

Delayed Donor Reactions

Data from AABB Donor Vigilance
System and from Blood Systems, Inc.

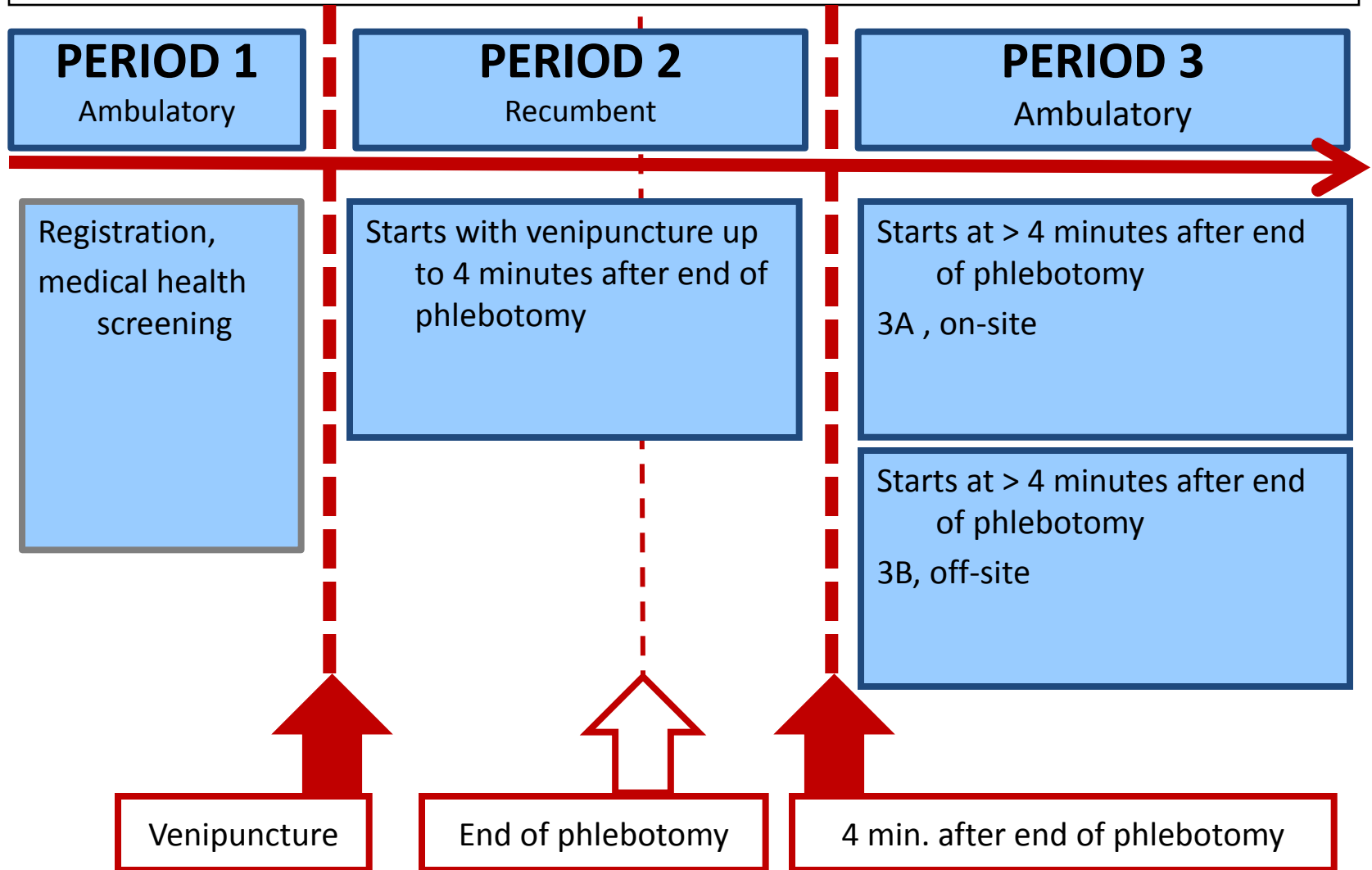
Delayed Donor Reactions

BSI DONOR VIGILANCE DATA

Rate of Adverse Events by Donation Type

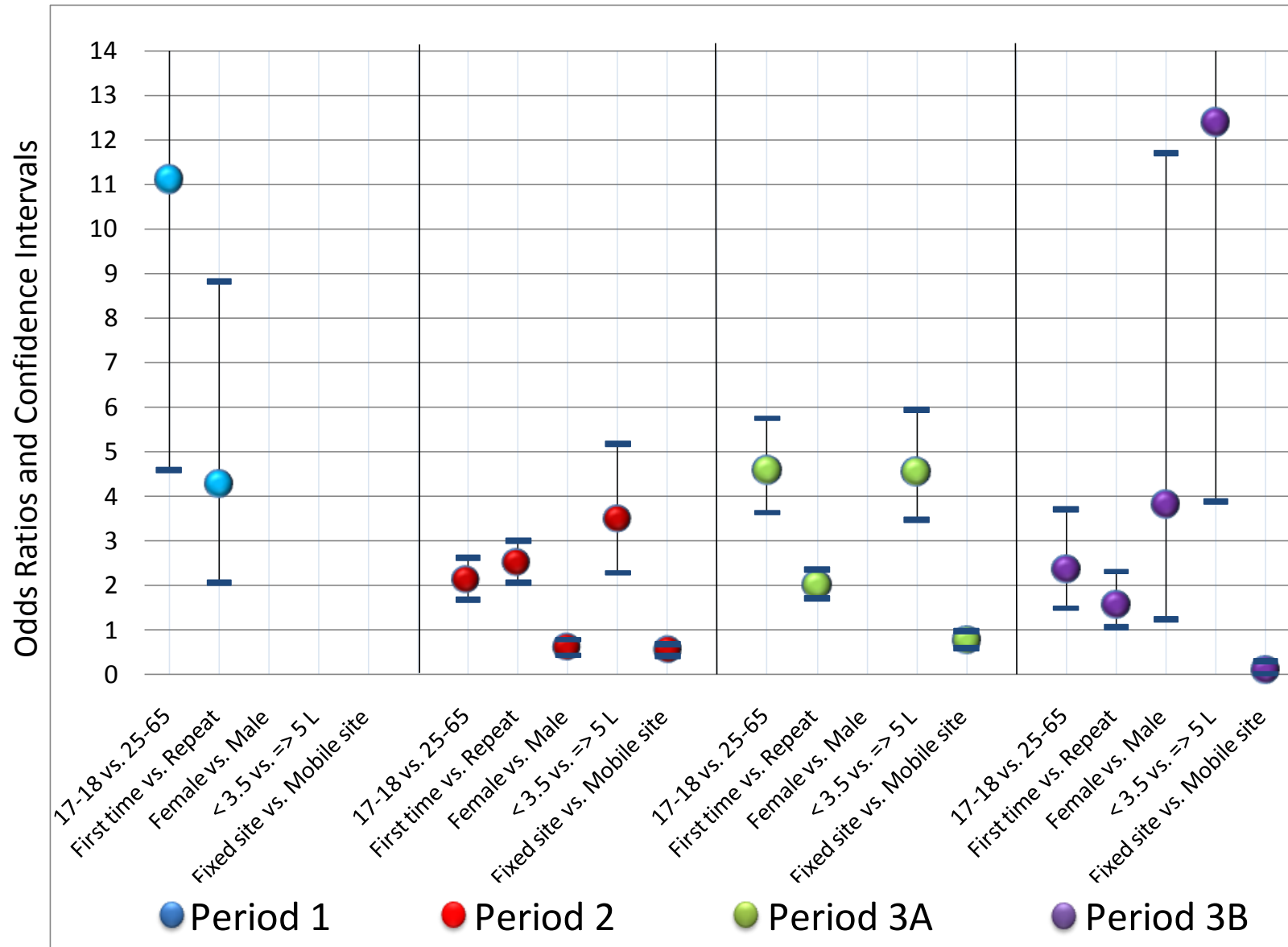
Collection Procedure (N)	Whole Blood (555,186)	2 RBCs (165,064)	Multi-Comp (18,895)	Plts +Plasma (55,002)
Rate	/10,000	/10,000	/10,000	/10,000
LOC	26.8	7.5	21.7	3.5
Fall	2.0	0.1	1.1	0.7
Head Trauma	0.6	0.0	0.5	0.2
Other Injury	0.6	0.1	0.5	0.0
Outside Medical Care	4.3	0.9	2.1	0.9

