Summary of Results Bacterial Contamination Task Force Survey

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Chair, 23rd edition

AABB Standards for Blood Banks and Transfusion Services

Member - Bacterial Contamination Task Force

Goals of the Survey: To Gather Information on:

- Platelet usage, supply and outdating
- Currently used bacteria detection methods
- Follow up procedures after an initial positive or abnormal result
- Notification of physicians and donors when positive results are obtained
- Rate of initially positive and confirmed positive test results
- Impact of bacterial detection testing on QA activities

SURVEY CONDUCTED 9/17/04 – 10/1/04

Survey Response

Approx 38% response rate – 350 / 900 responses

Facility Type	# Responses
Blood Center	35
Hospital Blood Bank	47
Transfusion Service	262

- Data from ARC (all sites) is represented as 1 response
- Data from Blood Systems (all sites) is represented as 1 response
- These two institutions collect approximately 50% of the nation's blood supply

- Facilities who collect, process and transfuse blood components

- Facilities who receive all components from outside sources

Platelets Manufactured in 2003

Facility type (n)	WBDPC	Aph Plts
Blood Center (35)	1,672,855	893,465
Hospital BB (47)	131,942	65,692
Total	1,804,797	959,157

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Platelet Components Manufactured

Source of Data	WBDPC	Aph Plts
Task Force Survey (Data from 2003)	1,804,797	959,157
NBDRC, 2001	4,164,000	1,456,000

Using 2001 data on the manufacture of blood components, it appears that survey respondents included facilities responsible for the manufacture of approximately 66% of apheresis platelets and at least 44% of WBDPC

Platelets Transfused 2003 / 2004

Time Frame	WBDPC	Aph Plts
May – August, 2003	166,012	93,478
May – August, 2004	147,273	98,753

Availability Since Implementation

- 91% of blood centers stated that there is no change in ability to provide platelets for transfusion
- 64% of hospital blood banks stated that there is no change in ability to provide platelets for transfusion
- 68% of transfusion services stated that there is no change in ability to provide platelets for transfusion

- The change is not in the number of platelet components available, but is likely due to the length of time units are available for transfusion

Transfusion Service Experiences with Inventory Management

- Management of platelet inventory for most days of each month is no worse than prior to implementation of testing for bacterial contamination
- There are days during the month when the management of platelet inventory has been more challenging for some institutions
- This experience has led to a change in the management of inventory for platelet components at some institutions

“Are you Currently Experiencing Increased Platelet Outdating?”

Facility Type	No Incr	1-5% Incr	6-10%	Unk
Blood Center	66% (23)	17% (6)	6% (2)	11% (4)

- One of the reasons that Blood Centers may not have experienced an increase in platelet outdating is related to a change in policy by many centers that does not allow for “return for credit” of platelet components that were not transfused prior to expiration. Any change in platelet outdate rate would be reflected in transfusion service data, not data provided by blood centers

“Are you Currently Experiencing Increased Platelet Outdating?”

Facility Type	No Inc	1-5%	6-10%	10-15%	16-20%	Unk
Hospital BB	68% (32)	11% (5)	2% (1)	2% (1)	6% (3)	11% (5)

- Data from 47 hospital blood banks who manufacture ~ 132,000 WBDPC and ~ 66,000 apheresis platelets per year

"Are you Currently Experiencing Increased Platelet Outdating?"

Facility Type	No Inc	1-5%	6-10%	10-15%	16-20%	Unk
Trans Serv	66% (172)	11% (29)	4% (10)	1% (3)	4% (10)	9% (23)

- As a result of the "no return" policy changes for platelet components, 6% of Transfusion Services no longer maintain a platelet inventory; platelet components are requested from their supplier only when there is an order to transfuse. This is a change in practice
- One facility reported a 39% outdate rate

Screening Method for Apheresis Platelets

Blood Centers

- 88% (30/34) blood centers use a culture method
  - 12% (4/34) facilities use glucose / pH by dipstick
  - 1 center responded N/A as they perform a “visual check”

- Hospital Blood Banks
  - 80% (8/10) of Hospital BB use a culture method if they have not been previously tested by their supplier
  - 88% (38/43) use a culture method for those they manufacture

Screening Method for Whole Blood Derived Platelets

Blood Centers	Transfusion Service
Culture methods	Culture methods
Glucose	Glucose
pH	pH
	Gram's Stain

Methodology:

Dipstick, electrode, paper, gas analyzer, chemistry analyzer

If Using BacT/Alert or Similar Culture Method

	Aerobic only	Aero & Anaerobic
Blood Center (27)	85%	15%
Hospital BB (26)	54%	46%

For Facilities Using a Culture Method

- Component is held 24 hours prior to sampling for bacterial testing
- Components held for varying periods of time following sampling, prior to release for transfusion

For Facilities Using BacT/Alert or Similar Culture Method

- In virtually all facilities surveyed, cultures are continued for 5-7 days from initiation, or until expiration of the component, consistent with manufacturer's recommendations
- Most facilities inoculate each bottle with 4-5 ml; next most common is 6-10 ml of inoculum

