

# **Donor Adverse Reactions and Some Possible Interventions**

10<sup>th</sup> European Haemovigilance  
Seminar

February 2008

# Blood Systems, Inc.

- Non-profit 501 (c) (3) Organization
- Governed by community-based Board of Trustees
- Established 1943
- 2<sup>nd</sup> largest blood organization in the US
- Exclusively voluntary, non-remunerated blood donors
- Policies generated internally; based on data whenever possible to meet National/International Standards



# Structure

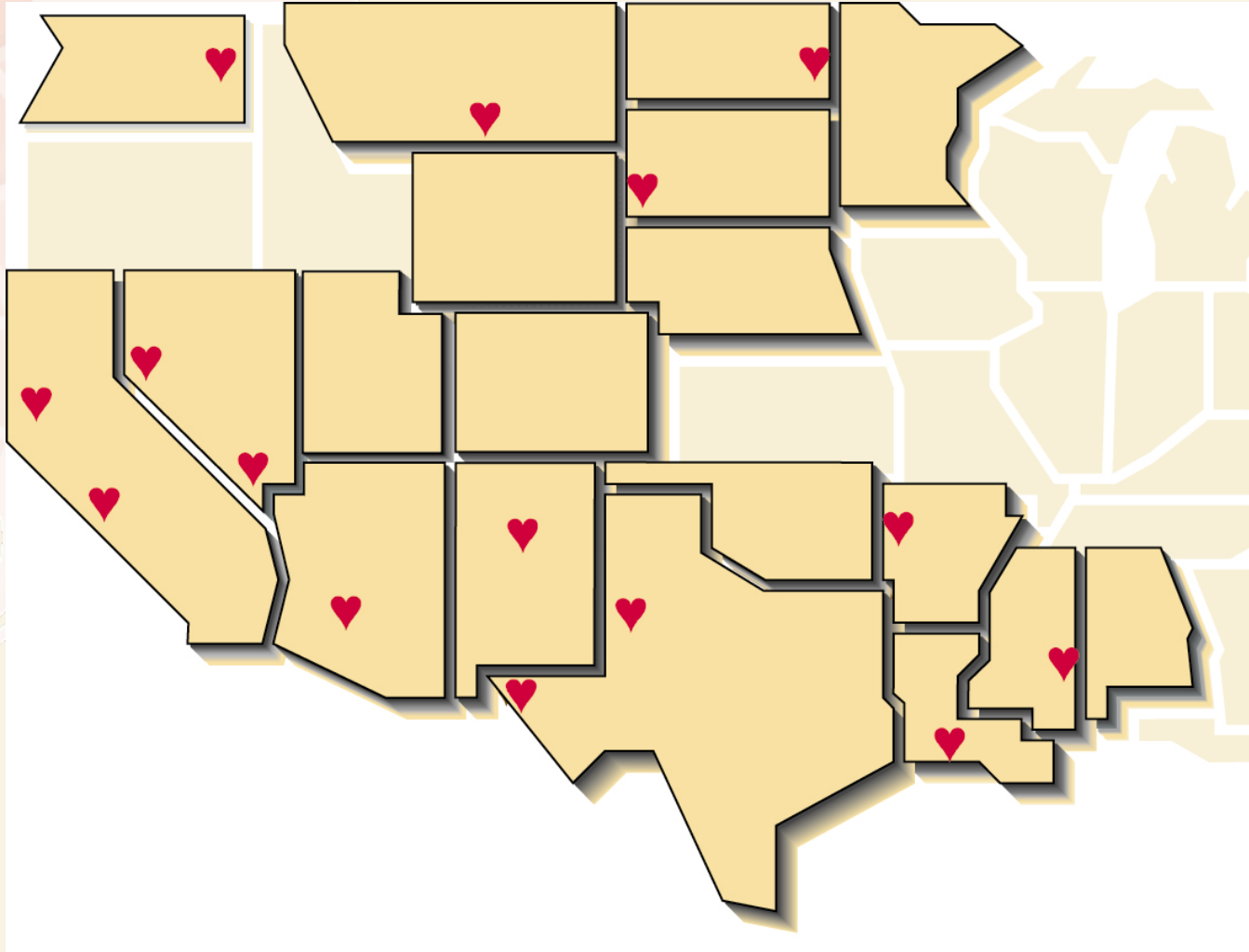
- **United Blood Services**  
community-based blood centers
- **BioCARE**  
plasma therapy products
- **Blood Systems Laboratories**  
donor and patient testing, stem cell processing
- **Blood Systems Research Institute**  
international collaborators in transfusion medicine research

