

Bacterial Detection in Apheresis Platelets versus Prestorage-pooled WB-platelets

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**American
Red Cross**

ARC Hemovigilance Program

- The risk of bacterial sepsis following platelet transfusion has been substantially reduced by routine methods to **limit and detect bacteria** in platelet components
- Septic transfusion reactions to apheresis platelets reported to the American Red Cross are most often caused by **skin bacteria that escape detection** by quality control (QC) culture testing
- Prestorage pooled WB-derived platelets are **potentially more likely** to be contaminated with bacteria than apheresis platelets, because they require phlebotomy of 5 WB donors

- To evaluate the **rate** and **timing** of bacterial detection with routine QC testing of apheresis (**APH**) platelets compared to prestorage-pooled WB-derived (**PSP**) platelets
- To compare the rates of reported **septic transfusion reactions** with APH and PSP platelets

Quality Control Bacterial Testing

BacT/ALERT™ 3D, bioMérieux

	APH	PSP 5 LR WB-platelets
Initial diversion	Yes	Yes
Skin decontamination	Povidone iodine or chlorhexidine	Povidone iodine or chlorhexidine
Time to sample	≥ 24 hours	≥ 24 hours
Volume cultured, aerobic bottle	8 mL	8 mL
Release	≥ 12 hours	≥ 12 hours

Quality Control Bacterial Testing

INTERPRETATION	Initial Positive	Reculture / Confirmatory
True (confirmed) positive	Bacteria 1	Bacteria 1
False positive - sampling	Bacteria 1	No Growth
Indeterminate	Bacteria 1 (or other)	Not performed

CLASSIFICATION	
Likely skin bacteria	Most <i>Staphylococcus</i> spp.; <i>Streptococcus</i> spp. (except <i>S. bovis</i>)
Nonskin bacteria (possible bacteremia)	Most enteric isolates; gram-negatives e.g., <i>E. coli</i> , <i>Klebsiella</i> spp.

Endpoints

1. Rate of bacterial detection
 - By interpretation (true positive, false positive, indeterminate)
 - By isolate classification (likely skin, nonskin)
2. Time to positive culture
 - By Interpretation
 - By Isolate
3. Transfusion of platelet components before initial positive QC results
4. Reported septic transfusion reactions

Results: Bacterial Detection Rates

2007-2010

	APH (1,773,988 donations)		PSP (157,048 pools)	
	n	Rate*	n	Rate*
Initial Positives	638	(36.0)	200	(127.3)
True Positive	335	(18.9)	123	(78.3)
False Positive	218	(12.3)	46	(29.3)
Indeterminate	85	(4.8)	31	(19.7)

