

**DO WE THINK ENOUGH ABOUT  
DONOR WELFARE?  
ARE MORE EFFORTS NEEDED TO  
PROTECT DONOR HEALTH?**

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International Haemovigilance Seminar  
March 2014  
Barcelona, Spain

# It is not in the patients' best interests to reduce the availability of blood in the US

- More donors – increase in patient safety
  - TRALI (male)
  - Infectious disease risk (travel)
  - Shorter Shelf Life (?)
  - ABO identical components
  - Group O Rh negative donors for RBCs
  - Group AB donors for plasma
- More donors – increase in donor safety
  - Vasovagal reactions (% BV donated)
  - Iron deficiency (male, women > 45 yo)

# Duty to Donor: Information, Policy

- Donor Communication
  - Risk Explanation
    - Of Course
  - Risk Mitigation – Empowering Donor to Reduce Risk – More Important
- Donor Suitability Restrictions
  - Donor BV
  - Frequency of Donation
  - Age

# Empowering Donor to Reduce Risk

- Staff role
  - Education predonation physiology, prevention and treatment
    - VVR – salt loss, volume loss, restoration of volume, compensate for change in BP
    - Fe – iron loss and replacement
    - Value of Donation – patient lives depend on donors
  - Distraction
    - Reduce Impact of Uncertainty/Fear
    - Internalize Tools to Reduce Risk

# Empowering Donor to Reduce Risk

- Staff Role (continued)
  - Venipuncture
    - Hematoma
    - Nerve Injury
    - (Arterial puncture)
  - Managing Dizzy or Fainting Donor (Confidence)
    - Protect
    - Monitor
    - Ensure Recovery
    - Maintenance of Safe Environment

# Empowering Donor to Reduce Risk: What and When

- Staff Role Before Venipuncture (youth and FT status)
  - Explanation
  - Reassurance – Distraction
  - Attention
  - Percent blood volume donated for low EBV donors
- Staff Role When Donor in Chair (low EBV, male, FT status and youth)
  - Explanation
  - Reassurance – Distraction
  - Attention
  - Tool to compensate for hypovolemia (muscle tension)
  - Restore blood volume post donation

# Empowering Donor to Reduce Risk: What and When

- Staff Role After Donation (low EBV, female, FT and youth) On and Off-site
  - Warning about orthostatic change in BP
  - Instruction on AMT, squatting and lying down
  - Instruction on restoring blood volume
  - Instruction on restoring iron
  - What role does distraction play in refreshment area and off-site?
  - Can refreshment area be monitored with trained staff?

# Which Donors Need Special Attention

- Citrate Education and Prevention of Reactions
  - Women
  - Platelet donors
  - Amicus donors
- Venipuncture Injury
  - Light donors
  - Females
  - Platelet and Multicomponent procedures
  - VVR
- Iron Education and Prevention of Deficiency
  - Low iron stores – How Do We Know?
  - Young donors who donate frequently
  - Women in the child bearing years who donate frequently



# BSI Study Objectives

## **Ferritin testing program targeted to acceptable Low Hb donors**

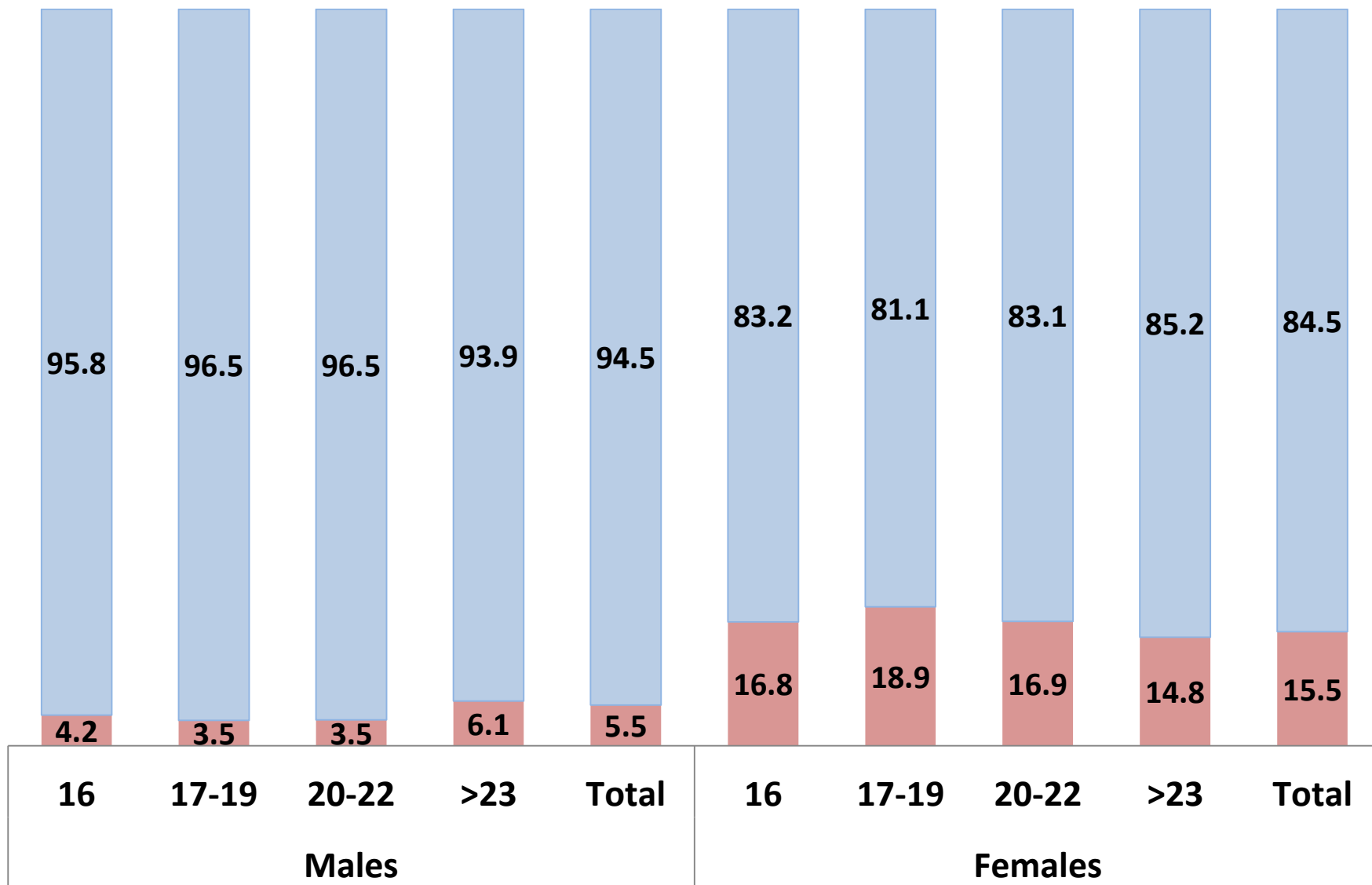
Evaluate donor and donation factors associated with absent iron stores (AIS) and low ferritin (LF) among donors who were tested

