.

Mississippi Blood Services

- 50,000 unit collection facility
- 30% African American donors
- Oct. 1999 implemented ULR

Increase in African American donors

2000	30%
1999	29%
1998	27%
1997	24%

Sickle Cell Disease

- Inherited blood disease affecting red blood cells
- Affects 1 in 400 African Americans
- Sickle trait is not a disease
- Sickle trait 1 in 7 African Americans
- Newborn testing
- Estimated prevalence in our donor pool

Filter Failures 10/99 - 12/99

	No Flow	Sickle Pos	Sickle Neg
Oct. 99	90	80	10
Nov. 99	22	22	0
Dec. 99	31	24	7

Sepacell Study

- Mobiles selected to have high number of African American donors
- All donors screened regardless of race
- All units from selected mobiles counted for residual white cells after filtration

Sepacell Study - Results

- 485 donors tested
- 15 sickle trait positive (3%)
- 228 African American
- 255 Caucasian
- 2 other
- Race identified by donor historian

Sepacell Study - Results

- Sickle trait positive - 14 failed WBC
- Sickle trait positive - 1 passed WBC
- Confirmed sickle trait +

Sepacell - WBC Results

5xE6

- 485 donors
- 452 passed (93.2%)
- 33 failed (6.8%)
- 14 sickle trait pos which failed (2.8%)
- 19 sickle trait neg which failed (3.9%)

	WBC pass	WBC fail
Sickle pos	1	14
Sickle neg	451	19

Pall Study

- Only African American donors selected
- Sickle cell screened
- Residual white cell count by flow cytometry

Pall - WBC Results

5xE6

- 67 donors
- 59 passed (88%)
- 8 failed (12%)
- 0 units screened sickle trait pos

	WBC pass	WBC fail
Sickle pos	0	0
Sickle neg	59	8

Summary

- Currently meeting QC requirements
- No Flow units
- Sickle trait positive flow but don't leukoreduce
- Sickle trait negative
- Slow flow units

Impact on Mississippi Blood Services

- **Lost units (no flow) 1.3%**
- **Sickle trait testing - slow flow investigation**
- **Subsequent donations**
- **Redirect to non red cell collections**