# Operational Scope

- Collect 1.15 million blood donations (6% of US blood supply)
- Test 2.7 million blood samples for 78 blood and tissue facilities (18% of US blood supply)
- 3,600 employees
- 15 regional blood centers serving patients in 550 hospitals in 19 states



# United Blood Services Locations



**United Blood Services**



# Donor Adverse Reaction Analysis

- Study Period – 1 July 2005 – 31 March 2006
- Study Sample – 422,231 whole blood donation records
- Progesa Centers
- Outcome assessed – Loss of consciousness or pre-loss of consciousness and complications
- Analysis – database constructed from adverse reaction and donation databases.



# Donor Adverse Reaction Analysis

- Donor Acceptability (525 ml donation)
  - Weight > 50 Kg
  - Pulse – 50 to 100 bpm
  - BP – 90/50 to 180/100 mm Hg
  - Hct – 38%
  - No heart or lung disease restricting daily activity
  - 17 years old to ?



# Donor Adverse Reaction Analysis

## ■ Data Collected

- Age, gender, first time/repeat, blood center, predonation pulse, blood pressure
- Height and weight (self-reported)
- Race (self-reported)
- Information on off-site reactions (self-reported)
- Observations concerning on-site reactions



# Donor Adverse Reaction Analysis

Mild Reactions	Moderate Reactions	Severe Reactions
Nervous, weak, nausea, dizzy  Pallor, sweating, hyperventilation  Recovery < 15 minutes	Nervous, weak, nausea, dizzy  Pallor, sweating, hyperventilation, emesis, syncope, low BP  Recovery 15-30 min	Nervous, weak, nausea, dizzy  Pallor, sweating, hyperventilation, emesis, syncope, low BP, incontinence, convulsions  Recovery > 30 min