Predonation capillary hemoglobin (Hb) triggered ferritin testing

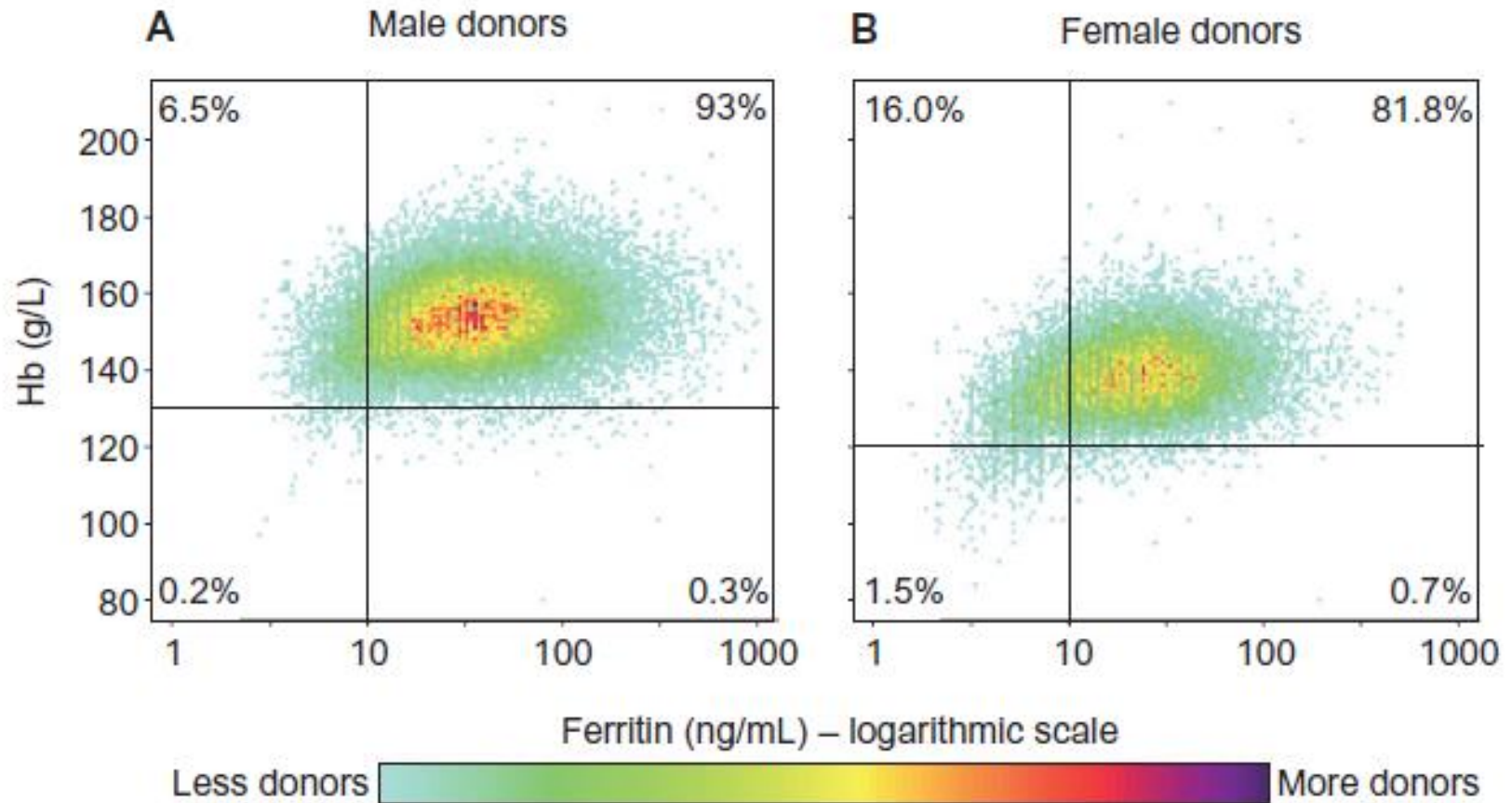
- Males between **12.5-13.4 g/dL**
- Females between **12.5-12.9 g/dL**
  
- LF – Males with ferritin <30 and females with ferritin <20 mcg/L
- AIS – Defined as ferritin <12 mcg/L in both males and females
  
- Screening commenced at UBS centers 11/26/2012

# Proportion of Low and Normal Hemoglobin by Age and Sex

- Low hemoglobin (M: 12.5-13.4; F: 12.5-12.9)
- Normal (M: => 13.5; F: =>13)