Time course of blood donation

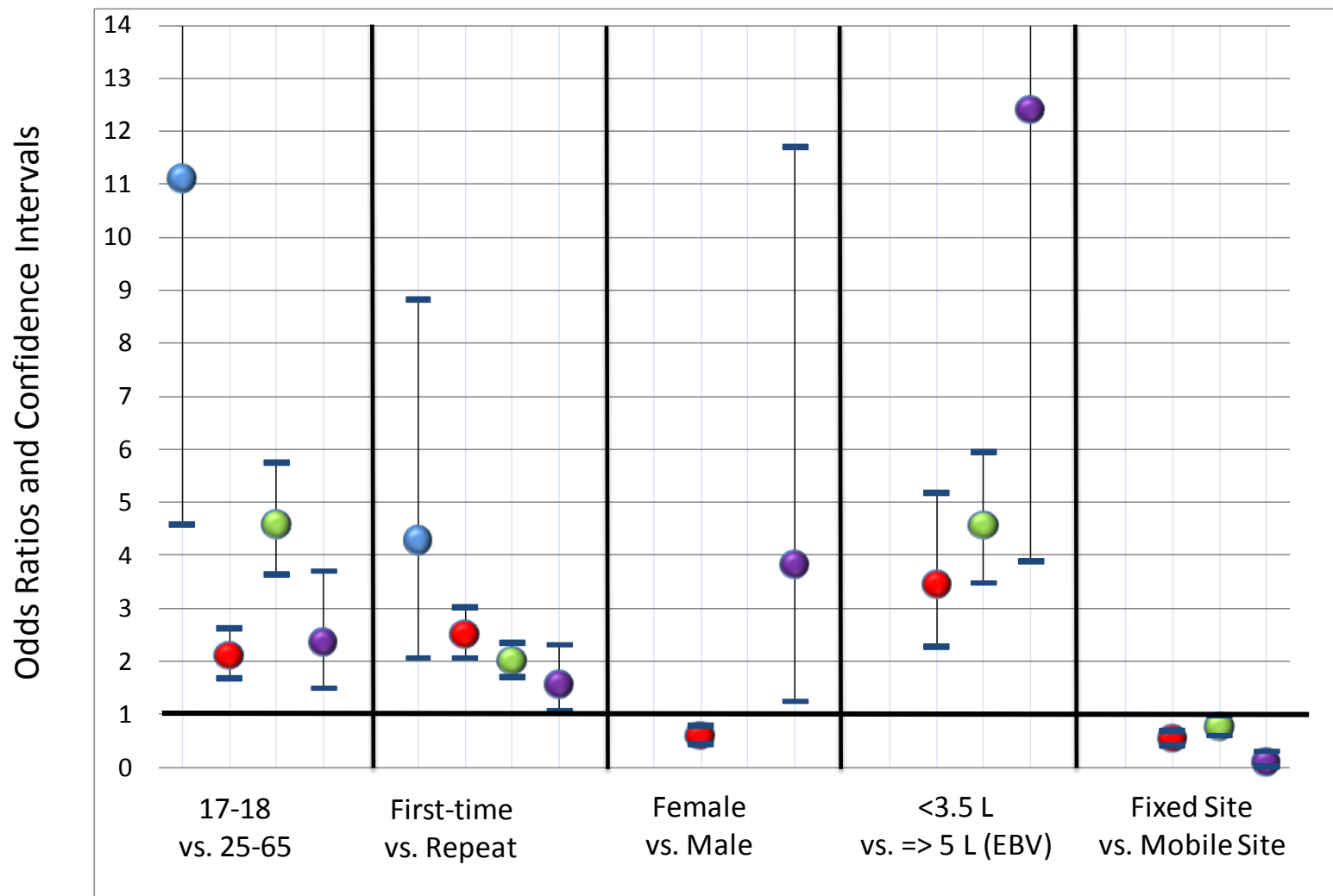


Fainting: Summary of Multivariable Model By Period

Adjusted Odds Ratios Across Time Course of Blood Donation

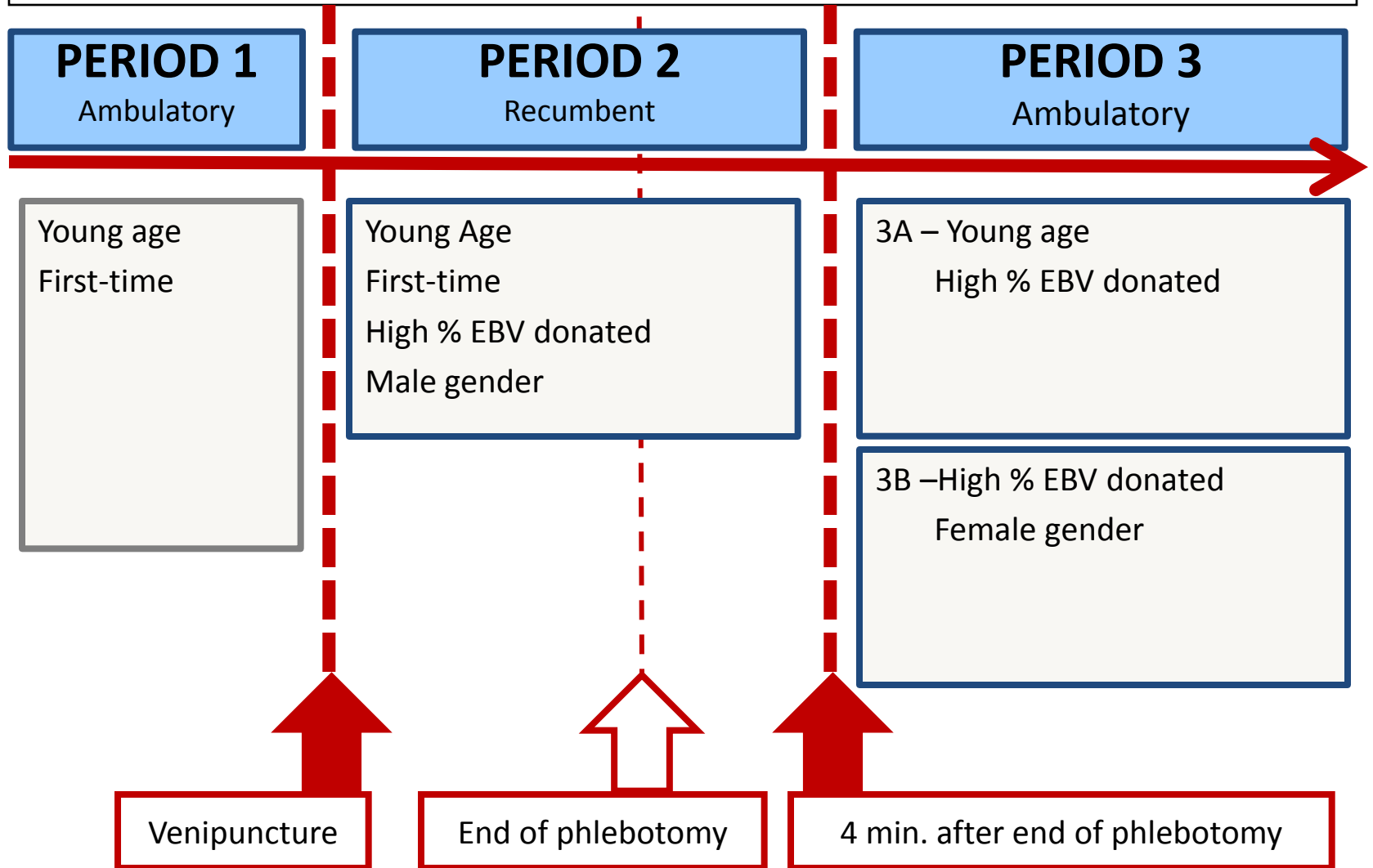


Fainting: Summary of Multivariable Model (Donor / Donation Characteristics) Adjusted Odds Ratios Across Time Course of Blood Donation

