

# ABC Member Survey: impact of PASSPORT suspension

Responses from

- 16/18 ABC PASSPORT participants
- 40/57 Non-participants

# Apheresis platelet availability

- 10/16 participants need 3-6 months to reach prior distribution goals
  - 5/16 need >6 months
- 5 larger centers need to increase pheresis collections 1,000-6,000 units/year to compensate for increased outdates from ~3% to 10%
- 1 center will replace losses with prepooled platelets from whole blood (Acrodose®)
- 3/16 will increase distribution of whole blood derived platelets by 20-30%
- 5/40 non-participants responded that discontinuation of PASSPORT affected their operations

# Bacterial Detection

- 4/15 changed bacterial detection procedure from 2 bottles (aerobic+anaerobic) to single aerobic bottle
  - 2 plan change in near future
- 6/15 reduced incubation to product release after inoculation to <24 h

# TRALI Mitigation

- 11/15 participants say discontinuation requires delay in the timeline for TRALI mitigation plans for platelets
  - 7 for ~6 months
  - 4  $\geq 9$  months
- 4/40 non-participants delayed implementation of TRALI mitigation by 6 months or more

# A risk assessment of the consequences of discontinuation of seven day storage of apheresis platelets (PASSPORT) on recipient safety

Prepared by AABB ad hoc subcommittee

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# The issues

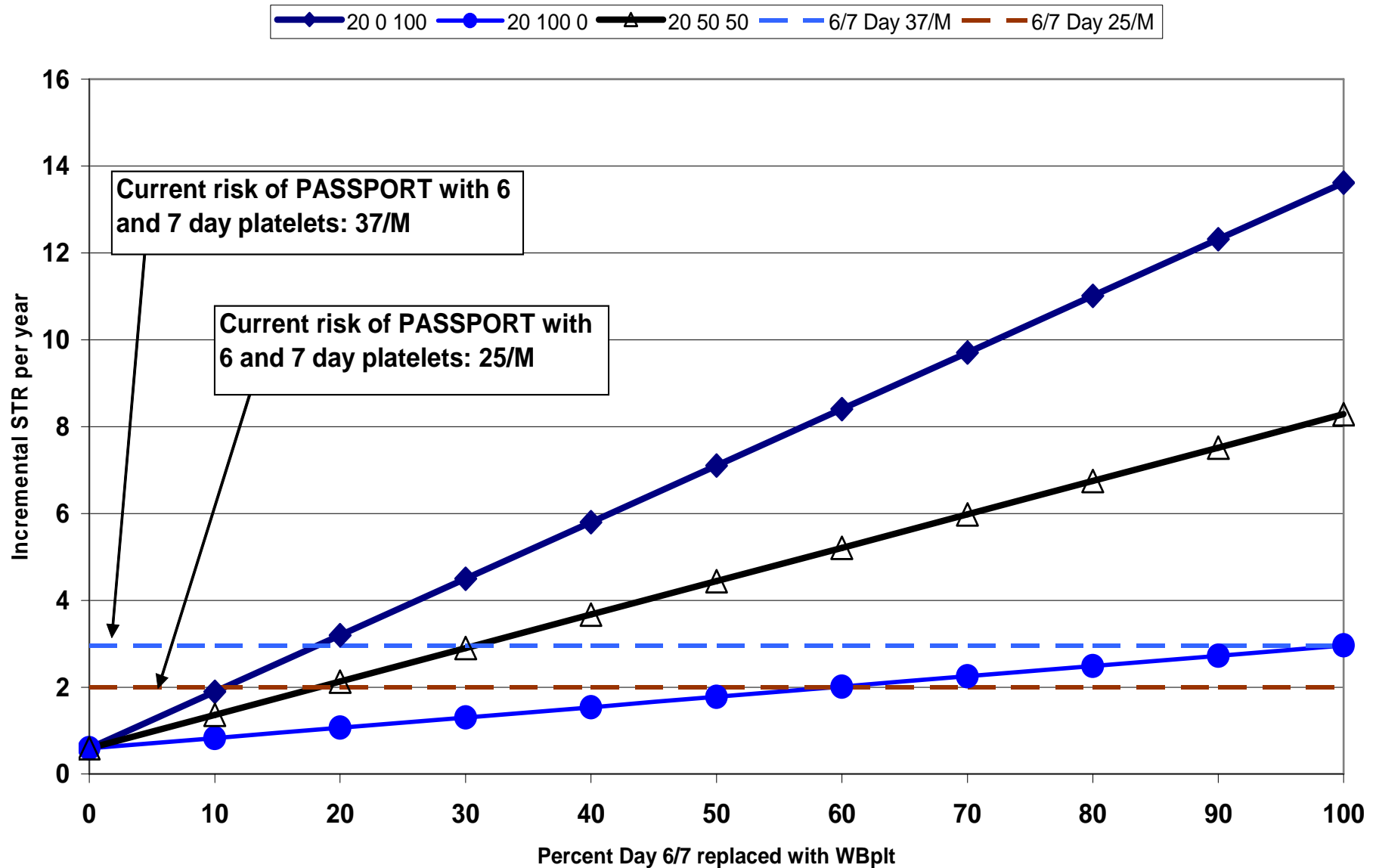
- PASSPORT discontinued after preliminary report of  $778/10^6$  (95% CI 94-2807) culture positive 7-day platelets
- Sensitivity model developed to explore the risk reduction for clinical sepsis by limiting bacterially screened single donor apheresis platelets (SDP) to a 5 day shelf life
- Second model developed to assess the range of impacts of delays in *TRALI mitigation strategies* with the reversion to 5 day platelets and increased apheresis platelet outdates