# Hb to Ferritin in male and female donors



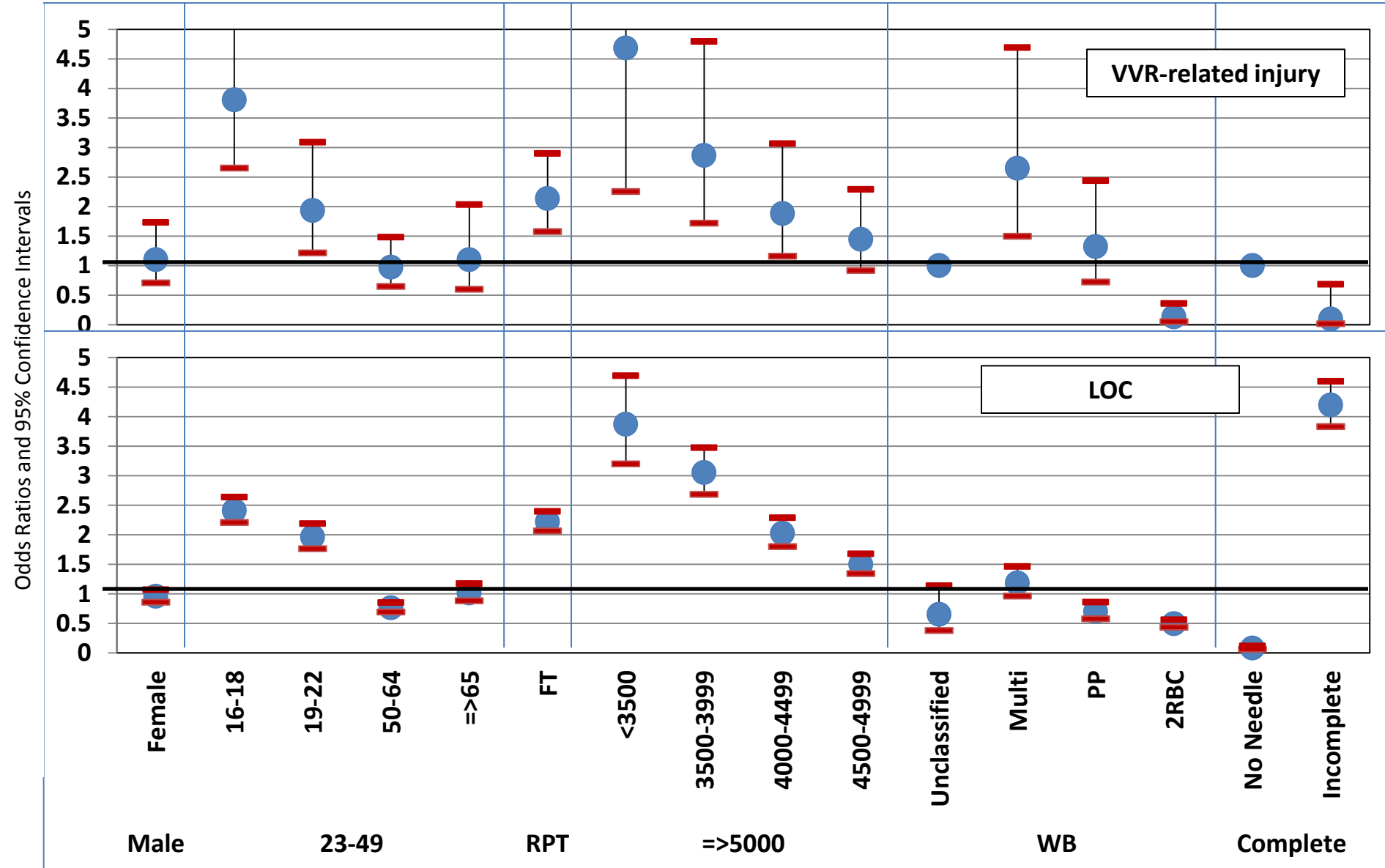
# Risk for Absent Iron Stores

|                            |       | FEMALE-AIS             | MALE-AIS                |
|----------------------------|-------|------------------------|-------------------------|
| Age                        | 16-18 | <b>1.6 (&lt;0.001)</b> | 1.0 (0.98)              |
|                            | 19-22 | <b>1.5 (&lt;0.001)</b> | <b>1.4 (0.001)</b>      |
|                            | 23-49 | 1                      | 1                       |
|                            | 50-64 | 0.6 (<0.001)           | 0.8 (<0.001)            |
|                            | =>65  | 0.4 (<0.001)           | 0.4 (<0.001)            |
| RBC in<br>Prior 2<br>years | 0     | 1                      | 1                       |
|                            | 1-3   | <b>2.4 (&lt;0.001)</b> | <b>2.2 (&lt;0.001)</b>  |
|                            | 4-5   | <b>4.3 (&lt;0.001)</b> | <b>5.4 (&lt;0.001)</b>  |
|                            | 6-9   | <b>5.2 (&lt;0.001)</b> | <b>10.7 (&lt;0.001)</b> |
|                            | 10+   | <b>5.6 (&lt;0.001)</b> | <b>15.9 (&lt;0.001)</b> |
| Prior 2<br>years PP        | 0     | 1                      | 1                       |
|                            | 1-3   | 0.9 (0.37)             | 0.9 (0.25)              |
|                            | 4-5   | 1.2 (0.34)             | 1.3 (0.09)              |
|                            | 6-9   | 1.0 (0.73)             | 1.1 (0.46)              |
|                            | 10-13 | <b>1.8 (&lt;0.001)</b> | 1.0 (0.88)              |
|                            | =>14  | <b>1.8 (&lt;0.001)</b> | <b>2.4 (&lt;0.001)</b>  |

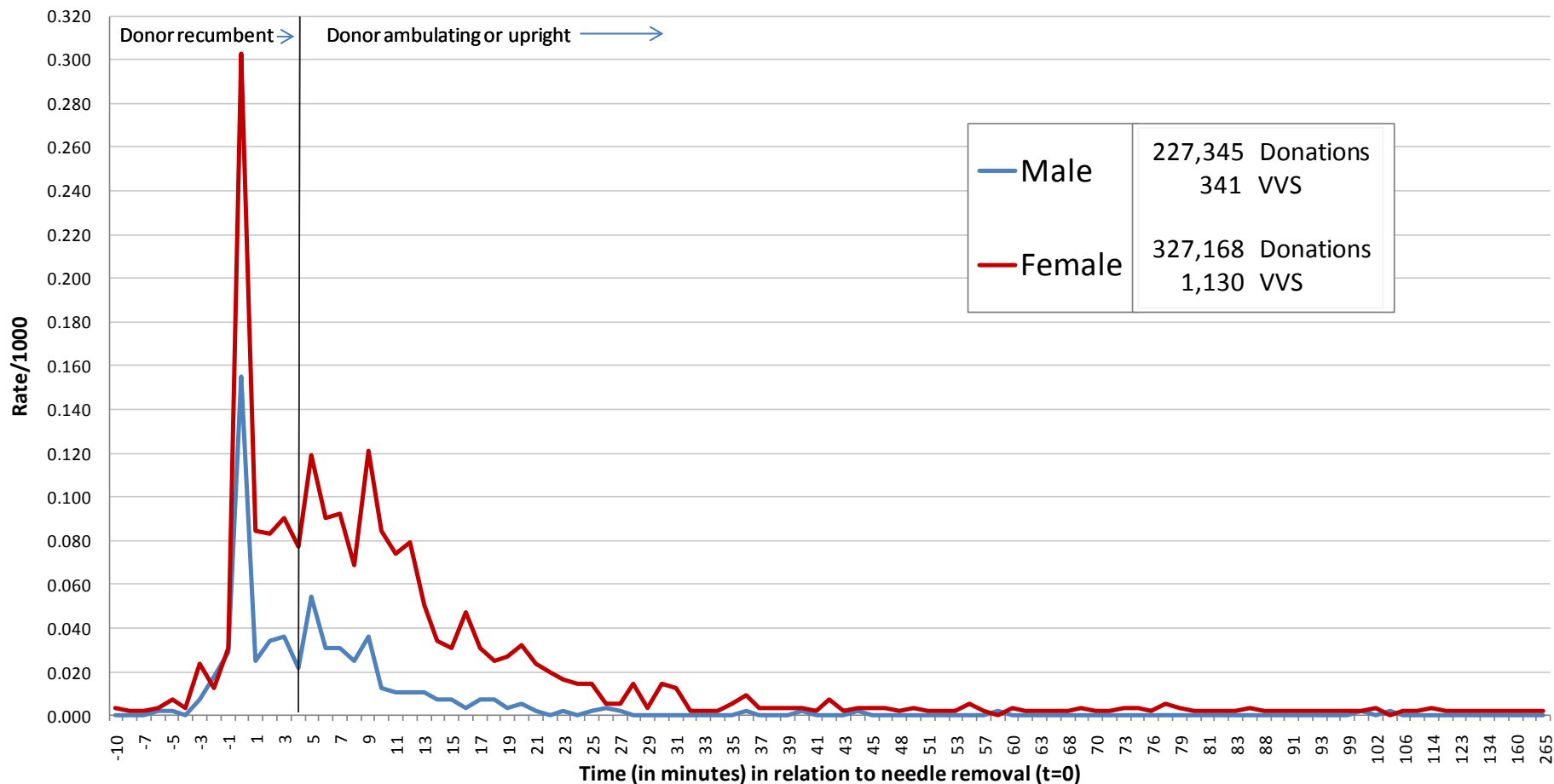
# Special Attention to Reduce VVR Injury