# Donor Adverse Reaction Analysis

## ■ Calculated Data

### ■ Blood Volume, Female

- $BV = 0.356 H^3 + 0.03308 W + 0.1833$

### ■ Blood Volume, Male

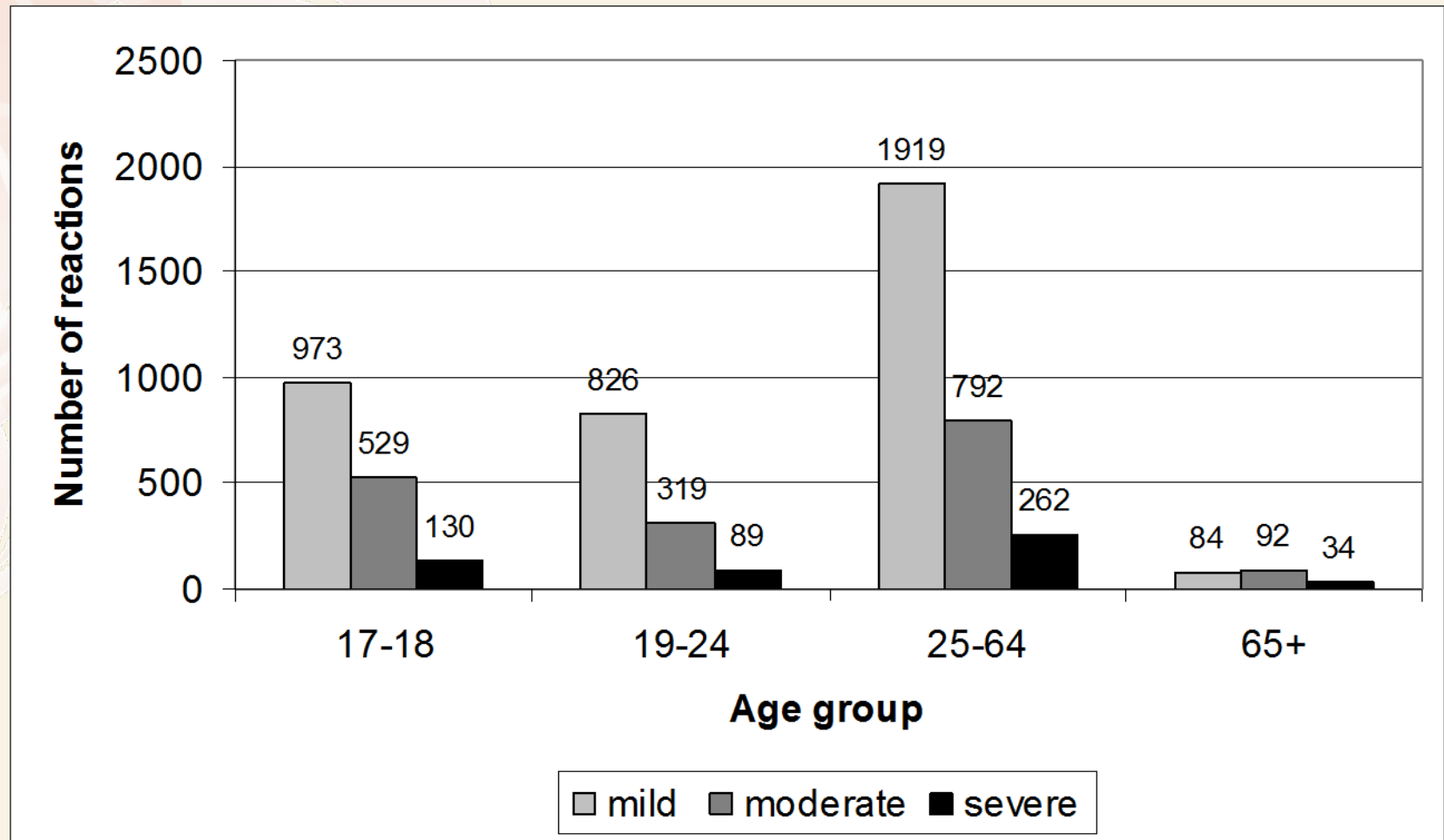
- $BV = 0.3669 H^3 + 0.03219 W + 0.6041$

