

*Promoting the highest standard of care for
patients and donors in all aspects of
blood banking and transfusion medicine*

Bacterial Detection Standards: Implementation Issues

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AABB Survey

- Developed by Scientific Section Coordinating Committee
- Distributed on March 30, 2004
- 1,100 Institutional member contacts

AABB Survey Specifics

- Online survey instrument
- Four-part survey
 - Approximately 20 questions per part
- 310 respondents

Q: Increase in Platelet Shortage?

Have you experienced platelet shortages as the result of bacterial contamination testing since March 15, 2004?

Transfusion Service Response to Q: Increase in Platelet Shortage?

	<i>Response %</i>	<i>Response #</i>
Yes	16%	38
Yes, cause unknown	26%	60
No	<u>58%</u>	<u>134</u>
Total	100%	232

Hospital Blood Bank Response

Q: Increase in Platelet Shortage?

	<i>Response %</i>	<i>Response #</i>
Yes	12%	4
Yes, cause unknown	18%	6
No	<u>70%</u>	<u>24</u>
Total	100%	34

Q: Percentage Increase in Platelet Shortage?

Considering your usual inventory of platelets, what is the % of the shortage?

Transfusion Service Response

Q: Percentage Increase in Platelet Shortage?

	<i>Response %</i>	<i>Response #</i>	
Not applicable	59%	133	
<10%	25% (61%)	58	} 94
10-25%	12% (31%)	27	
25-50%	2% (5%)	5	
>50%	<u>2%</u> (3%)	<u>4</u>	
Total	100%	227	

Hospital Blood Bank Response

Q: Percentage Increase in Platelet Shortage?

	<i>Response %</i>	<i>Response #</i>	
Not applicable	70%	24	
<10%	18% (60%)	6	} 10
10-25%	9% (30%)	3	
25-50%	3% (10%)	1	
>50%	<u>0%</u>	<u>0</u>	
Total	100%	34	

Q: Freshest Platelet?

What is the dating on your freshest platelets (in hours?)

Transfusion Service Response

Q: Freshest Platelet?

	<i>Response %</i>	<i>Response #</i>
96-120 hrs.	3%	6
72-96 hrs.	16%	35
48-72 hrs.	51%	115
24-48 hrs.	29%	65
<24 hrs.	<u>1%</u>	<u>3</u>
Total	100%	224

Hospital Blood Bank Response

Q: Freshest Platelet?

	<i>Response %</i>	<i>Response #</i>
96-120 hrs.	9%	3
72-96 hrs.	15%	5
48-72 hrs.	35%	12
24-48 hrs.	35%	12
<24 hrs.	<u>6%</u>	<u>2</u>
Total	100%	34

Q: Increased Platelet Outdating?

Are you experiencing platelet outdating as the result of bacterial contamination testing and if so, what is the increase in % of the outdating?

Transfusion Service Response

Q: Increased Platelet Outdating?

	<i>Response %</i>	<i>Response #</i>	
No increase	63%	147	
Yes, between 1-4%	4% (26%)	9	} 35
Yes, between 4-7%	5% (30%)	11	
Yes, greater than 7%	6% (43%)	15	
Other / Don't know	<u>22%</u>	<u>51</u>	
Total	100%	233	

Hospital Blood Bank Response

Q: Increased Platelet Outdating?

	<i>Response %</i>	<i>Response #</i>	
No increase	61%	21	
Yes, between 1-4%	6% (20%)	2	} 10
Yes, between 4-7%	9% (30%)	3	
Yes, greater than 7%	15% (50%)	5	
Other / Don't know	<u>9%</u>	<u>3</u>	
Total	100%	34	

Q: Platelets Available for Distribution?

Since implementing a method of bacterial detection on platelets, has your facility been able to meet platelet supply needs of your transfusion service customers?

Blood Center Response

Q: Platelets Available for Distribution?

	<i>Response %</i>	<i>Response #</i>
Yes	79%	34
No	7%	3
Other	<u>14%</u>	<u>6</u>
Total	100%	43

Q: Platelet Need Unmet?

What % of need for platelets has your facility not been able to meet?

Blood Center Response

Q: Platelet Need Unmet?

	<i>Response %</i>	<i>Response #</i>	
Not applicable	67%	28	
<10%	21% (64%)	9	} 14
10-25%	7% (21%)	3	
25-50%	0%	0	
>50%	<u>5%</u> (35%)	<u>2</u>	
Total	100%	42	

85 AABB Assessments March 1 – 31, 2004

- Blood Centers 5
- Hospital Blood Banks 29
- Transfusion Services 51

One (1%) nonconformance written (non-US blood center)

MD Anderson Experience

- Transfuse 250-400 WBD platelets/day (95,000/year)
- Transfuse 10-15 apheresis platelets/day (5,000/year)
Platelets are <30 hours old when transfused
- Collect @40,000 units of WB and produce @35,000 units of WBD platelets/year
- Collect @4,500 apheresis platelets/year
- Import @60,000 WBD platelets

MD Anderson Experience (cont.)

DATE	Methods for bacterial limitation/detection
▪ 5/02 -	Planning/evaluation
▪ 10/03-4/04*	WB Collection with diversion *Manufacturer has withdrawn bags
▪ 2/04	Arm prep changed → no Green Soap
▪ 1/04 - 2/04	Swirling CD reviewed
▪ 2/25/04	Culture of apheresis donors/collection using automated culture system
▪ 3/1/04	Dipstick of WBD plt pools - Culture of <u>sample</u> of WBD plt pools

MD Anderson Experience (cont.)

WHOLE BLOOD DERIVED PLATELETS DATA

Criteria for positive dipstick: pH <6.5; Glucose <1000*

No. tested

1,690 pools (10,789 indiv.)

Results

NEGATIVE

Criteria for positive culture: Growth within 30 hours (held for 7 days)

No. tested

40 pools (300 indiv.)

Results

NEGATIVE

*Glucose <1000>500 evaluated by TMP

MD Anderson Experience (cont.)

Apheresis Platelets DATA

- Culture taken from donor
- Culture for minimum of 12 hours → issued
- 282 apheresis platelets cultured (since 2/25/04)
 - 3 (1%) culture positive**
 - 1 negative on Gram's stain
 - 2 GPC - Staph

AABB Task Force

Members: Experts from blood banks and hospitals working with both apheresis and whole blood derived platelets.

Task Force Charges

- Review Data from AABB Survey
- Make recommendations concerning further guidance
- Recommend further data collection
- Provide feedback about implementation and efficacy of methods in identifying bacterially contaminated units
- Continue monitoring platelet availability

Supply Issues

- In order to promote adequate platelet supply, AABB urges FDA to take steps to:
 - Increase storage time for pooled platelets
 - Extend outdate of platelets to seven days

FDA should think creatively and act expeditiously to meet these needs for improved patient safety

Conclusion

AABB's bacterial contamination
standard improves
patient care and saves lives