- Education to prevent VV LOC
  - Young donors
  - First time donors
  - Young donors who donate > 13.5 % of EBV
- Injury Education and Prevention
  - Donors who donate > 13.5 % of EBV (EBV < 4200 mL)
  - Young donors
  - First time donors

# Multivariate analysis on factors associated with vasovagal (VVR)-related injuries (n=470) and loss of consciousness (LOC) (n=7074)

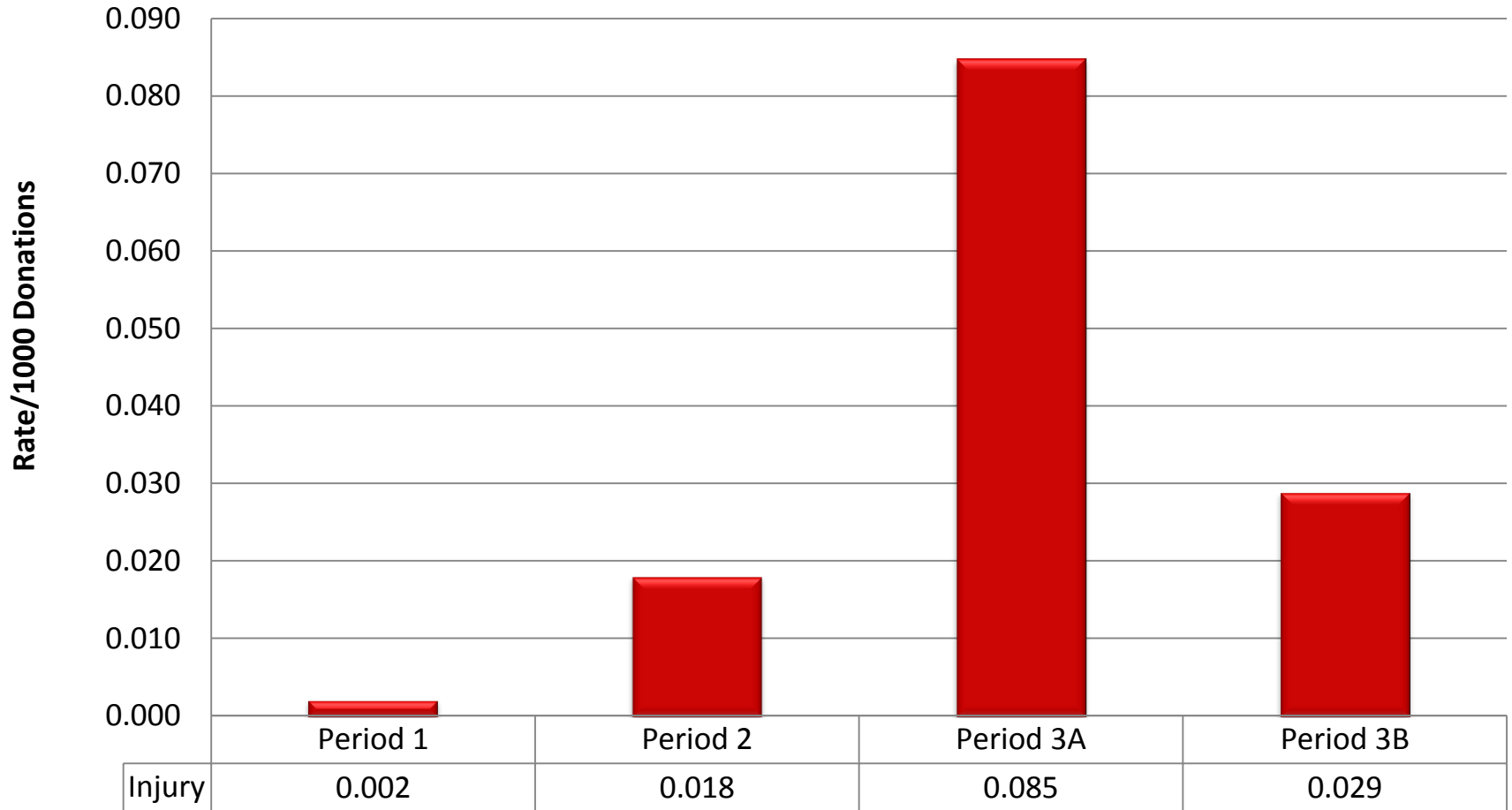


## Overall Vasovagal Syncope Rate in Allogeneic WB Intended Donations, 2007



# Injury / 1000 Donations

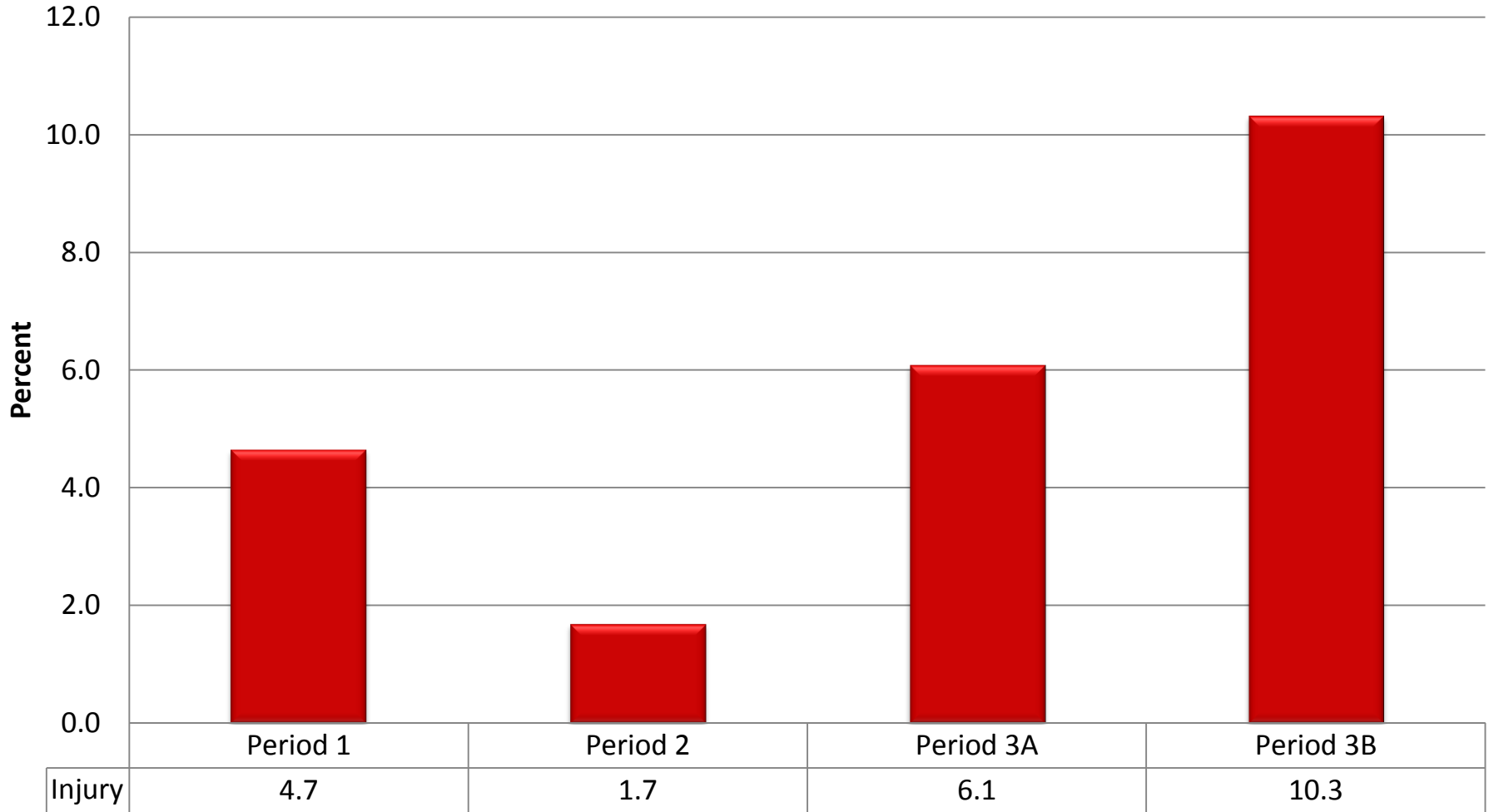
(Males and Females)



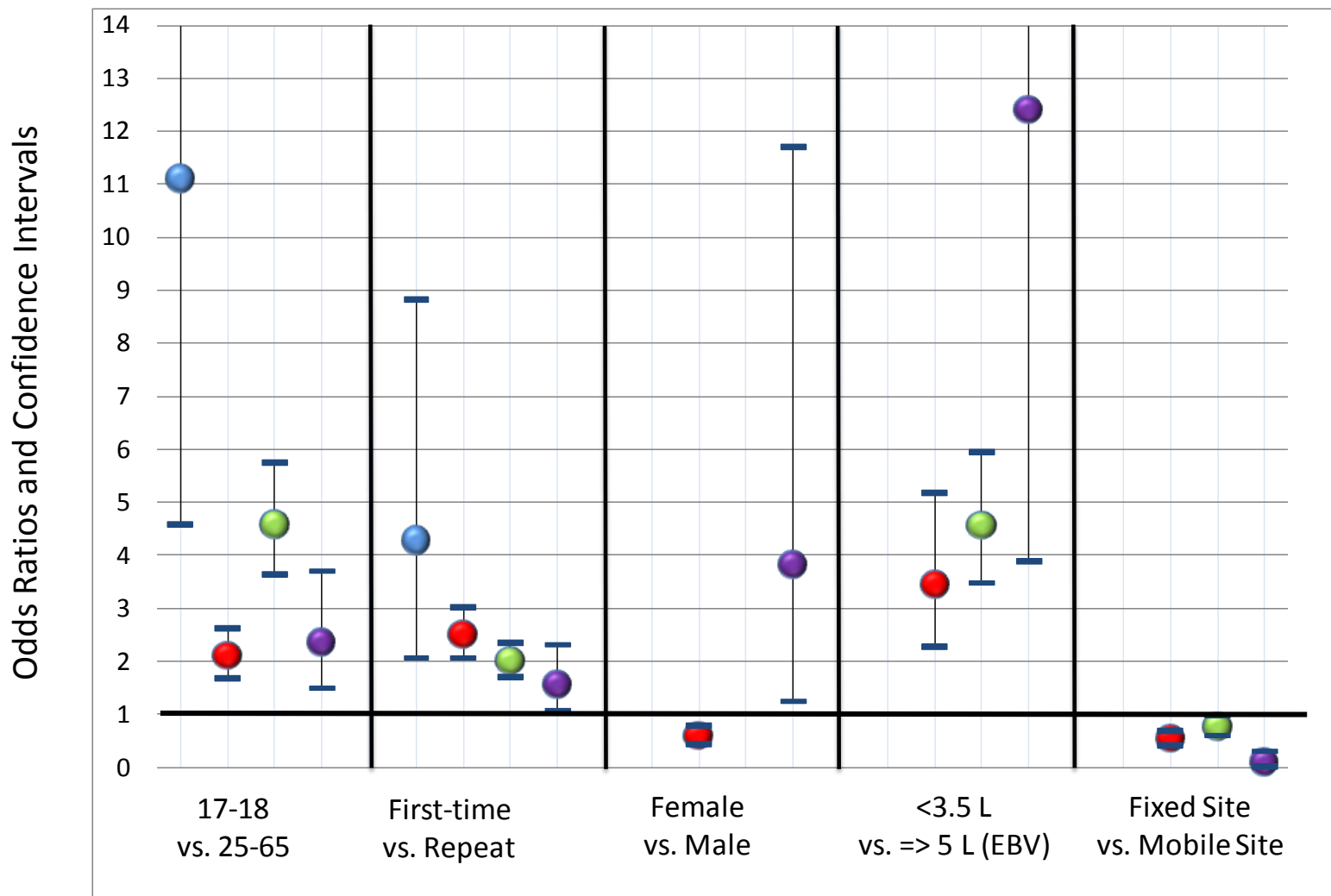


# Injury / 100 Faints

(Males and Females)