### ■ Body Mass Index

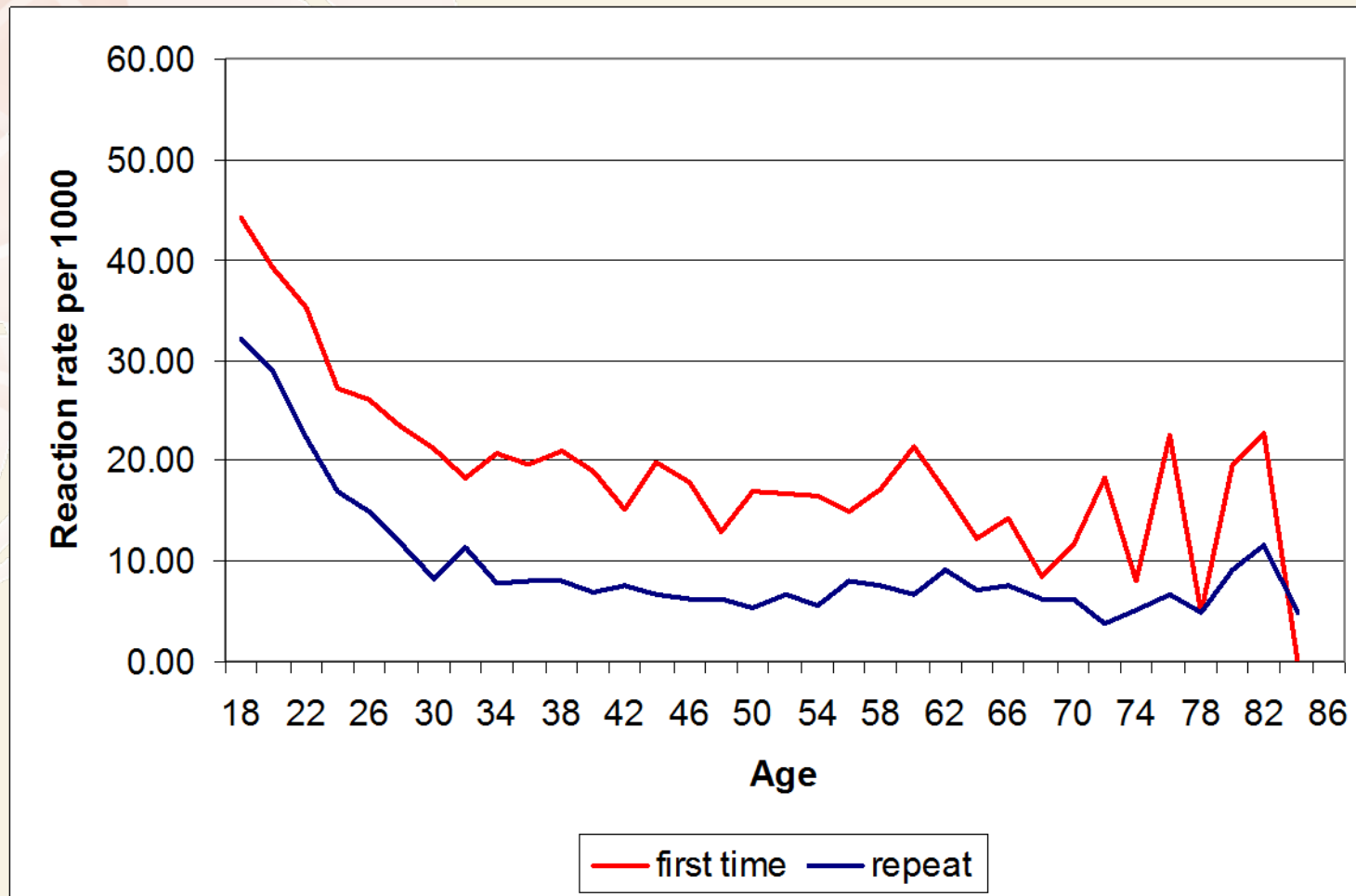
- $BMI = W/H^2$

BV = liters, H = meters, W = kilograms