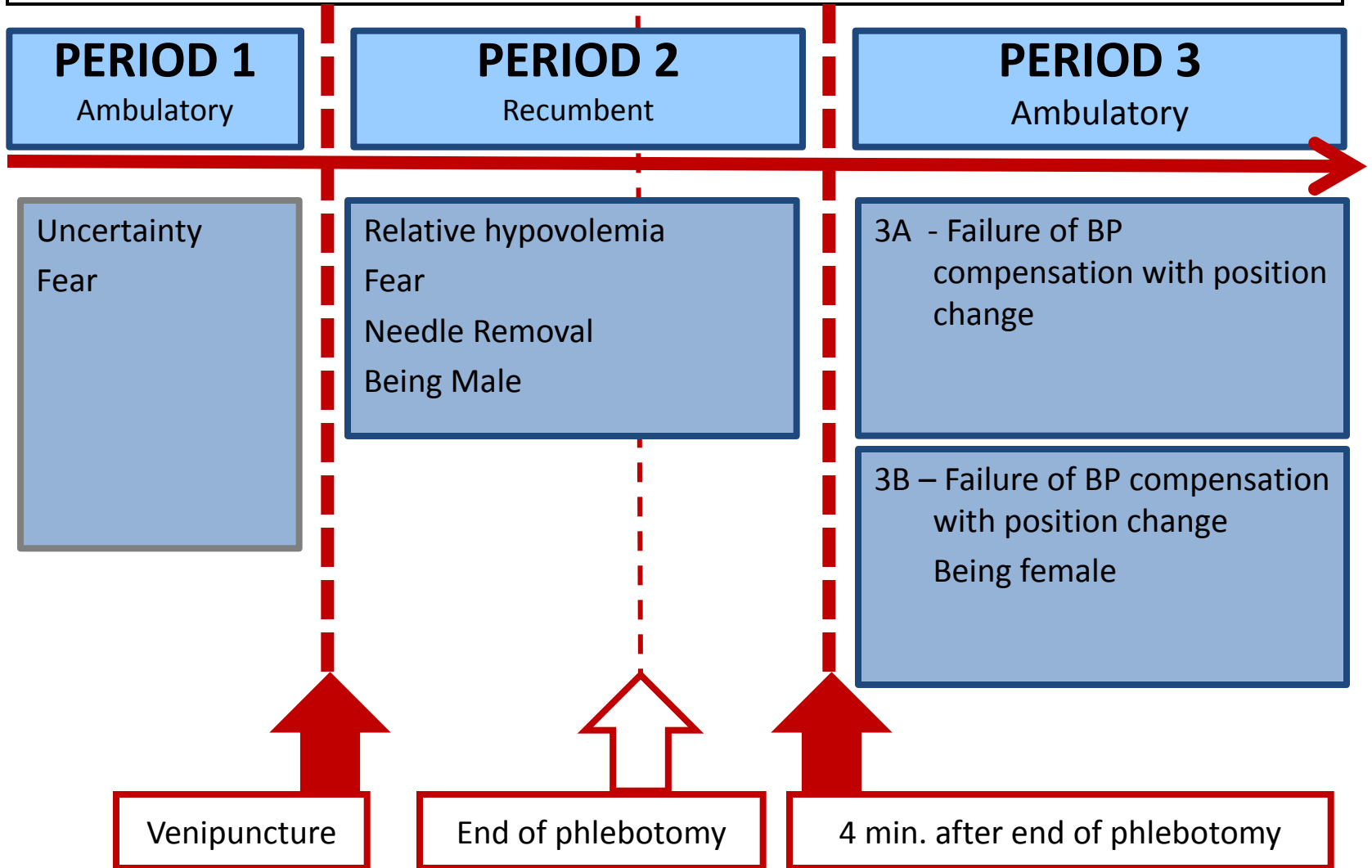


● Period 1 ● Period 2 ● Period 3A ● Period 3B

Factors associated with fainting

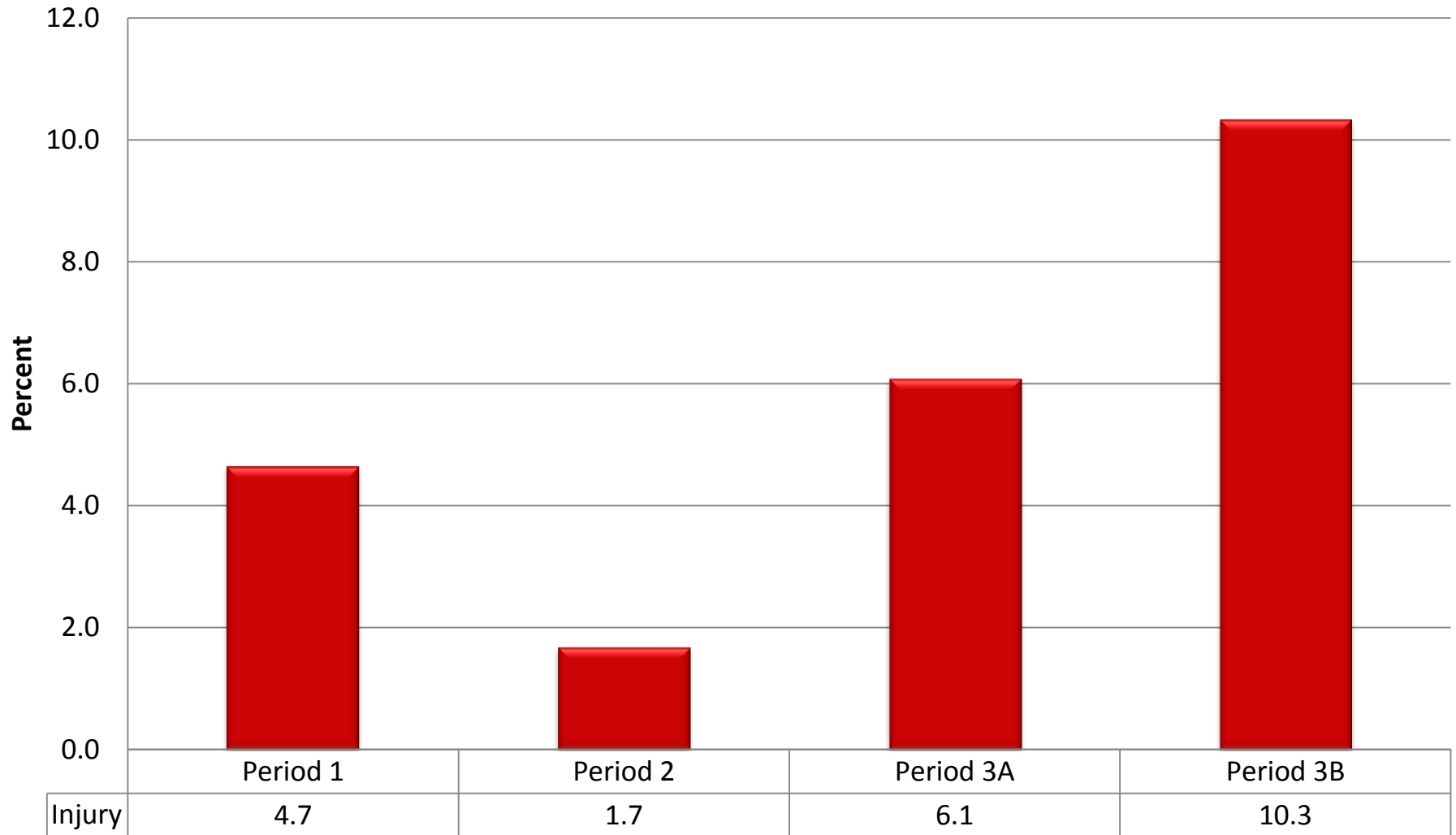


Possible Underlying Mechanisms



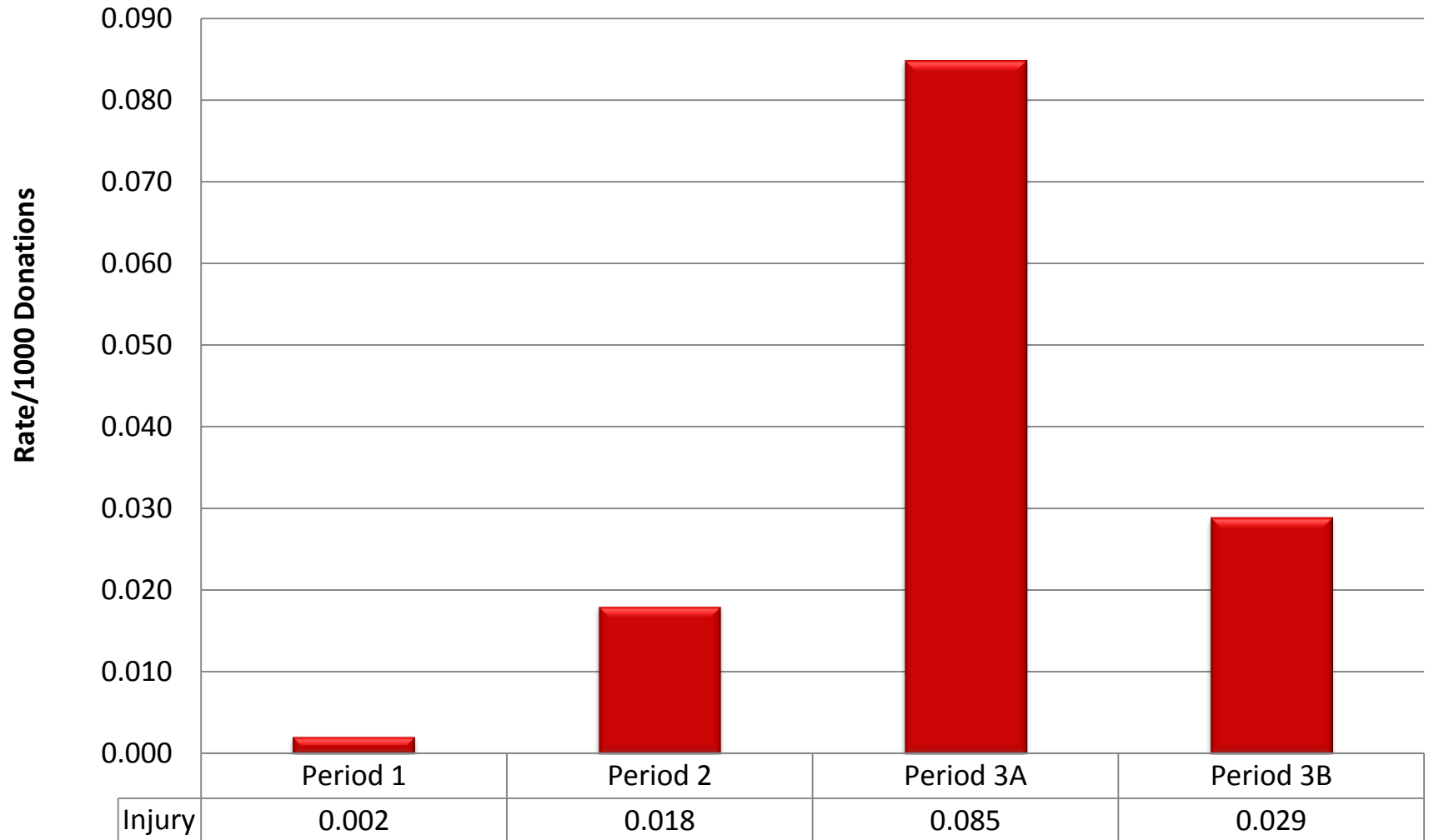
Injury/ 100 Faints

(both Males and Females)



Injury/1000 Donations

(both Males and Females)



What do we know/do about injury?