Culture Methods: Results

Facility Type	# Cultures	Init Pos	True Pos
Blood Center	429,827	1:930	1:4723
Hospital BB	45,531	1:328	1:1686

Non-Culture Methods: Results

Facility Type	# Tests	Init Abn	True Pos
Blood Center	51,025	1:158	1:5,672
Hospital BB	118,567	1:184	zero
Trans Service	89,903	1:244	1:17,986

Rate of “True Positive” Results

	Culture Method	Non-Culture Method
# Tests Performed	475,358	259,495
Blood Center	1:4,723	1:5,672
Hospital Blood Bank	1:1,686	zero

Additional Survey Findings

- When an abnormal result is obtained by a non-culture method, most facilities are performing additional investigation
  - 19 facilities discard the product with no additional investigation. This applied to WBDPC
- Most facilities quarantine co-components (whether Apheresis or WB) pending results of the investigation
- If confirmed positive test is identified following transfusion, ALL facilities have defined a plan of action to include notification of the facility, physician and follow up

Additional Survey Findings

- Follow up action related to the donor:
  - Additional action taken depends on the results of the culture
- Practices most commonly reviewed or modified as a result of testing for bacterial contamination
  - Training to perform bacterial detection test
  - Sampling procedures
  - Evaluation of blood bag or collection system
  - Choice of arm scrub materials
  - Instructions in interpreting test

Changes in Practice

- Increased scrutiny in training
- Increase trend in use of apheresis platelets
  - Transfusion of apheresis platelets appears to have increased in 2004 as compared to 2003
  - This was already noted in 2001 (NBDRC survey)
  - It cannot be determined from the survey if the implementation of testing for bacterial contamination accelerated this change
- "Just-in-time" inventory in transfusion services
  - This practice will need to be evaluated by each facility as to their patient needs

Survey Summary

- Platelet usage, supply and outdating
  - Moderate shift to using apheresis platelets
  - 91% of blood centers state the availability of platelet components has not changed since implementation of AABB Standard 5.1.5.1
  - 66-68% of facilities surveyed have experienced no increase in outdate rate; Up to 17% additional facilities have experienced < 5% increase in outdate of platelet components
  - Some Transfusion Services have revised their practice of “maintaining a platelet inventory” – only order platelet components when there is an order to transfuse

Survey Summary (continued)

- Currently used bacteria detection methods
  - Apheresis platelet components are usually tested by supplier, by a culture method
  - WBDPC are usually tested by the transfusing facility, using a non-culture method; glucose, pH by varied methodologies

Survey Summary (continued)

- Follow up procedures after an initial positive or abnormal result is to perform a culture
- Rate of initially positive and confirmed positive test results
  - For culture methods, the largest pool of data from this survey would support an approximate initial positive rate of 1:900 and an approximate true positive rate of 1:4700
  - The rate at some institutions may be higher and could be related to the use of an anaerobic bottle or sampling processes; this is subject to further research
  - For non-culture methods, the yield of the method may be related to variation in what is defined as an “abnormal” result

In Appreciation

The Bacterial Contamination Task Force would like to thank each institution who took the time to complete this survey. Without this support, these data would not have been made possible.

Related Association Bulletins

- # 02-08 Issued 12/10/02
- # 03-10 Issued 8/29/03
- # 03-12 Issued 10/1/03
- # 04-07 Issued 10/14/04
- # 05-XX Pending Issue

Association Bulletin #02-08: Update on Bacterial Contamination of Platelet Units

(Issued 12/10/02)

- Updates 1996 Bulletin
- Provides additional information on
  - Frequency
  - Cause
  - Outcomes
  - Prevention
  - Detection
- Annotated bibliography of key scientific literature

Association Bulletin #03-10: Guidance on Implementation of New Bacterial Reduction and Detection Standard
(Issued 8/29/03)

- Methods to limit bacterial contamination
  - Careful phlebotomy technique
  - Phlebotomy diversion
  - Use of apheresis platelets
    - Important role for WBDPC in transfusion therapy
- Methods to detect bacterial contamination
  - Culture
  - Staining
  - Dipsticks
  - Swirling (supplemental test only)

Association Bulletin #03-12: Further Guidance on Methods to Detect Bacterial Contamination of Platelet Components

(Issued 10/01/03)

- Supplements Association Bulletin #03-10
- Background information
  - Risk to recipient safety posed by bacterial contamination of platelets
  - Underpinnings of the approaches that have been considered to limit and detect contamination
- Practical guidance on implementation of techniques

Association Bulletin #04-07: Actions Following an Initial Positive Test for Possible Bacterial Contamination of a Platelet Unit
(Issued 10/14/04)

- Standardized definition for test results
- Investigation of units identified as positive by a bacteria detection test
- Management of other components associated with the same donation
- Guidance to address situations in which
  1) A positive test result is encountered only after the unit is transfused
  2) A recipient develops suspected or proven post transfusion sepsis after receiving platelets that have all tested negative

Association Bulletin #05-XX: Guidance on Management of Blood and Platelet Donors with Positive or Abnormal Results on Bacterial Contamination Tests (Pending Issue)

- General guidelines for medical decision making in managing donors with a positive result on a test for bacterial contamination
- Discusses organisms that have public health significance

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