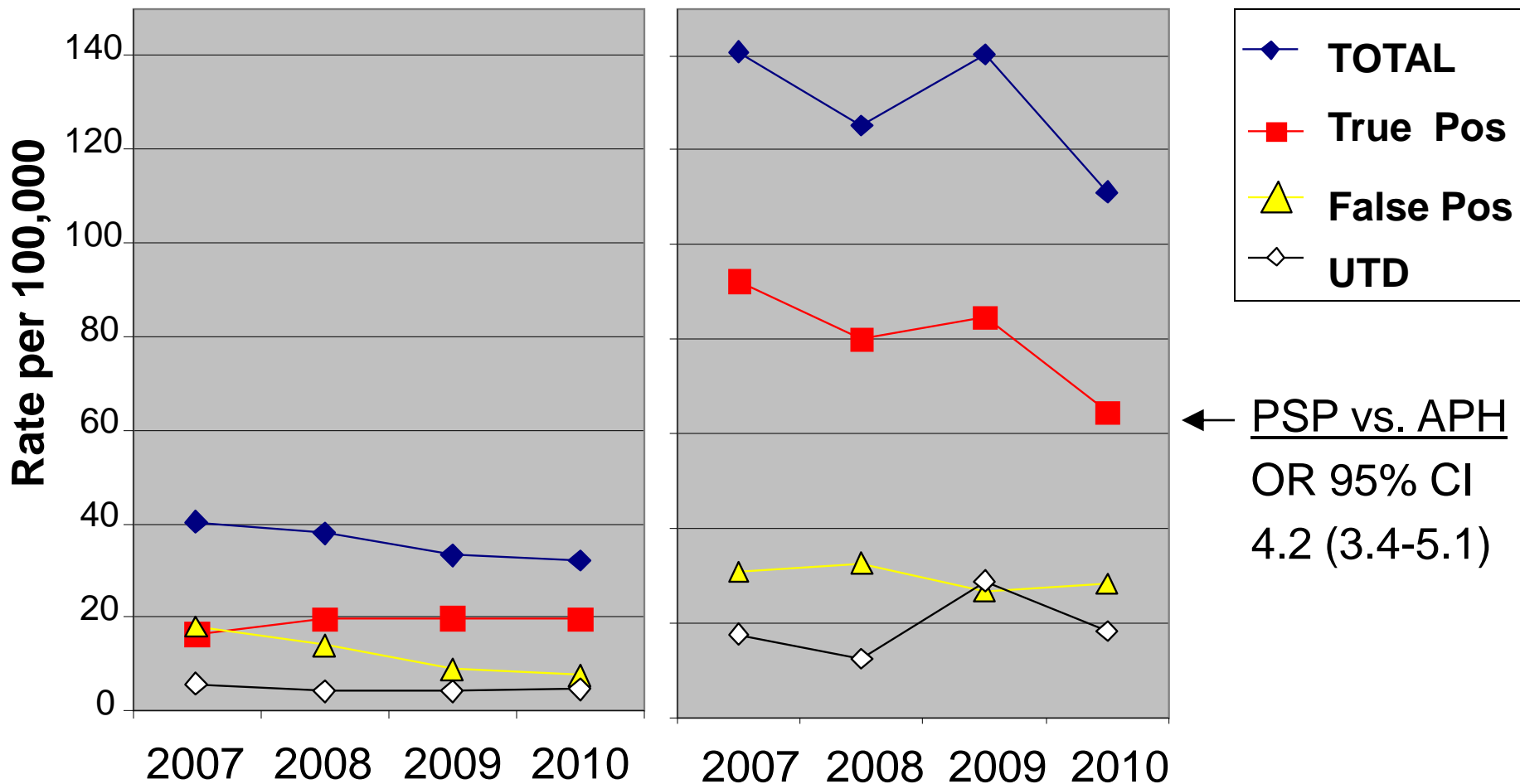
* Rate per 100,000

Results: Bacterial Detection Rates