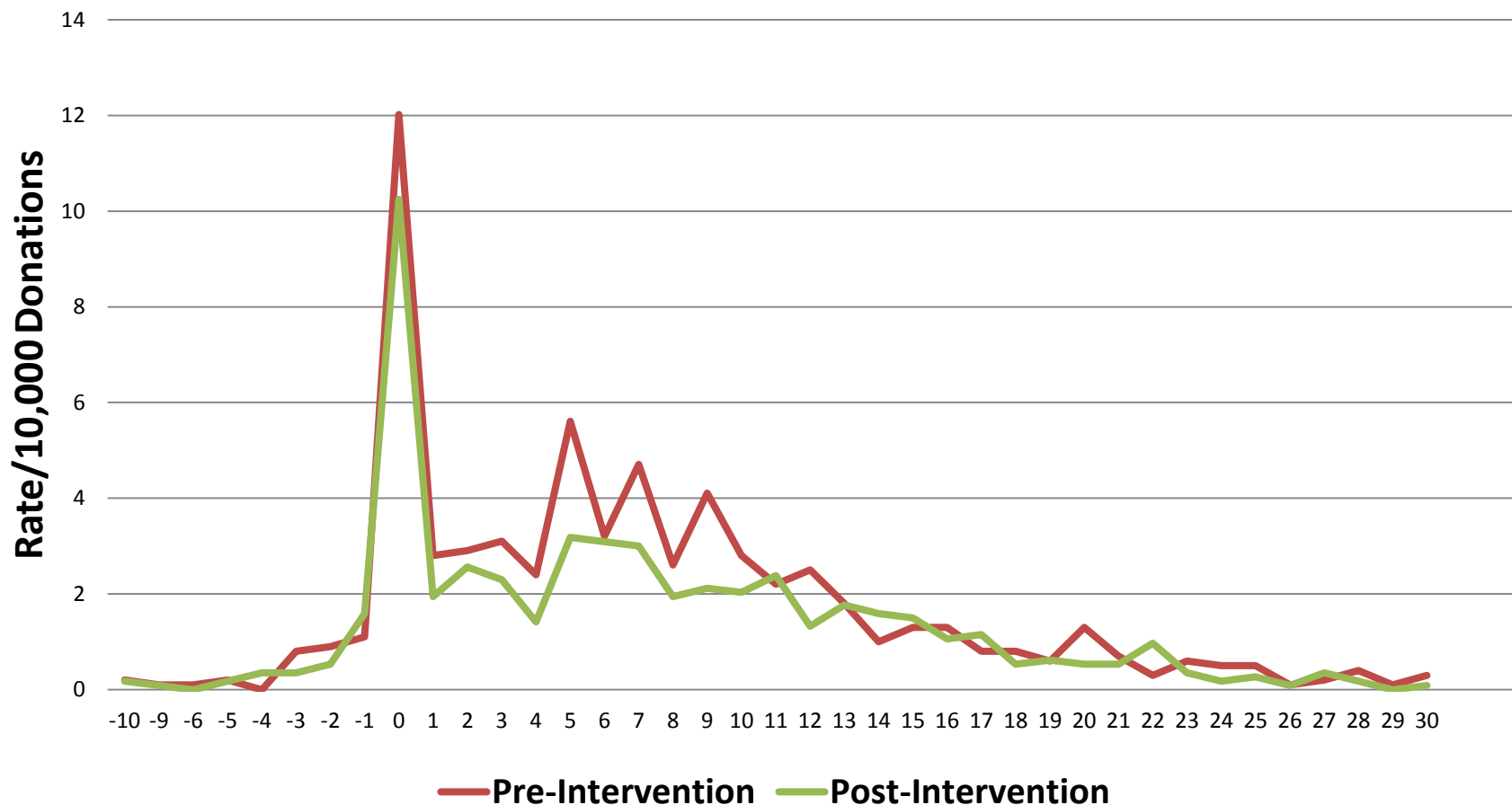
- Period 3 – injury period (upright and hypovolemic)
- Injury most associated with LOC after standing up
- Fainting while upright is most associated with high % EBV donated and off-site with female gender
 - Female [stiffer] heart fills more slowly
 - Lack of compensation for orthostatic change is associated with relative hypovolemia, % EBV lost
- Improving compensation for orthostatic change should reduce risk
- Can we reduce risk of injury without lowering donation limit [to 13% of EBV] for young donors?

Intervention #1 (7/2008 – Young Donors)

- Recruit higher EBV donors (or collect smaller units)
- < 15% EBV/donation
- Accept 16 yo donors
- 500 ml water offered < 30 minutes before donation
- Muscle tensing encouraged during phlebotomy
- 15 minutes in refreshment area
- Monitor refreshment area at high schools
- Educational sessions with school RNs
- Instruction manual for school RNs
- Discharge sheet for HS reactions
- Inform school RN of reaction for monitoring
- Inform parents of reaction

RESULTS FROM INTERVENTION #1

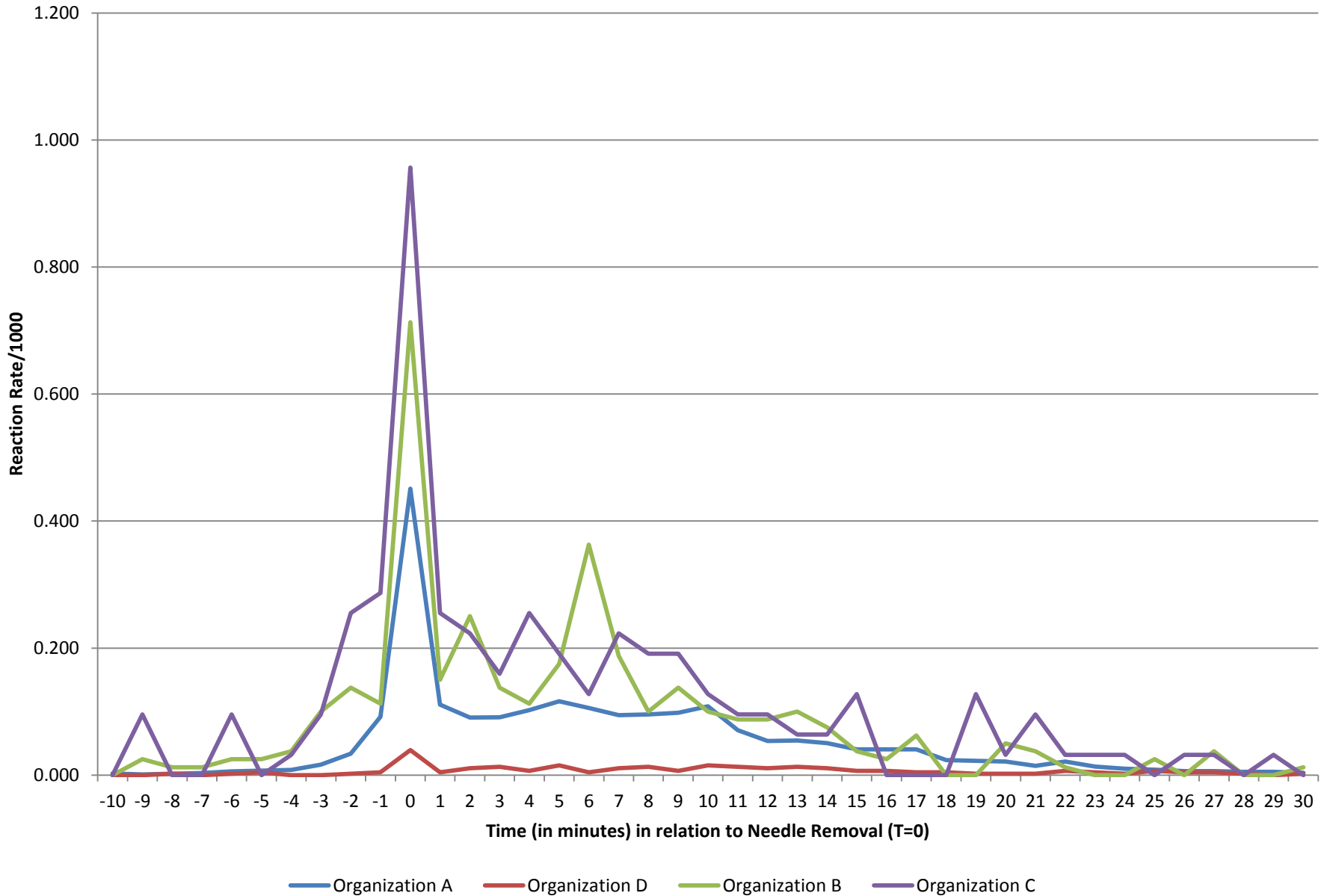
**Comparison of LOC Rate Across Time Course of
Donation:
Pre- and Post-intervention, all 17-22 y/o donors**