# Some assumptions

- 400,000 PASSPORT platelets/year (ABC)
- Platelet shortfall replaced with combinations of 5D apheresis, WBD<sub>surr</sub>, WBD<sub>cult</sub>
- STR (95% CI) @ 5D =  $7.4/10^6$  (2.5-16) (ARC)
- Clinical risk 5D=6D=7D
- ~20% transfused days 6 or 7 (BSI and MVRBC)
- WBD<sub>cult</sub> pools of 5 units = 5 x risk of apheresis (ARC)
- WBD<sub>surr</sub> 4.6 x risk false negative c.f. cultured  
(*Transfusion* 2006; 46: 636)
- Replacement platelets distributed without bias over shelf life

# **PASSPORT Discontinuation Sensitivity Analysis** Assuming 7.4/M STR rate for 5-day labeled SDP

Legend shows:  
 Percent Day 6/7  
 Percent WBplt with culture screen  
 Percent WBplt with surrogate





# STR: risk of platelets transfused on D5

Labeled shelf life	Replacement inventory mix			Annual no. STR	
	SDP	WBD <sub>cult</sub>	WBD <sub>surr</sub>	5D risk = $7.4/10^6$	5D risk = $16/10^6$
7D (PASSPORT)	100%	0%	0%	2-3*	4-6*
5D	100%	0%	0%	0.6	1.3
5D	50%	50%	0%	1.8	3.8
5D	0%	100%	0%	3.0	6.4
5D	50%	25%	25%	4.4	9.6
5D	0%	50%	50%	8.3	17.9
5D	0%	0%	100%	13.6	29.4