# 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

# Using Evidence-Based Medicine to Reduce Risk of Injury associated with Vasovagal Reactions in Blood Donations

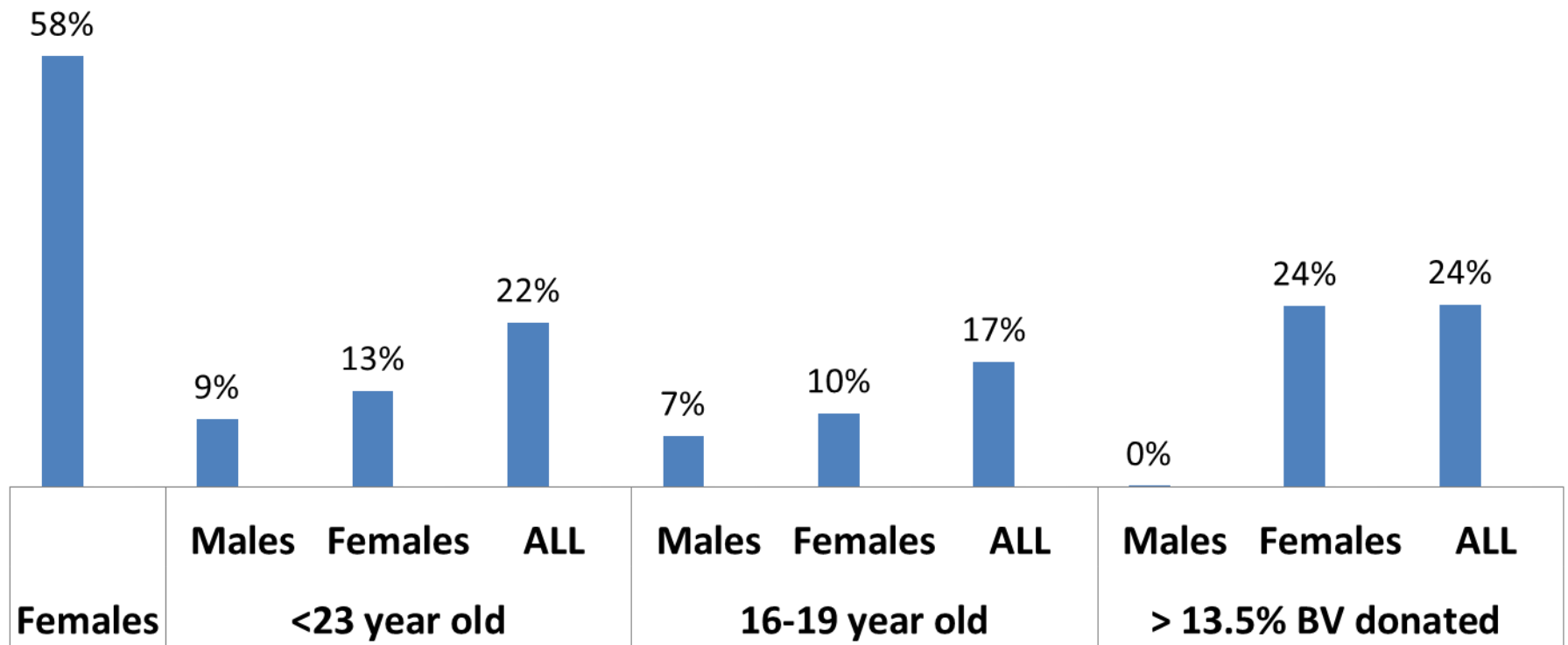
|   |   | PERIOD 1<br>Ambulatory  | PERIOD 2<br>Recumbent  | PERIOD 3<br>Ambulatory   |
|---|---|---|--|--|
| Time course of blood donation             |   | Registration, Medical Health Screening  | Starts with venipuncture up to 4 minutes after end of phlebotomy             | Starts at > 4 minutes after end of phlebotomy<br>3A: On-site and 3B: Off-site                              |
|   |   |   |  |  |
| Significant factors associated with LOC   |   | Young age<br>First-time donor   | Low EBV<br>First-time donor<br>Young Age<br>Male                             | Low EBV<br>Female (off-site)<br>Young age<br>First-time donor  |
| Possible Underlying Mechanism/ Physiology |   | Uncertainty<br>Fear   | Relative Hypovolemia,<br>Uncertainty, Fear,<br>Needle Removal,<br>Being Male | Relative hypovolemia<br>Being Female (off-site)<br>Low EBV<br>BP compensation failure with position change |
| Prevention                                | Fluid & Salt Intake   | Soup night before (increased sodium intake to promote fluid retention), salty snacks and isotonic sports drinks on donation day |  |  |
|   |   | Salty meal day before   | Replace Blood Volume (salt and water)  | Replace Blood Volume (salt and water)  |
|   | AMT   | Muscle Tension, Squat, Lie Down   | Muscle Tension   | Muscle Tension, Squat, Lie Down  |
|   | Education & Skills Training   | Provide educational materials and donor skills training   |  |  |
|   | Pre-donation instructions<br>Reassurance  | Distraction at needle removal<br>Reassurance  | Post-donation instructions   |  |
| Treatment                                 | Trendelenburg position, Muscle Tension, Fluid and Salt Intake, Reassurance, Outside Medical Care (if necessary) |   |  |  |
| Injury                                    | ++  | +   | +++ On-site; ++++ (Off-site)   |  |
|   |   | Venipuncture  | End of phlebotomy  | 4 min. after end of phlebotomy   |

Abbreviations: LOC – Loss of Consciousness; EBV – Estimated Blood Volume; BP – Blood Pressure; AMT – Applied Muscle Tension