Delayed Donor Reactions

AABB DONOR VIGILANCE DATA

Reaction Time Relative to Needle Removal



Summary of Data from AABB Donor Vigilance Participants

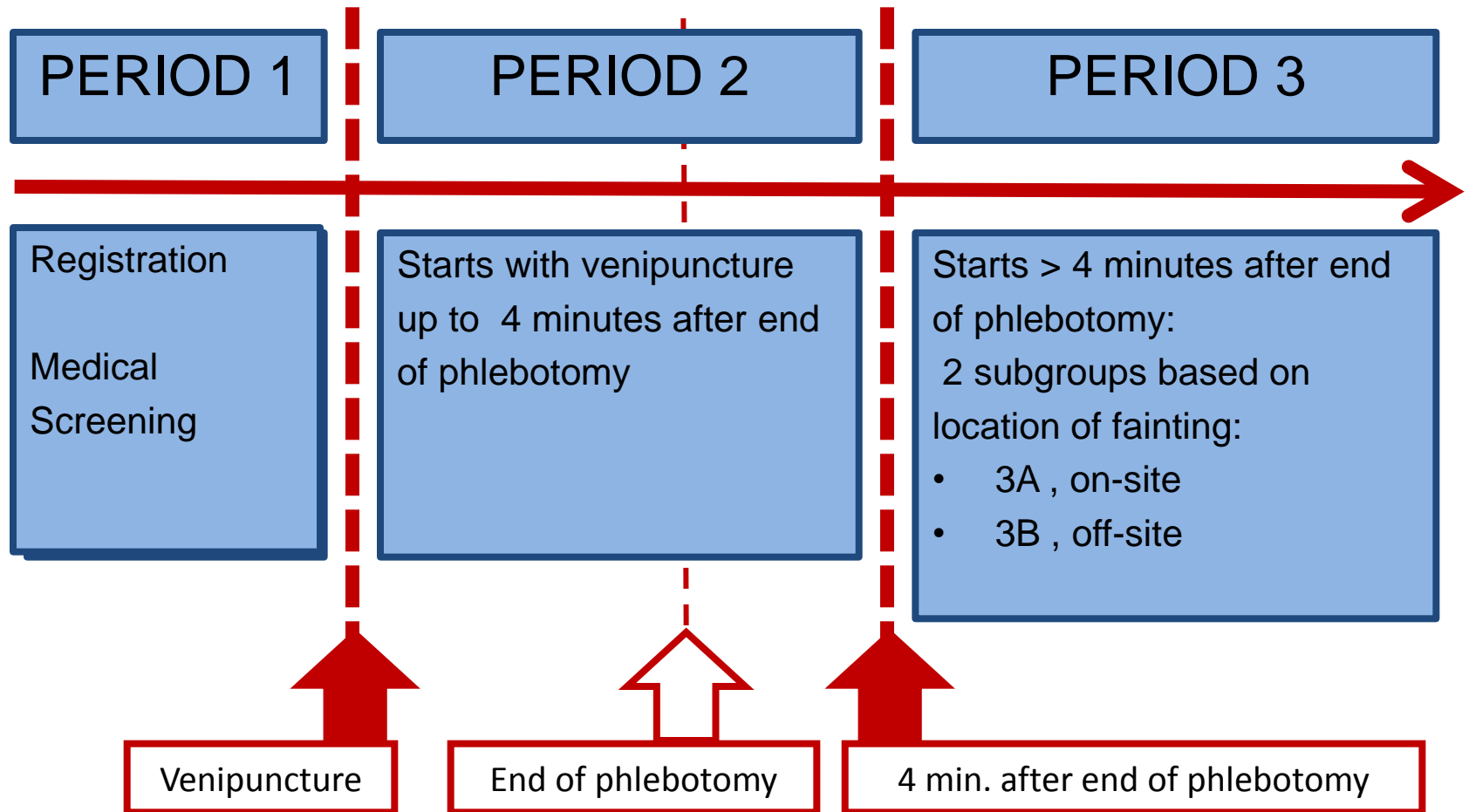
(January 2013)

	Organization					TOTAL
	A	B	C	D	E	
Participation (# of months)	38	42	12	39	12	143
Allogeneic WB Donations	1865204	79922	31363	456077	168941	2601507
Allogeneic WB Donations with LOC	4867	302	167	1046	497	6879
LOC Rate/1000 Donations	2.6	3.8	5.3	2.3	2.9	2.6
Allogeneic WB Vasovagal Reactions with LOC and Time of Reaction	4821	301	164	245	479	6010
% with Temporal Information	99	100	98	23	96	87
Type of Participation / Data Upload	File Upload	File Upload + Manual Updates	Manual + Possible File Upload (tested)	File Upload + Manual Updates	File Upload + Manual Updates	

5 Pilot centers Contributing Data to AABB Donor Vigilance System

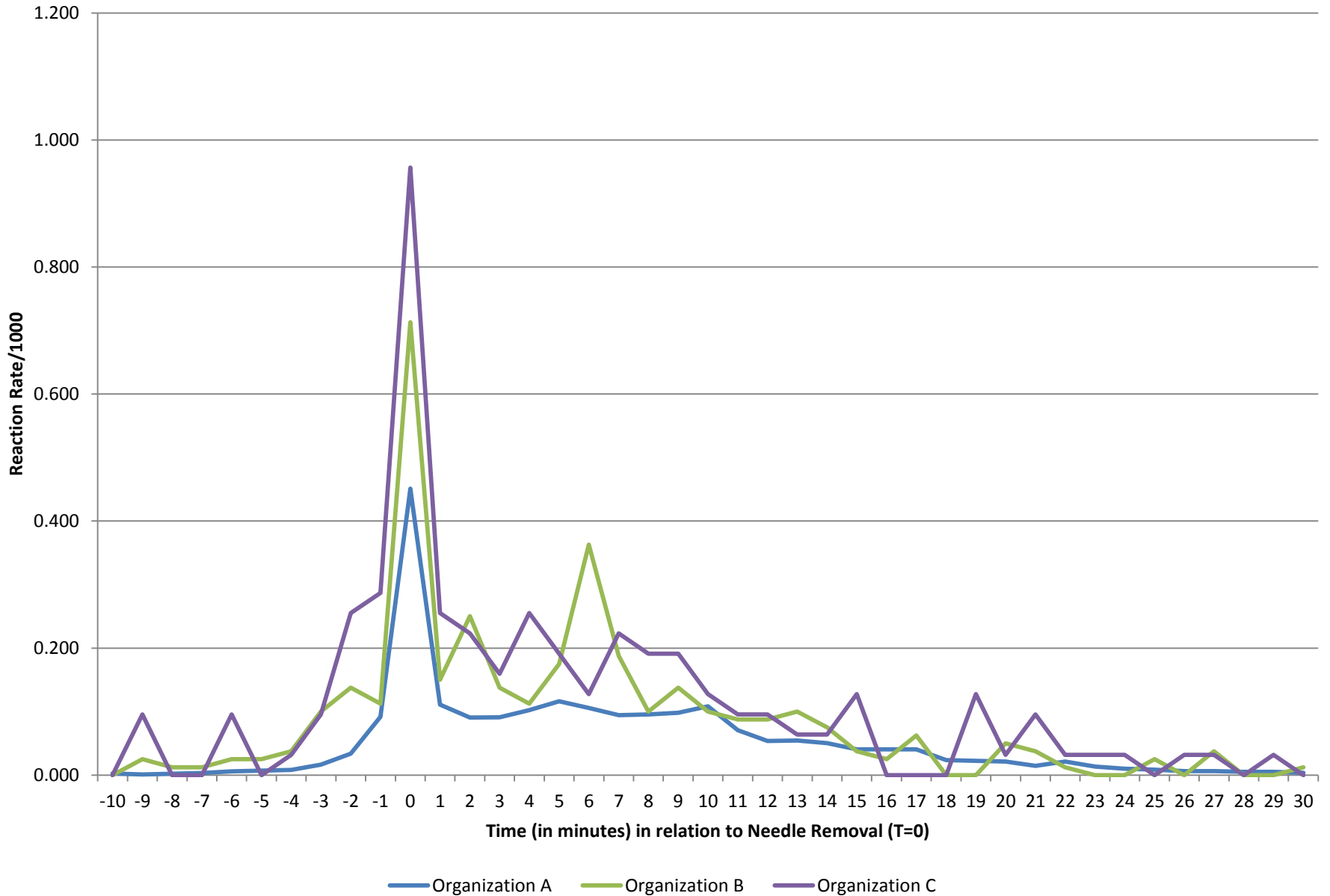
	A	B	C	D	E
Numerator (# reactions)	Yes	Yes	Yes	Yes	Yes
Denominator (# donations)	Yes	No	No	No	Yes
Time Needle Inserted; Removed; Reaction Start Time	Yes	Yes	Yes	Low %	No
Temporal Information Based on Reaction Location	yes	Yes	Yes	Low %	Yes. But Missing Data is treated as "Bed" (period 2)
Height (and EBV)	Yes	No	Yes	Low %	No

Time Course of WB Donation



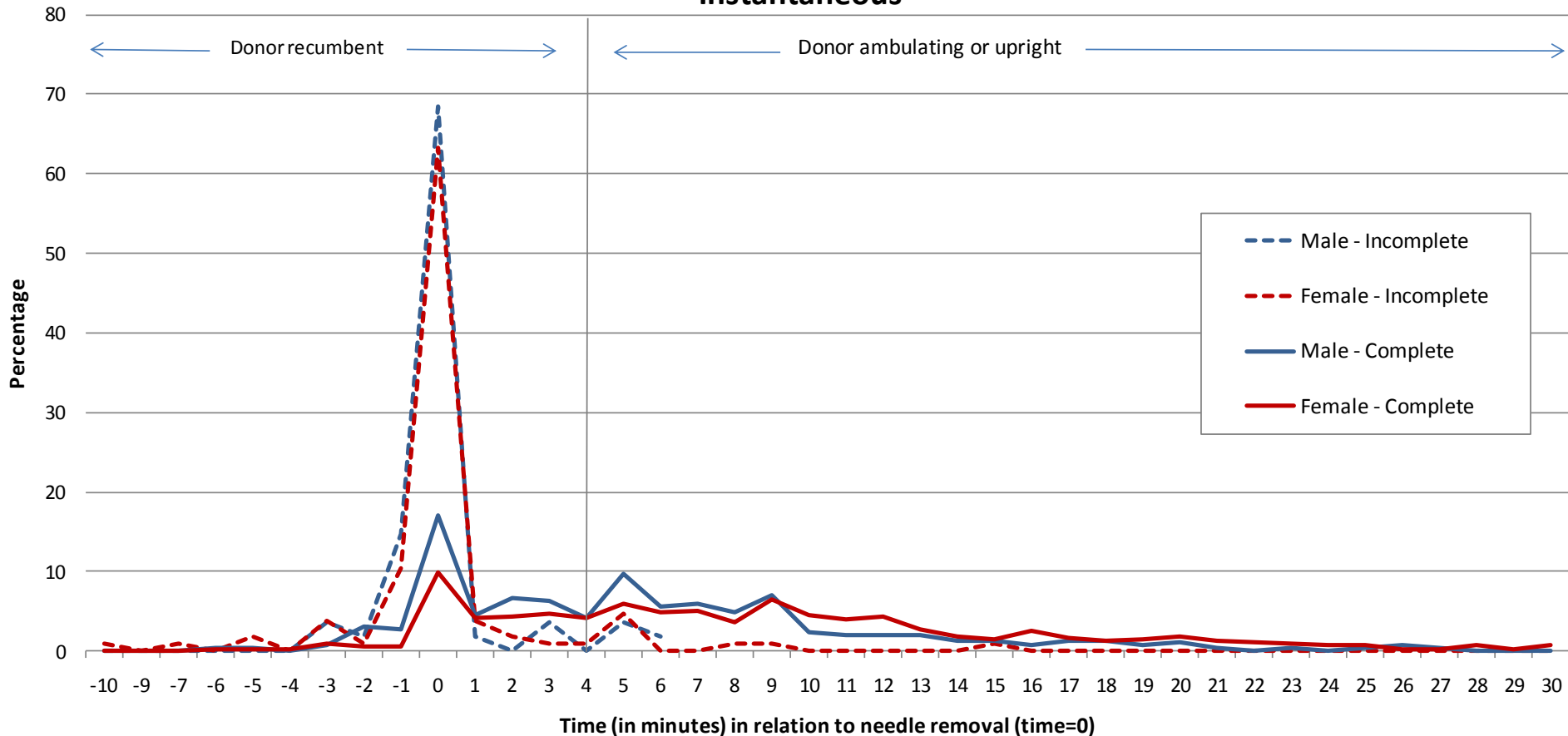
Multivariable logistic regression analysis to identify factors associated with fainting