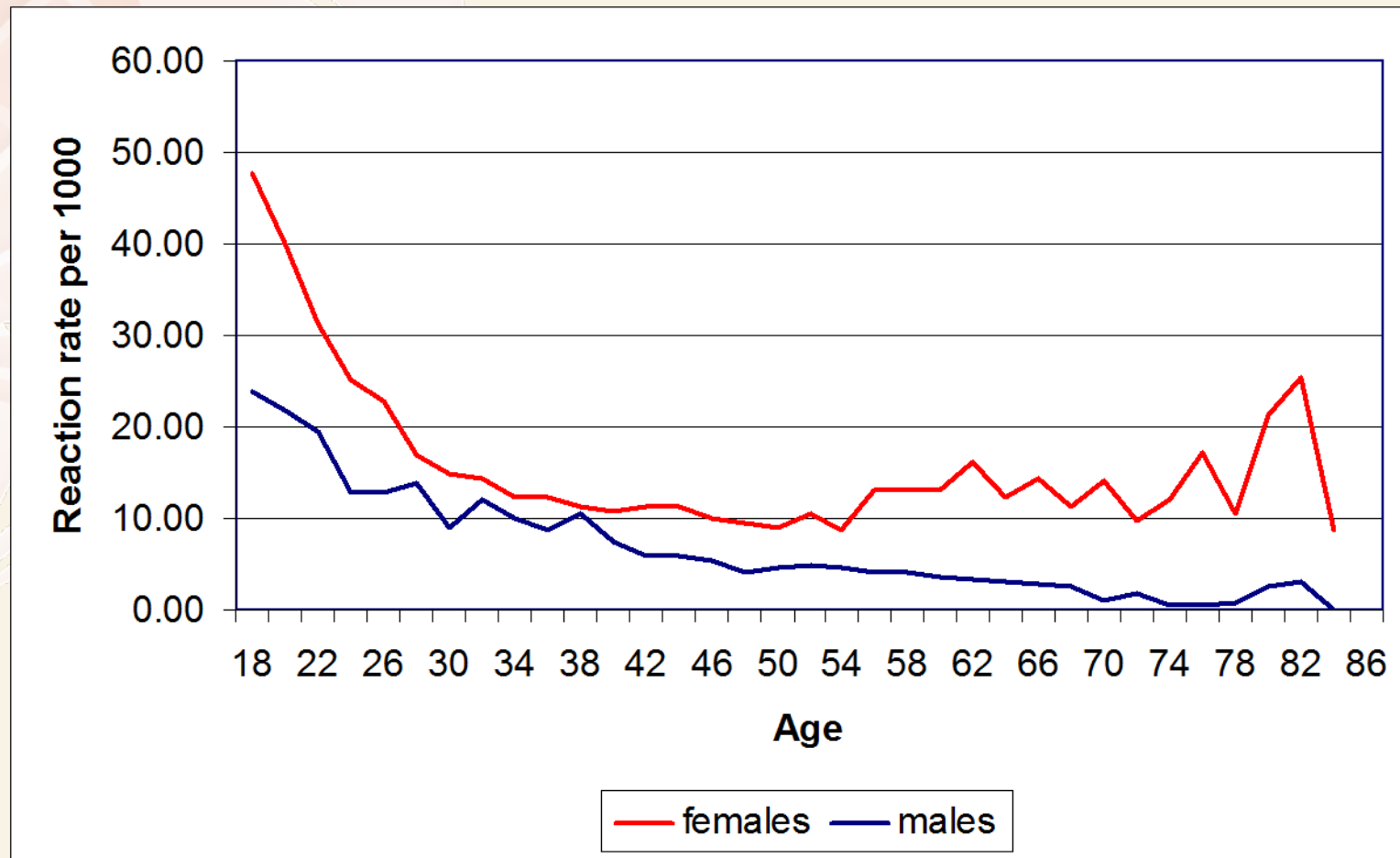
# Total number of reactions by severity and age group (n=422,231)