# Injuries Associated with Vasovagal Reactions

Allogeneic WB, Needle-In Donations, BSI data 2009 to 2012

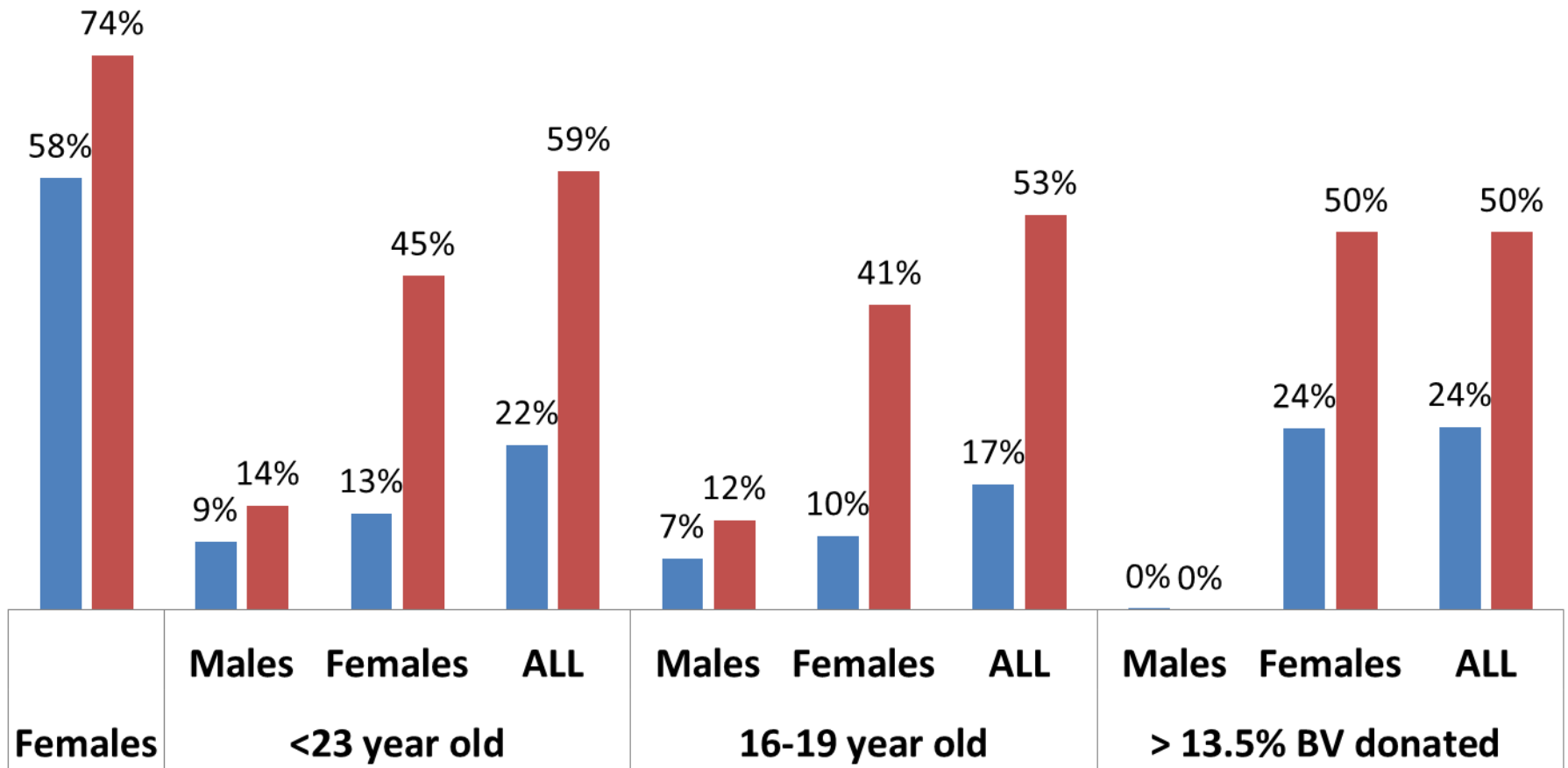
■ % of total blood donated



# Injuries Associated with Vasovagal Reactions

Allogeneic WB, Needle-In Donations, BSI data 2009 to 2012

■ % of total blood donated      ■ % of total injuries experienced



# Donor Recruitment and Communication

- Best donors for patients – male, never pregnant female, repeat, phenotyped
- Safest donations – male, repeat, EBV > 4000 mL, > 23yo, 2 unit red cell donations
- What do we tell young, small females? What do we tell first time donors?
  - Detailed explanation of blood donation risks
  - Distraction, reassurance by trained, qualified staff
  - Empower to reduce risk through muscle tension, squatting and lying down
  - Nutritional education, including iron and blood volume
  - Measure iron levels
  - Specific iron therapy for selected donors

# Summary

- Should we tolerate current level of risk in donor subgroups for injury and iron deficiency?  
Is education enough for these donors?
- Can we reduce risk through known interventions?
- Should we measure iron levels in some donors?
- Or, should we restrict donation by certain donors?

# Injury from VVR

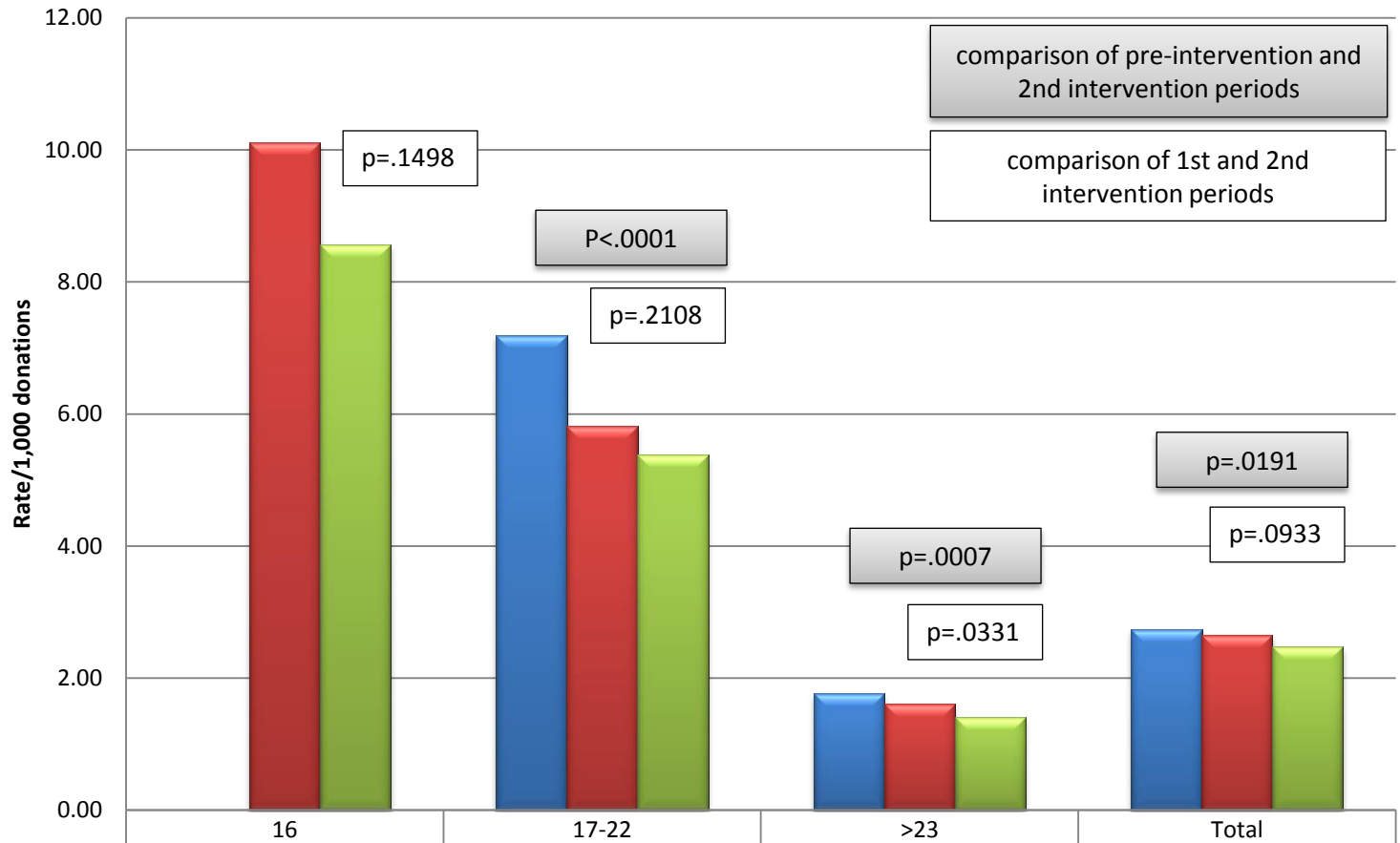
| Donor Group           | % of total blood donated | % of total injuries experienced |
|-----------------------|--------------------------|---------------------------------|
| Females               | 61%                      | 74%                             |
| Females < 23          | 15%                      | 45%                             |
| Males < 23            | 9%                       | 14%                             |
| Total < 23 year olds  | 24%                      | 59%                             |
| Males 16-19           | 7%                       | 12%                             |
| Females 16-19         | 11%                      | 41%                             |
| Total 16-19 year olds | 18%                      | 53%                             |
| Males > 13.5%         | 0%                       | 0%                              |
| Females > 13.5%       | 26%                      | 51%                             |
| Total > 13.5% of EBV  | 26%                      | 51%                             |