Reaction Time Relative to Needle Removal



Vasovagal Syncope Onset Time Distribution in Complete and Incomplete WB Donations, 2007

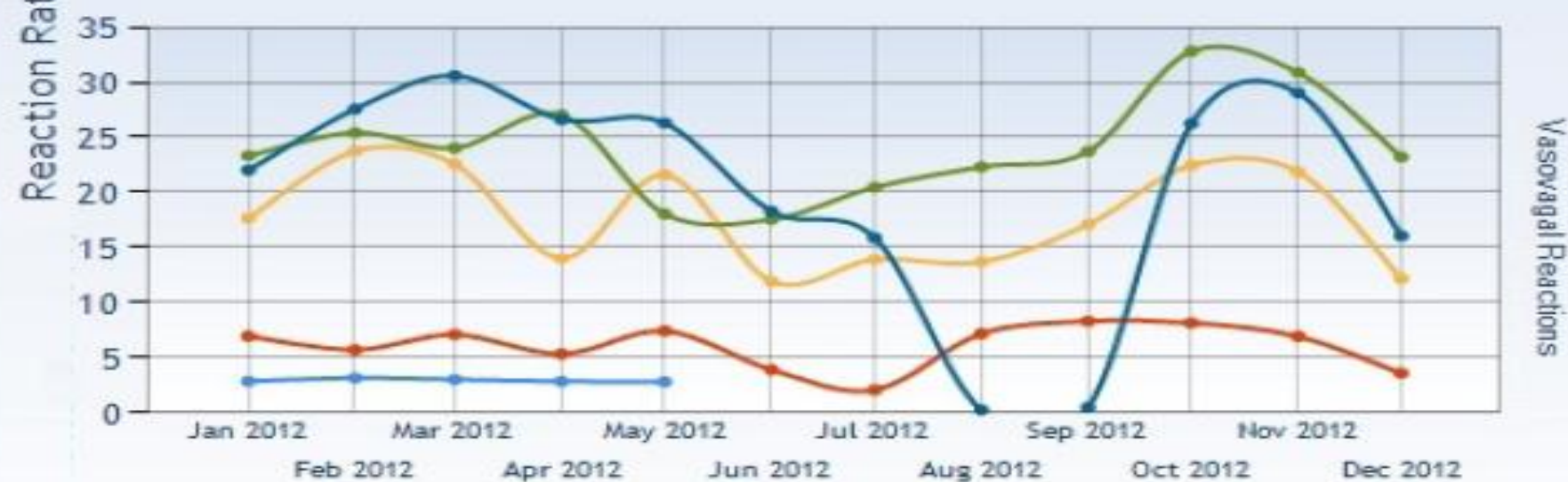
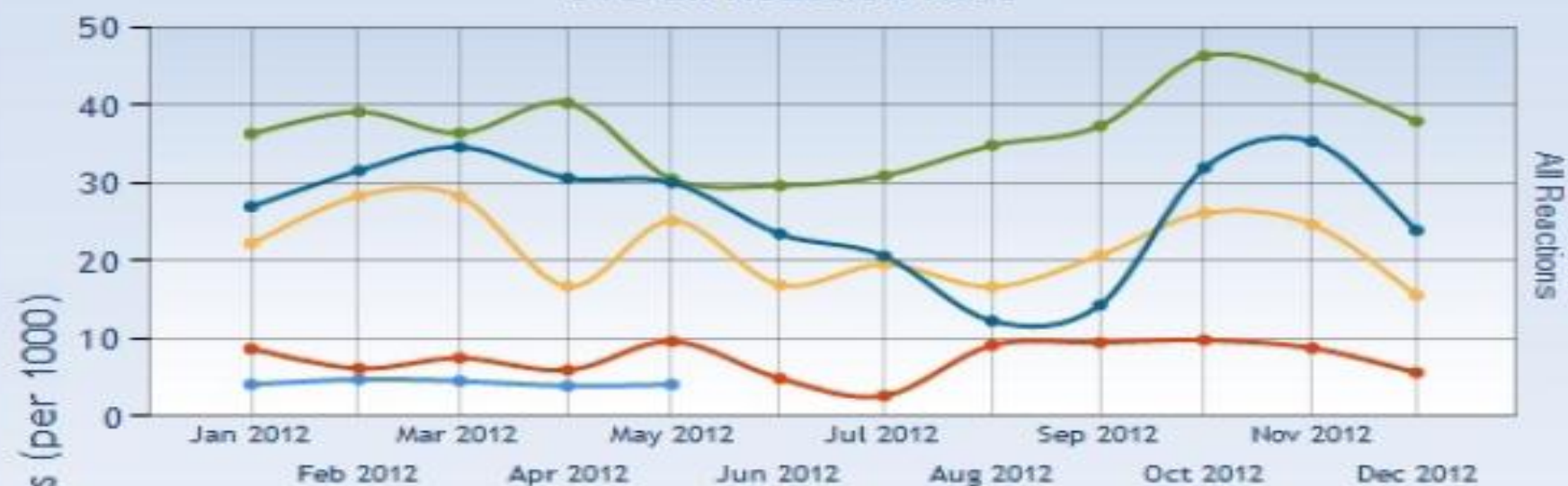
Instantaneous



LOC rate/10,000 WB Donations (DonorHART)