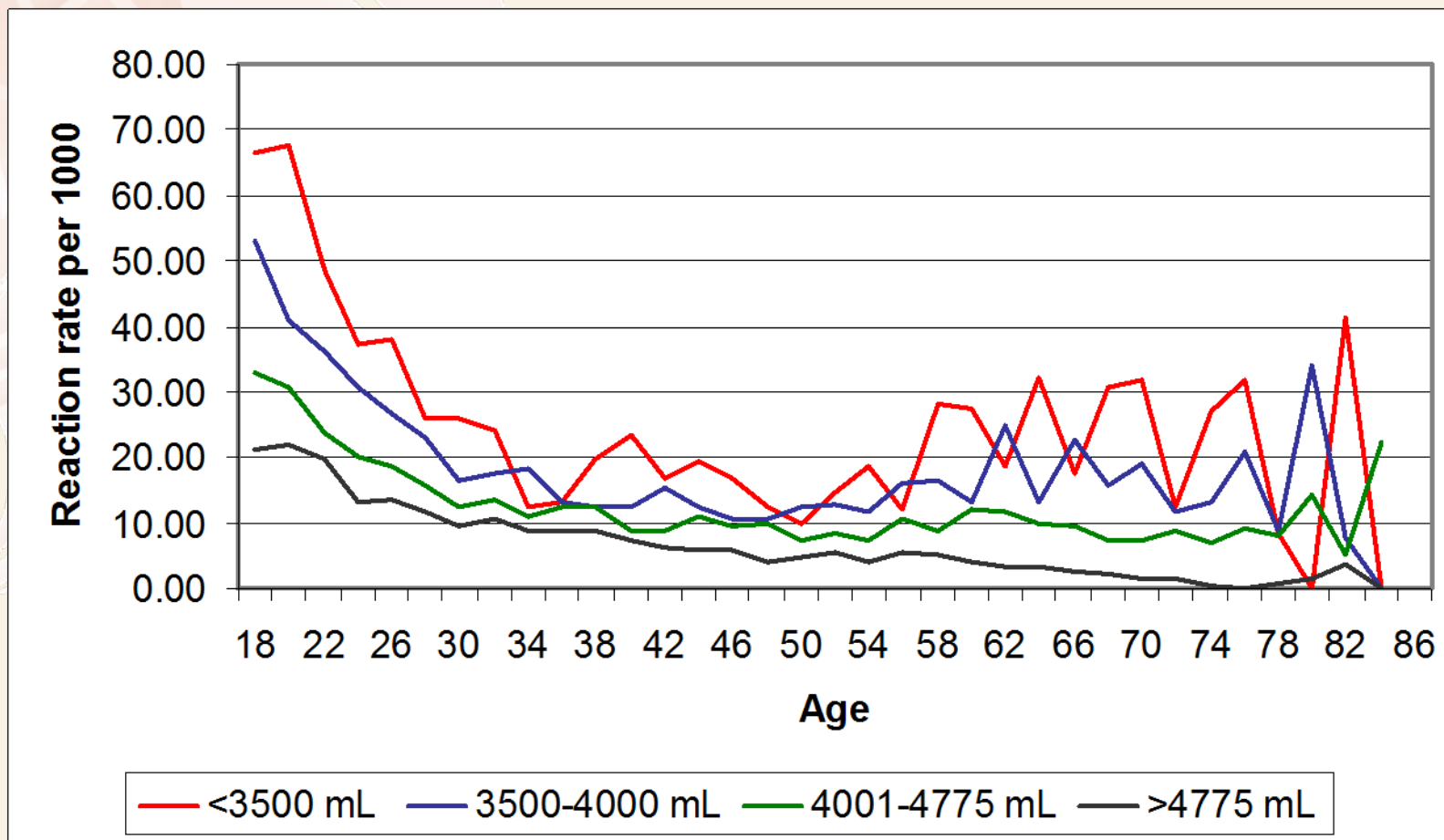
# Reaction rates defined by age and first time or repeat status (n=422,231)



# Reaction rates defined by age and gender (n=422,231)



# Reaction rate defined by age and blood volume groups (n = 422,231)



# Reaction Rate, Odds Ratios, Adjusted and Unadjusted

Gender and Donation History	Rate (per 1,000)	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio* (95% CI)
Female	18.6	2.21 (2.09-2.35)	1.20 (1.10-1.31)
Male	8.5	1.0	1.0
First Time	27.5	2.80 (2.66-2.94)	2.20 (2.08-2.33)
Repeat	10.0	1.0	1.0

\*\*Includes age group, gender, donation history, race/ethnicity, estimated blood volume, pulse, systolic blood pressure and blood center as covariates

# Reaction Rate, Odds Ratios, Adjusted and Unadjusted

<b>Pulse</b>	<b>Rate/1000</b>	<b>Unadjusted Odds Ratio (95% CI)</b>	<b>Adjusted Odds Ratio* (95% CI)</b>
<b>&lt;65</b>	<b>9.7</b>	<b>0.65 (0.60-0.71)</b>	<b>0.73 (0.66-0.78)</b>
<b>65-90</b>	<b>14.7</b>	<b>1.0</b>	<b>1.0</b>
<b>&gt;90</b>	<b>19.5</b>	<b>1.33 (1.24-1.43)</b>	<b>1.25 (1.16-1.34)</b>

\*Includes age group, gender, donation history, race/ethnicity, estimated blood volume, pulse, systolic blood pressure and blood center as covariates

# Reaction Rate, Odds Ratios

Systolic BP	Rate/1000	Adjusted Odds Ratio*(95% CI)
<100 mmHg	20.4	1.02 (0.92-1.15)
100-140 mmHg	14.9	1.0
>140 mmHg	7.8	0.82 (0.74-0.91)
Diastolic BP	Rate/1000	
<70 mmHg	19.4	
70-85 mmHg	13.8	
>85 mmHg	8.6	