# Is Targeted Recruitment + Education Enough?

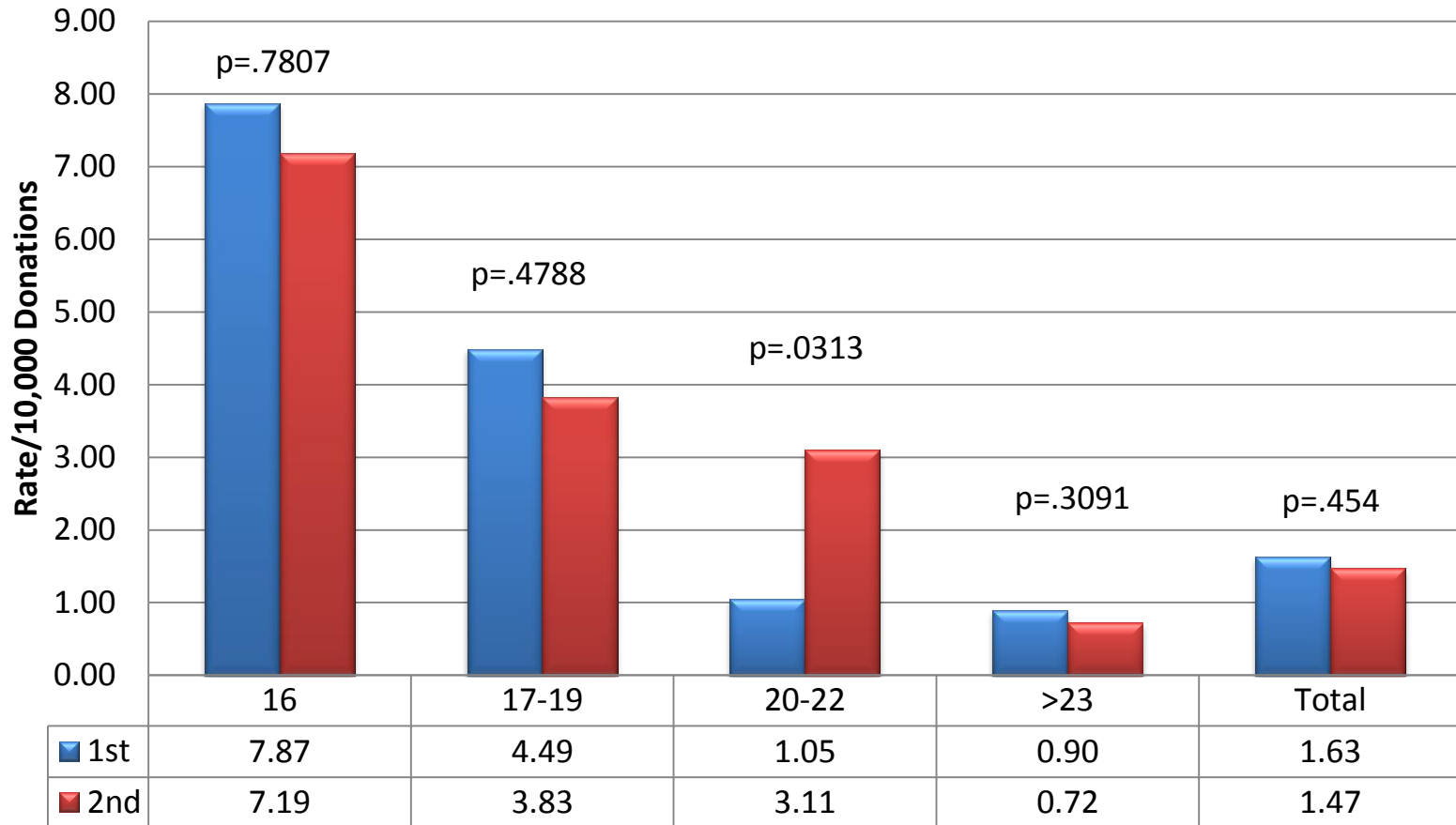
- Male donors
  - TRALI
  - Iron deficiency
- Donors with EBV > 4000 mL (tall)
  - Decreased # of VVR
- Blood Group recruitment
  - ABO identical components
  - Selected phenotypes for alloimmunized patients
  - Group O Rh negative donors for RBCs
  - Group AB donors for plasma

# LOC rate in WB donations by age across intervention period



|  | 16    | 17-22 | >23  | Total |
|--|-------|-------|------|-------|
| ■ Pre-Intervention (2007)                          |       | 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  |

## Injuries associated with VVR by age across intervention period



Note: this summary has a different time period compared to prior slide

1st intervention period: 1/1/2010 to 11/30/2011

2nd intervention period: 12/1/2011 to 12/31/2012

# Fainting: Summary of Multivariable Model By Period

## Adjusted Odds Ratios Across Time Course of Blood Donation