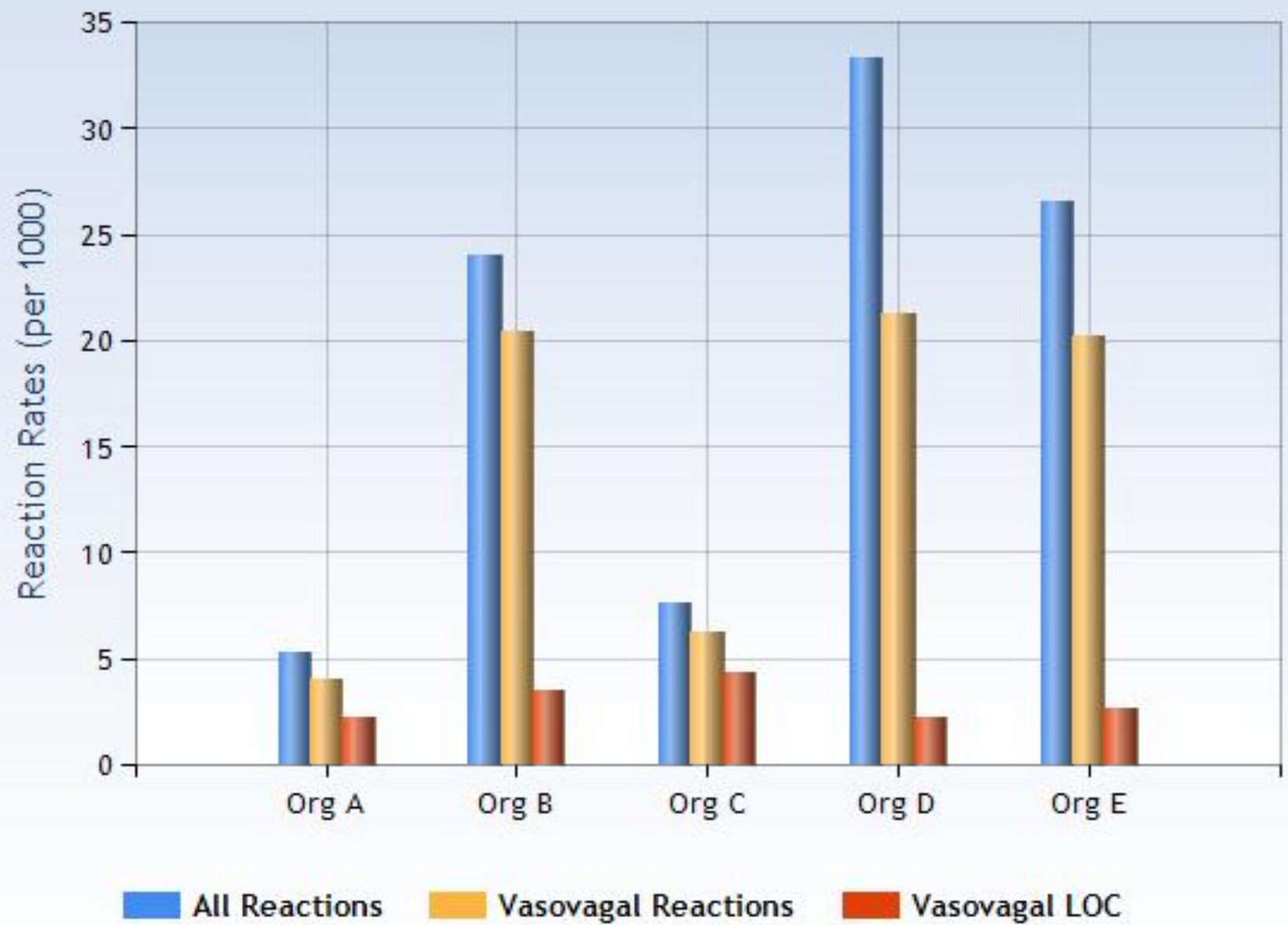
Overall Reaction Rate



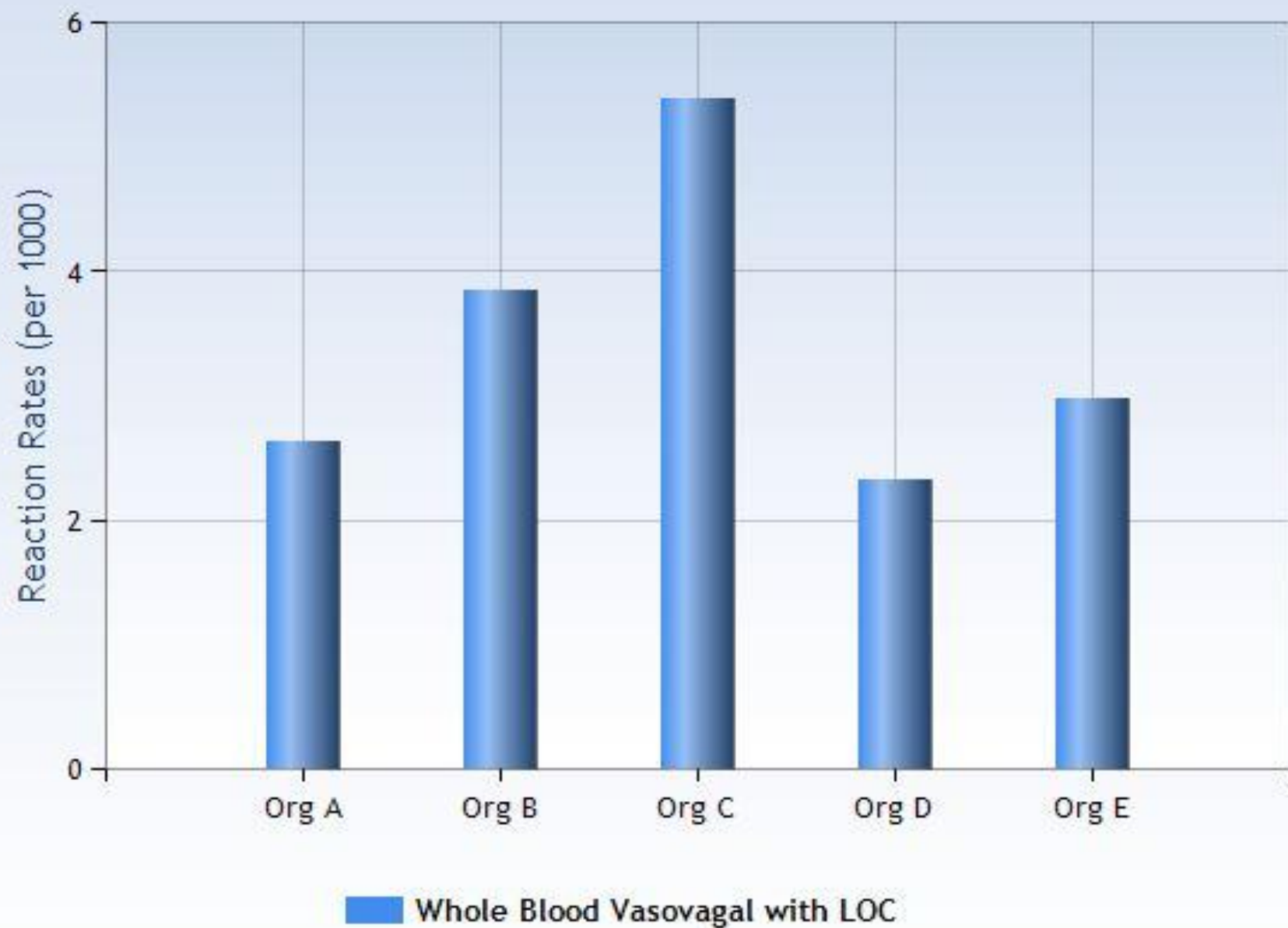
Reaction Rate Analysis by Total

■ Org A
 ■ Org B
 ■ Org C
 ■ Org D
 ■ Org E

Overall Vs Vasovagal Reactions



Whole Blood Vasovagal with LOC Reactions



Delayed Donor Reactions

BSI DONOR VIGILANCE DATA

RESULTS FROM INTERVENTION #1

Comparison of Rate and Proportion of LOC Reactions Across Time Course of WB Donations

	Pre-intervention	Post-intervention	% Change
Donation (N)	99,859	113,172	
LOC (N)	724	637	
Rate ¹	7.3	5.6**	23%
Donation Period	Rate ¹	Rate ¹	% Change
Period 2: (-10 to 4 min)	2.66	2.17*	18%
Period 3A: (>4 min, on-site)	4	3.13**	22%
Period 3B: (>4 min, off-site)	0.6	0.33*	45%
T= 5-10 min (early period 3A)	2.3	1.5**	35%

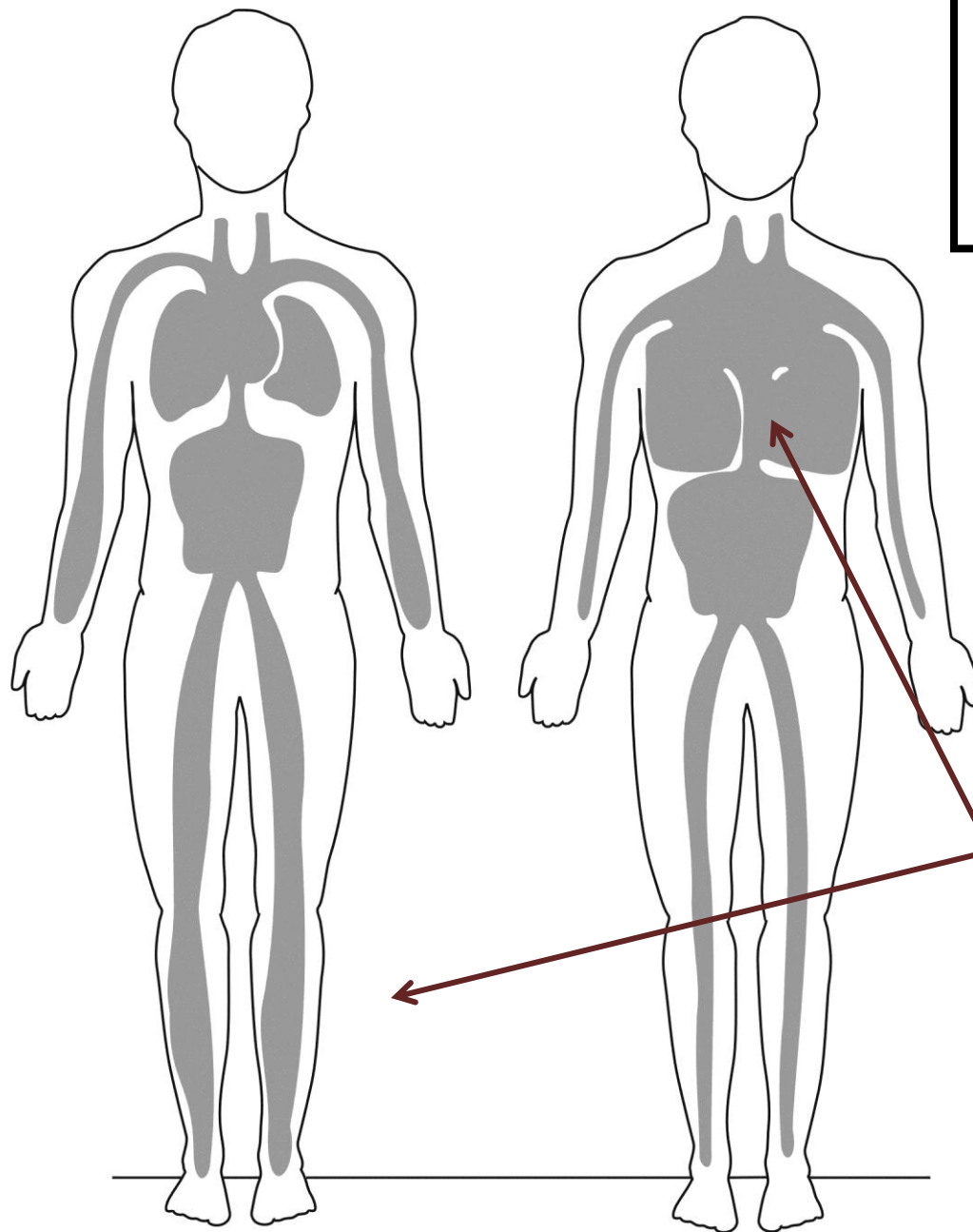
¹Rate per 1,000 donation; *p < 0.05; **p < 0.001

Weaknesses of First Intervention

- Limit on % EBV donated was effective
- No effort to restore blood volume rapidly
- No requirement to perform muscle tensing or drink water
- Not written into SOP [perception of optional]
- Water does not increase blood volume
- Appropriate time for muscle tension not specified (needle withdrawal, standing up, etc)