\*Includes age group, gender, donation history, race/ethnicity, estimated blood volume, pulse, systolic blood pressure and blood center as covariates

# Reaction Rate, Odds Ratios, Adjusted and Unadjusted

Race/Ethnicity	Rate/1,000	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio* (95% CI)
Black (non-Hispanic)	4.2	1.0	1.0
Hispanic	16.6	3.99 (3.05-5.23)	1.57 (1.19-2.08)
Other/mixed	14.8	3.55 (2.55-4.95)	1.52 (1.08-2.13)
Asian	12.3	2.95 (2.05-4.26)	1.37 (0.95-1.99)
White	14.3	3.42 (2.63-4.46)	2.15 (1.64-2.82)
Missing	15.5	3.73 (2.80-4.96)	2.35 (1.76-3.15)

\*Includes age group, gender, donation history, race/ethnicity, estimated blood volume, pulse, systolic blood pressure and blood center as covariates

# Reaction Rate, Odds Ratios, Adjusted and Unadjusted

Age (yrs)	Rate (per 1,000)	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio* (95% CI)
17-18	39.6	4.19 (3.94-4.45)	2.75 (2.56-2.94)
19-24	27.4	2.87 (2.68-3.06)	2.37 (2.21-2.54)
25-65	9.7	1.0	1.0
>65	6.8	0.69 (0.60-0.80)	0.72 (0.62-0.83)

\*Includes age group, gender, donation history, race/ethnicity, estimated blood volume, pulse, systolic blood pressure and blood center as covariates

# Reaction Rate, Odds Ratios

Body Mass Index	Rate/1000	Unadjusted Odds Ratio (95% CI)
<18.5	28.7	2.51 (1.99-3.15)
18.5-22.49	24.6	2.14 (2.00-2.29)
22.5-24.9	17.9	1.54 (1.44-1.65)
25.0-29.9	11.6	1.0
>30.0	8.8	0.75 (0.70-0.81)



# Reaction Rate, Odds Ratios, Adjusted and Unadjusted

Estimated Blood Volume	Rate/1000	Unadjusted Odds Ratio (95% CI)	Adjusted Odds Ratio* (95% CI)
< 3500	34.9	4.47 (4.10-4.88)	2.88 (2.57-3.23)
3500-4000	23.5	2.97 (2.77-3.17)	2.09 (1.90-2.31)
4001-4775	14.4	1.80 (1.68-1.93)	1.44 (1.31-1.57)
> 4775	8.0	1.0	1.0

\*Includes age group, gender, donation history, race/ethnicity, estimated blood volume, pulse, systolic blood pressure and blood center as covariates

# Donor Adverse Reaction Analysis

## 17 and 18 year old donors

Blood Volume (ml)	Female	Male	Total
< 3500	4,770 (100%)	2 (0%)	4,772
3500-4000	11,834 (98%)	250 (2%)	12,084
4001-4775	7,792 (66%)	4,256 (34%)	12,048
> 4775	2,053 (17%)	10,259 (83%)	12,312
Total	26,449 (64%)	14,767 (36%)	41,216



# Donor Adverse Reactions: Possible Interventions

- Collect less blood from light small donors, 450 ml
- Young small donors donate by apheresis
- Use height and weight to screen young donors
- Provide 500 ml of fluid to donors within 30 minutes of donation
- Instruct donors to do muscle tensing exercises
- Train staff in caring for younger donors
- Redesign refreshment area to protect donors who fall



# Investigators

- Brian Custer PhD
- Gerald Giordano MD
- Hany Kamel MD
- Peter Tomasulo MD
- Thomas Wiltbank MD



# High Level, All Reactions

Donation Type	Injury	% Injury	Mod	% Mod	Severe	% Severe	% Total	Total
Whole Blood	413	0.09%	1831	0.41%	555	0.13%	0.63%	443631
Apheresis RBC	567	0.43%	213	0.16%	54	0.04%	0.63%	131548
Apheresis Platelet	128	0.27%	75	0.16%	332	0.07%	0.49%	48108
Total	1108	0.18%	2119	0.34%	641	0.10%	0.62%	623287