By Interpretation

APH

PSP



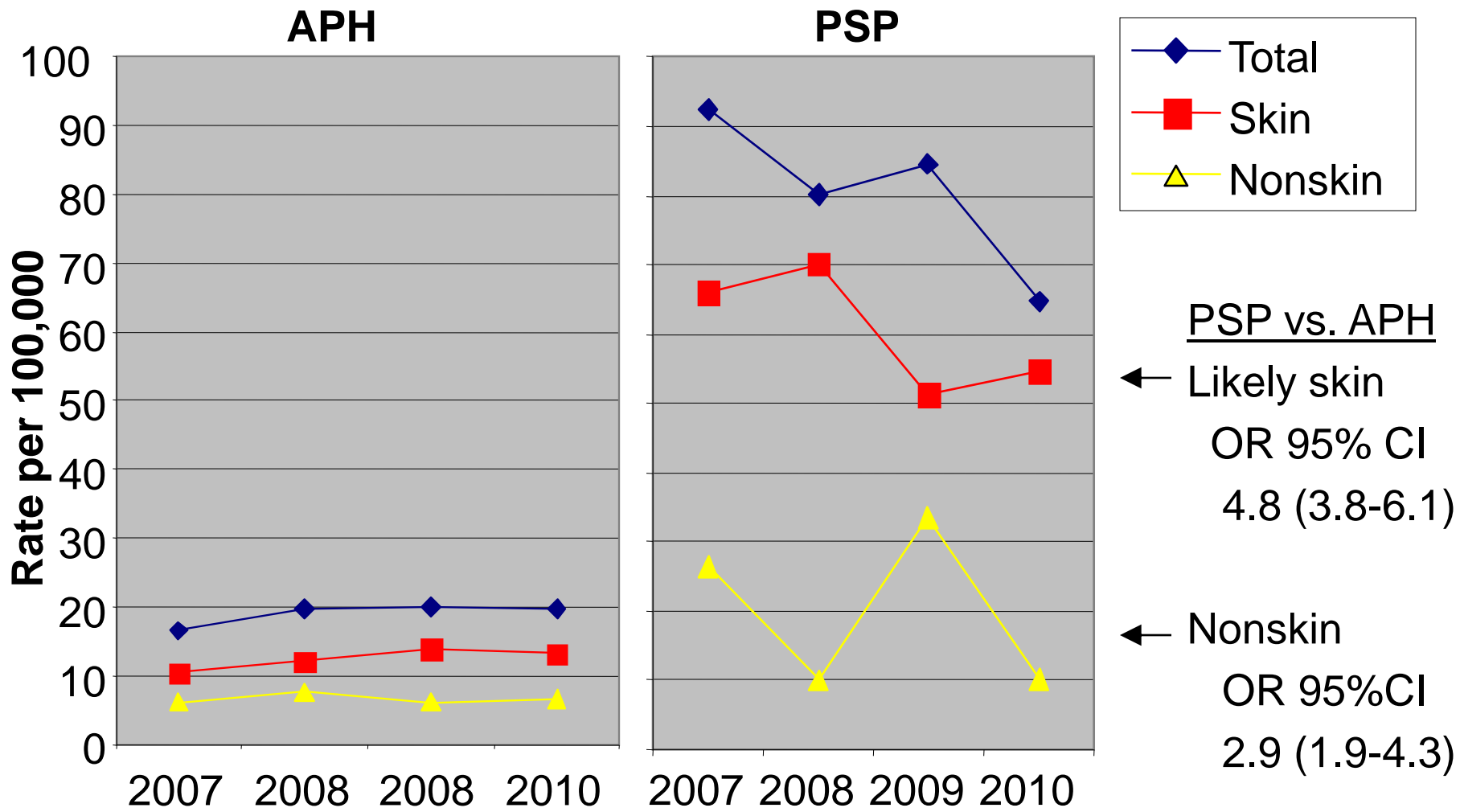
← PSP vs. APH
OR 95% CI
4.2 (3.4-5.1)