\* = when platelets transfused on day 6 & 7

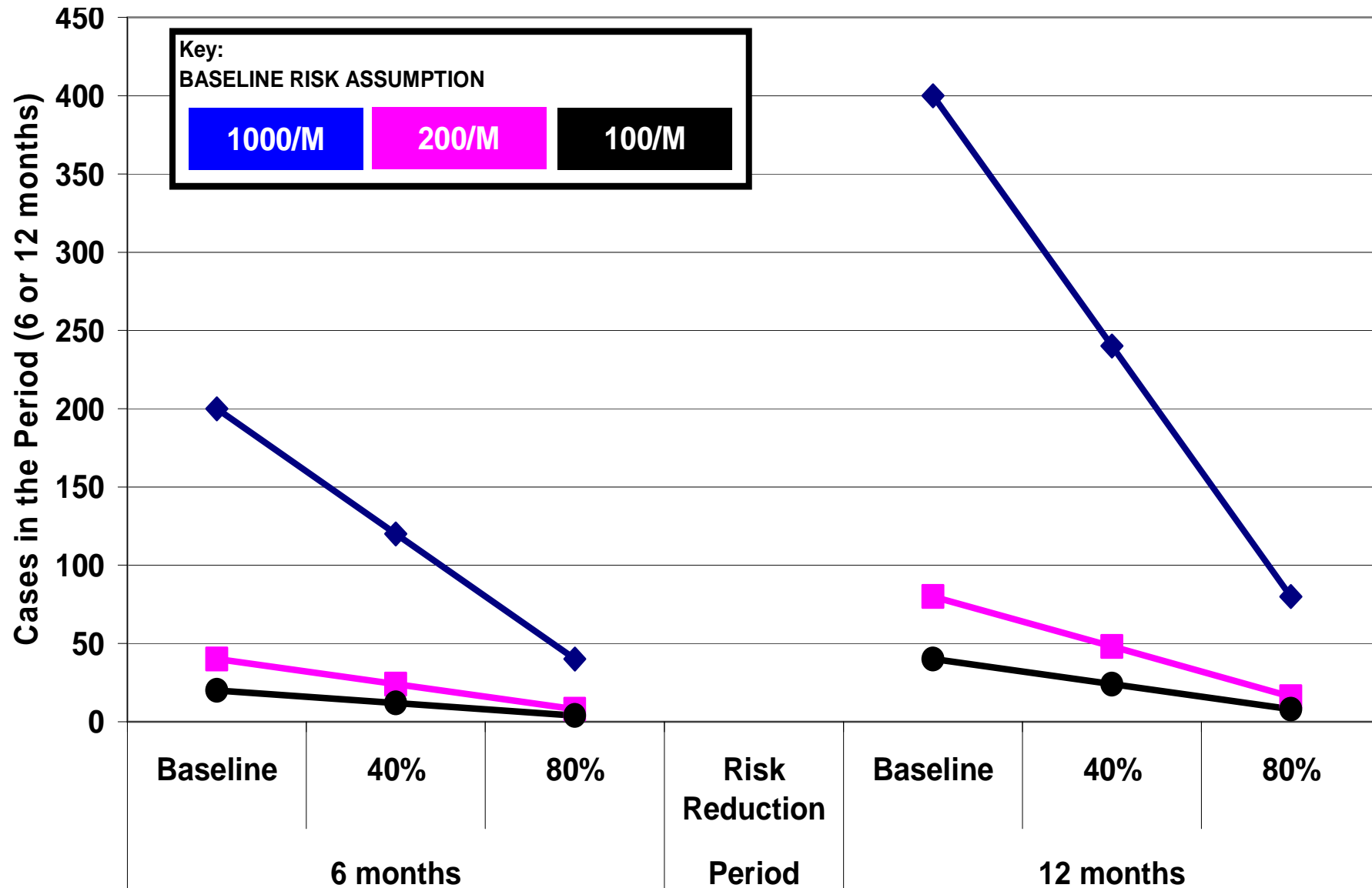
## Conclusions: STR

1. Replacing 7D SDP entirely with 5D SDP will reduce current risk avoiding 2 STR/yr. Worst-case analysis with the upper bound of ARC STR estimate suggests up to 6 STRs/yr may be avoided.
2. Replacing 7D SDP with 5D WBD<sub>surr</sub> screened is likely to increase STR risk.
3. Replacing 7D SDP with 5D WBD<sub>cult</sub> screened will not reduce risk of STR.

# TRALI assumptions

- Risk of TRALI from platelets unknown
  - 1/500-1000 (1000/10<sup>6</sup>) (Mayo)
  - 1/5000 (200/10<sup>6</sup>) (Popovsky *et al*)
  - 1/23000 (43/10<sup>6</sup>) (Canadian passive surr.)
- Risk reduction from HLA or gender-screening of apheresis platelet donors 40-80% (UK SHOT and others)
- TRALI risk from SDP is independent of storage day at transfusion
- TRALI risk of 5 unit pool of WBD is equivalent to that of SDP
- 6 or 12 month delay in “optimal” TRALI mitigation to replace 6% of platelet inventory that must be replaced (increased outdates) with reversion to 5D dating (BSI and MVRBC)

# Est. TRALI cases with 6 or 12 month delayed implementation of mitigation actions (400,000 7D platelets)



# Est. TRALI cases with 6 or 12 mo. delayed implementation of mitigation efforts

Mitigation delay	Total cases in interval				Cases not avoided from baseline	
	Baseline risk/ $10^6$	Baseline Cases	40% risk reduction	80% risk reduction	40% risk reduction	80% risk reduction
6 mo.	1000	200	120	40	80	160
	200	40	24	8	16	32
	100	20	20	4	8	16
12 mo.	1000	200	240	80	160	320
	200	40	48	16	32	64
	100	20	24	8	16	32

# Conclusions: TRALI

- If discontinuation of PASSPORT delays TRALI mitigation measures, 8 to 160 potentially avoidable TRALI cases may be observed with 6 months and 16 to 320 with 12 months delay.
- Delay in TRALI interventions due to PASSPORT discontinuation may result in more TRALI cases in 6 months than the anticipated maximum number of septic transfusion reactions avoided in one year.

# Transfusion fatalities reported to FDA

	FY 2005		FY 2006		Total	
	No.	%	No.	%	No.	%
TRALI	<b>29</b>	47%	<b>35</b>	56%	<b>64</b>	51%
	Attributed to apheresis platelets				<b>6</b>	
	Attributed to multiple components				<b>9</b>	
HTR (not ABO)	15	26%	9	14%	25	20%
Sepsis	<b>8</b>	13%	<b>7</b>	11%	<b>15</b>	12%
	Attributed to apheresis platelets				<b>8</b>	
HTR (ABO)	6	10%	3	5%	9	7%
TACO	1	2%	8	13%	9	7%
Other	2	3%	1	2%	3	2%
Total	<b>62</b>		<b>63</b>		<b>125</b>	

<http://www.fda.gov/cber/blood/fatal0506.htm>

# Conclusion

Suspension of PASSPORT may avoid 2-6 STR/year while resulting in an increased number of TRALI cases.

A comprehensive risk assessment conducted prior to the decision to discontinue PASSPORT would have allowed for a more informed debate about whether the risks of continuing PASSPORT exceeded the risks of its discontinuation.



# Members of the subcommittee

- Larry Dumont, Dartmouth-Hitchcock
- Mark Brecher, UNC
- Steven Kleinman, UBC and AABB
- Peter Tomasulo, BSI
- Richard Benjamin, ARC
- Celso Bianco, ABC
- Ognjen Gajic, Mayo
- Louis Katz, MVRBC