Donor Fainting: New Intervention

- Astronauts on day of return
 - Eat salt and drink water
 - Improve quickly
- Patients with fainting disorders (dysautonomia)
 - Perform muscle tensing exercises
 - Eat salt and drink water
 - Lie down, squat



- **WHOLE BODY MUSCLE TENSING**
- **BUTTOCK CLENCHING**
- **LOWER BODY MUSCLE TENSING**

Move blood from
legs to thorax (heart)

Increase cardiac filling
Raise blood pressure

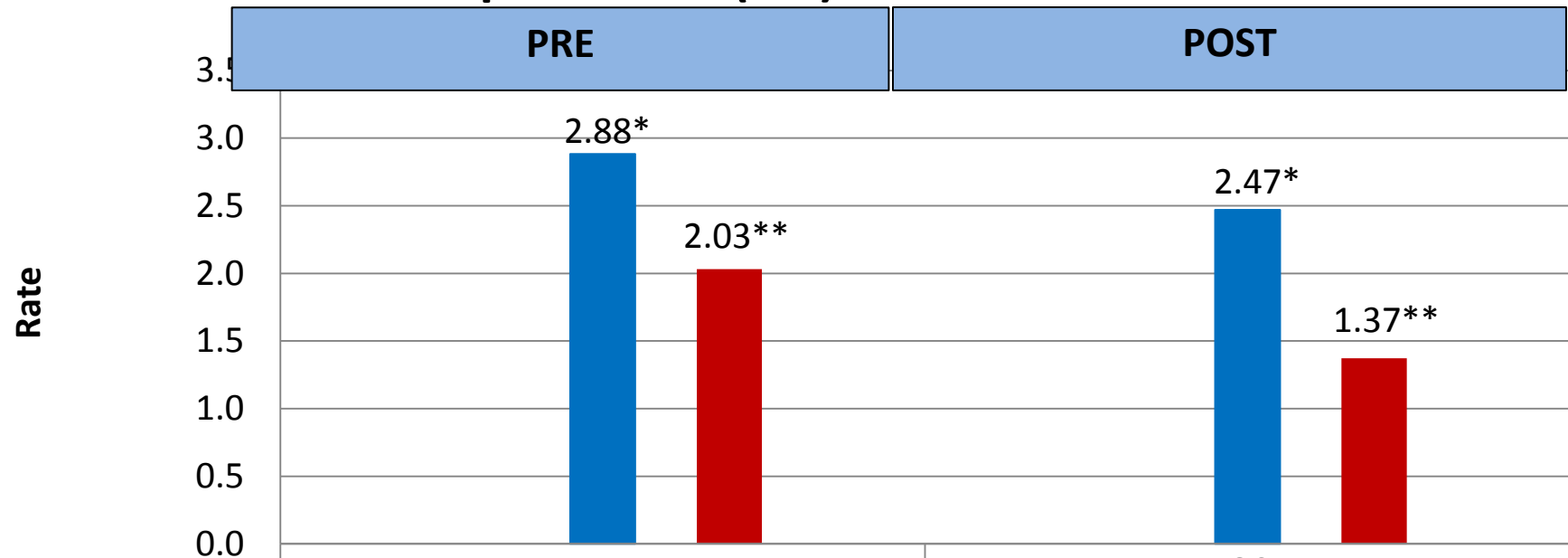
New Intervention (#2)

	Period 1	Period 2	Period 3A	Period 3B
Treatment and Prevention	<u>If dizzy:</u> Muscle Tension Squat Lie Down	<u>Last half (4 minutes) of donation:</u> Muscle Tension	<u>When standing up:</u> Muscle Tension <u>If dizzy:</u> Muscle Tension, Squat, Lie Down	<u>When standing up:</u> Muscle Tension <u>If dizzy:</u> Muscle Tension, Squat, Lie Down
Prevention	Reassurance Salty meal night before	Maintain Blood Volume (salt and water)	Replace Blood Volume (salt and water)	Replace Blood Volume (salt and water)
Prevention	Salty meal night before, salty snacks and/or isotonic sports drinks day of donation			

Will it be necessary to reduce EBV limit for young donors to $\leq 13\%$?

Monitoring
Effectiveness of 2nd
Intervention:
Preliminary Analysis

LOC and Injury Rates – 6 month comparison, pre- and post- new (2nd) intervention

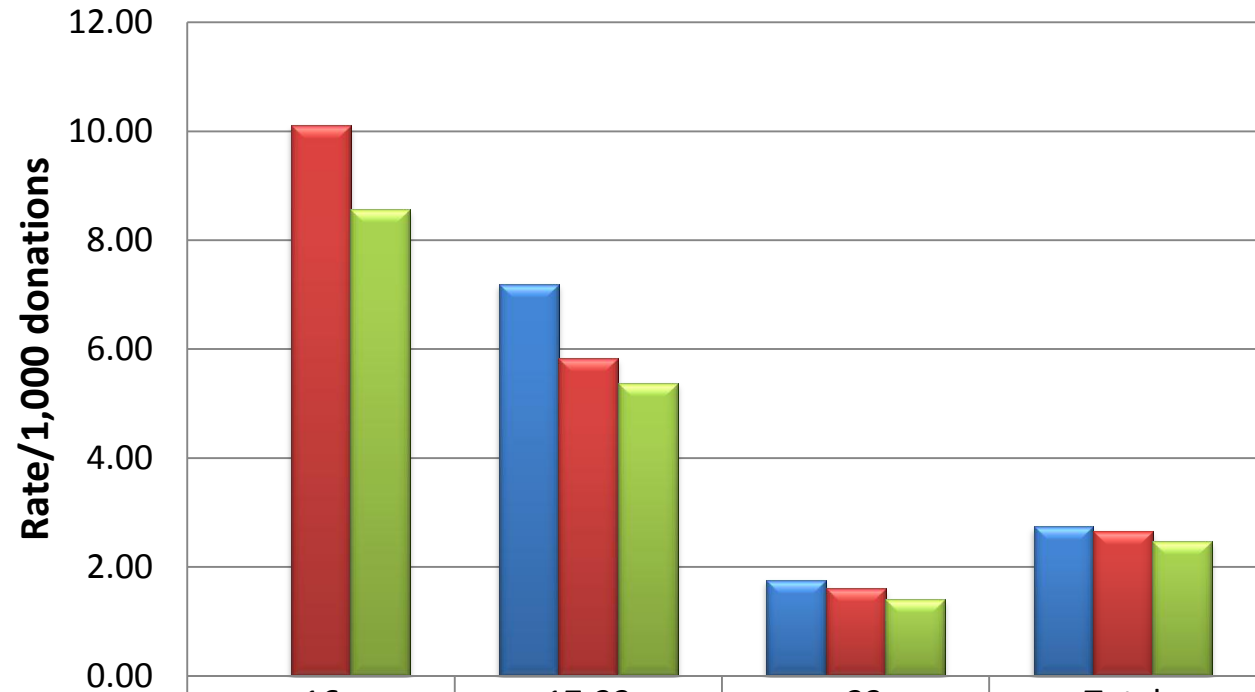


	PRE	POST
Donations (n)	275,787	262,337
LOC (n)	795	648
■ LOC (Rate/1000)	2.88	2.47
Injury (n)	56	36
■ Injury (Rate/10000)	2.03	1.37

For LOC, $p=0.0034$, significant difference of rates at $p<.05$;

For Injury, rates are not significantly different with $p=0.064$

LOC rate in WB donations by age across intervention period (BSI data)



	16	17-22	>23	Total
Pre-Intervention (2007)	Not applicable	7.20	1.76	2.74
1st Intervention (July 28, 2008 - Nov. 30, 2011)	10.11	5.82	1.61	2.65
2nd Intervention (Dec. 1, 2011 to May 31, 2012)	8.57	5.38	1.41	2.47

Hypothesis: Reducing Donor Injury

- Limit maximum donation volume to $\leq 13\%$
 - Young donors
 - All donors
 - Blood Availability?
- Increase salt/fluid intake before, during and after blood donation, especially for young donors
- Apply muscle tensing more aggressively
- Reduce needle adjustments and abortions

Contributors from the Pilot Centers

Kadi Schroeder (Bonfils)

Mary Townsend (Coffee Memorial Blood Center)

Mark Rust (Coffee Memorial Blood Center)

Barbara Hallenburg (LifeShare Blood Center)

Jerry Gottschall (Blood Center of Wisconsin)

Linda Gruber (Blood Center of Wisconsin)

Craig Beczkiewicz (Blood Center of Wisconsin)

Marjorie Bravo (BSI)

Kevin Land (BSI)

Hany Kamel (BSI)

Peter Tomasulo (BSI)

Sarita Khair (KBSI)

Priya Ramanujam (KBSI)

Madhav Erraguntla (KBSI)

AABB's Donor Hemovigilance Working Group

- **American Red Cross**
 - Anne Eder
 - Bruce Newman
- **Armed Services Blood Program**
 - David Lincoln
- **Blood Systems**
 - Peter Tomasulo
 - Hany Kamel
 - Kevin Land (formerly Bonfils)
 - Mary Townsend (formerly Coffee Memorial)
- **Canadian Blood Services**
 - Mindy Goldman
- **Hospital Perspective**
 - James Stubbs (Mayo Clinic)
- **HHS**
 - James Berger
- **ISBT**
 - Jo Wiersom-Osselton
- **PPTA**
 - Mary Gustafson
- **AABB**
 - Barbee Whitaker
 - Mike Strong (Steering Committee)
- **KBSI**
 - Madhav Erraguntla