No significant trends over time



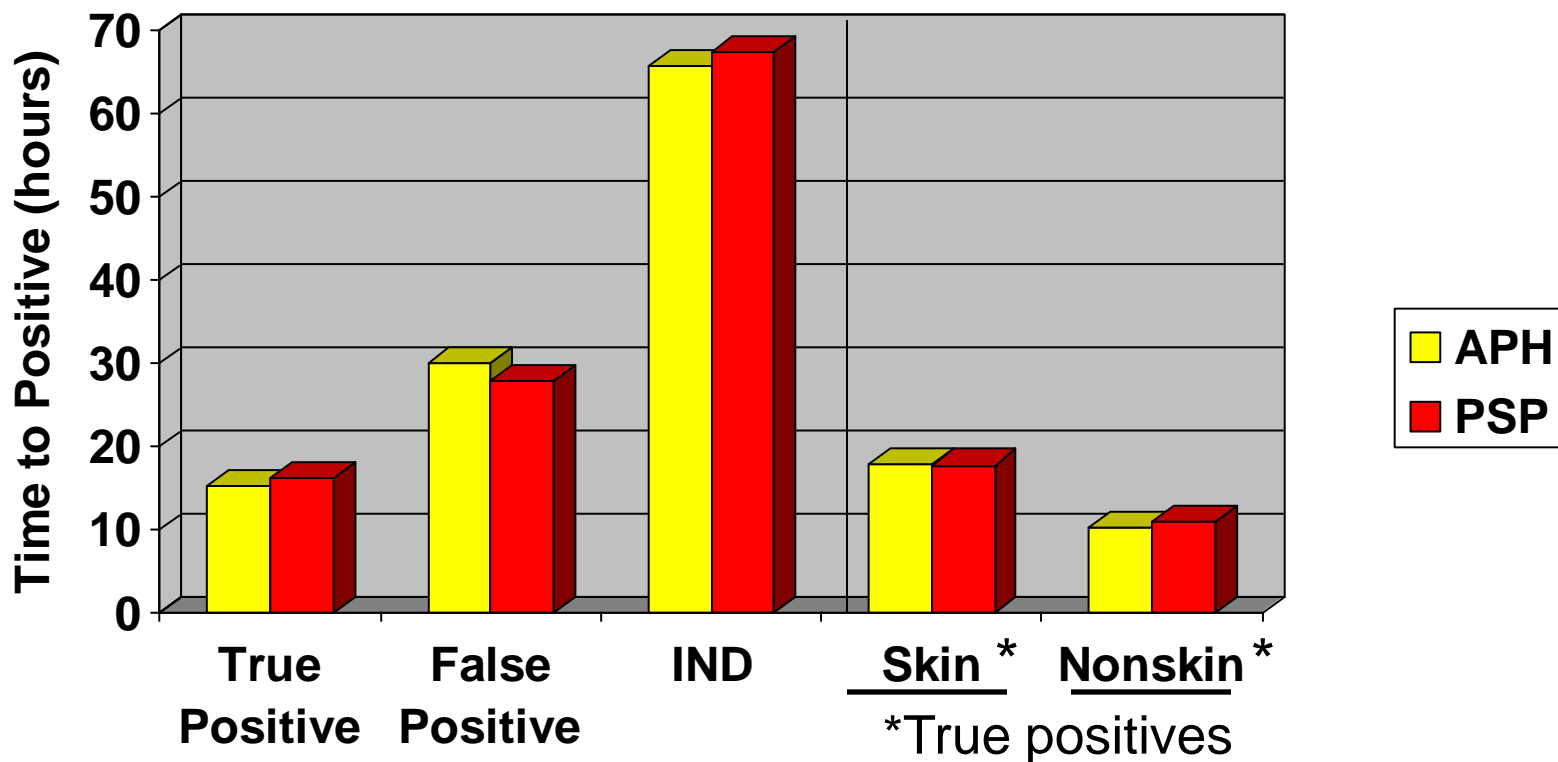
Results: True positives, by isolate

Likely skin vs. Nonskin



Time to Positive Culture Result

2007-2010



APH (n)	335	218	85	218	117
PSP	123	46	31	93	30

Transfusion Outcomes

		Donations (components) or Pools (n)	Transfused before initial positive (n)
APH	True positive	3 (7)	4
	False positive	15 (37)	16
	Indeterminate	45 (81)	75
	Total		95
PSP	Indeterminate	28	28

No septic reactions associated with delayed positive QC results

1 febrile nonhemolytic transfusion reaction but residual unit cultured negative at the hospital (QC initial bottle, corynbacteria day 4)

Apheresis platelets

- Risk of sepsis with APH ~ 1 per 100,000 components
 - 33 septic reactions (30 donations); ~ 3 million APH platelets distributed Jan 2007 – Dec 2010
- All donations had negative QC cultures through 5 day shelf life
- 31 of 33 (94%) implicated likely skin organisms
 - 20 Coagulase-negative *staphylococcus*
 - 8 *Staphylococcus aureus*
 - 2 *Streptococcus* sp.
 - 1 Acinetobacter

PSP platelets

- No septic transfusion reactions have been reported
- 147,844 PSP WB-platelets distributed Jan 2007 – Dec 2010

PSP has a 3-6 fold higher bacterial detection rate than apheresis platelets

- Likely reflects the donor-related risk of skin contamination and possibly asymptomatic bacteremia (5 donors/platelet pool)

No difference in the time to positive results based on interpretation or isolate (skin vs. nonskin)

No greater risk of reported septic transfusion reactions

The residual risk of bacterial sepsis after apheresis platelet transfusion (~1 per 100,000 components distributed) is entirely due to the limitation of current QC culture to detect all contaminants (ie. false negatives), most of which arise from the skin