

Donor Vigilance

International Haemovigilance Seminar

Montreal, April 2012

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Goals of Donor Vigilance

- ~~• Investigator satisfaction~~
- ~~• Investigator publications~~
- ~~• Publishing national reports~~
- Improve donor satisfaction
- Increase donation frequency
- Reduce the frequency of adverse events
- Reduce sequelae of adverse events
- Reduce donor injury
- Reduce donation-related disability

Goals of Donor Vigilance

- Improve donor satisfaction
- Increase donation frequency
- Reduce the frequency of adverse events
- Reduce sequelae of adverse events
- **Reduce donor injury**
- **Reduce donation-related disability**

Goals of Donor Vigilance

- Define events
- Count events
- Document denominators
- Calculate rates
- Make tables
- Analyze data
- Compare with other programs

In order to:

- **Reduce frequency of donor injury**
- **Reduce donation-related disability**

Donor vigilance is not “counting”

- Counting/reporting vs. analysis/interpretation
- Awareness vs. understanding – hypothesis
- Monitoring vs. intervening and then monitoring and then intervening again

If the goal is to understand, intervene and improve, the data must be collected and analyzed in a way that leads to theories about cause and effect. Rates alone are insufficient.

Can a blood program perform donor vigilance simply by reading the literature?

Continuous improvement requires monitoring.

Monitoring requires metrics.

Defining Data Elements

Symptoms

- More detailed – more work
- Reaction characteristics
- Can obtain most significant data – loss of consciousness
- Can be analyzed individually
- Can associate symptoms with outcomes
- Can be aggregated into categories when necessary
- Allows comparison to multiple other systems

Diagnoses, Categories

- Simple
- Define conclusions in advance
- Have capacity for multiple diagnoses
- *Institutions may differ in interpretation of diagnosis*
- *Consistency much more difficult to achieve*
- *Can't assess strength of association*
- *Less flexible for comparison*

Denominators

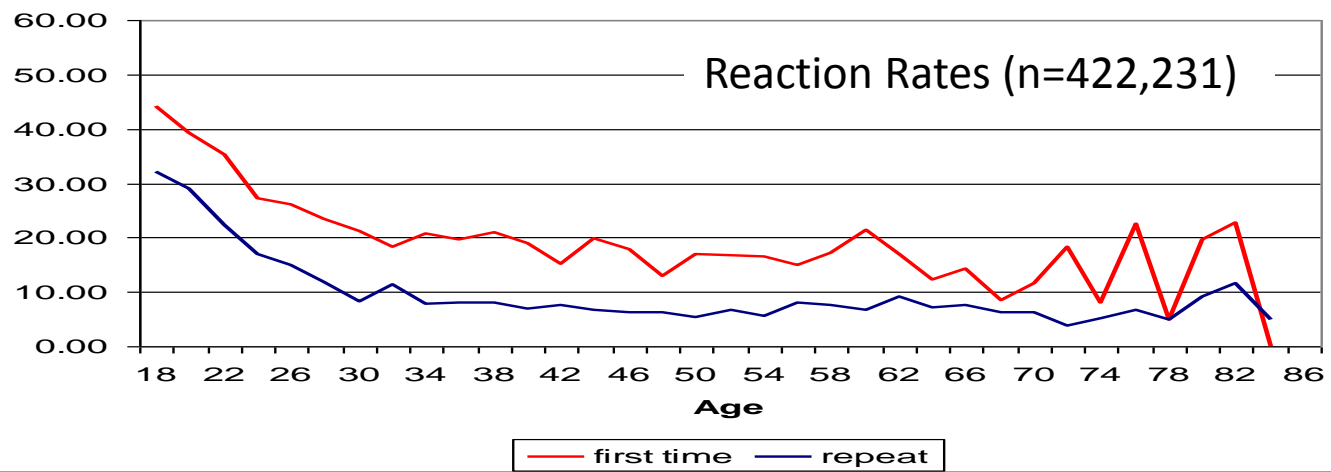
Every donation event

- Every procedure type with all donor, donation and site information
- Permits multivariable logistic regression analysis to calculate strength of association
- This requires much more work and a larger investment, but is essential

Categories – Stratified

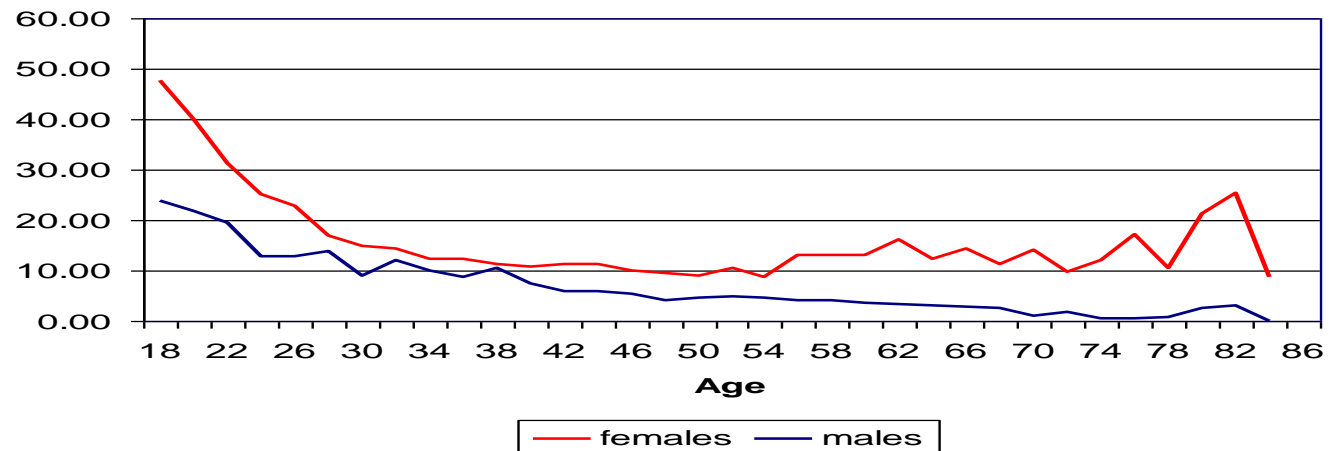
- Age categories, by decades?
- Gender
- Donation site, mobile, fixed?
- Can't compare strength of association
- Allows stratification and calculation of rates which is of limited utility when events are multifactorial

age and
first time
or repeat
status

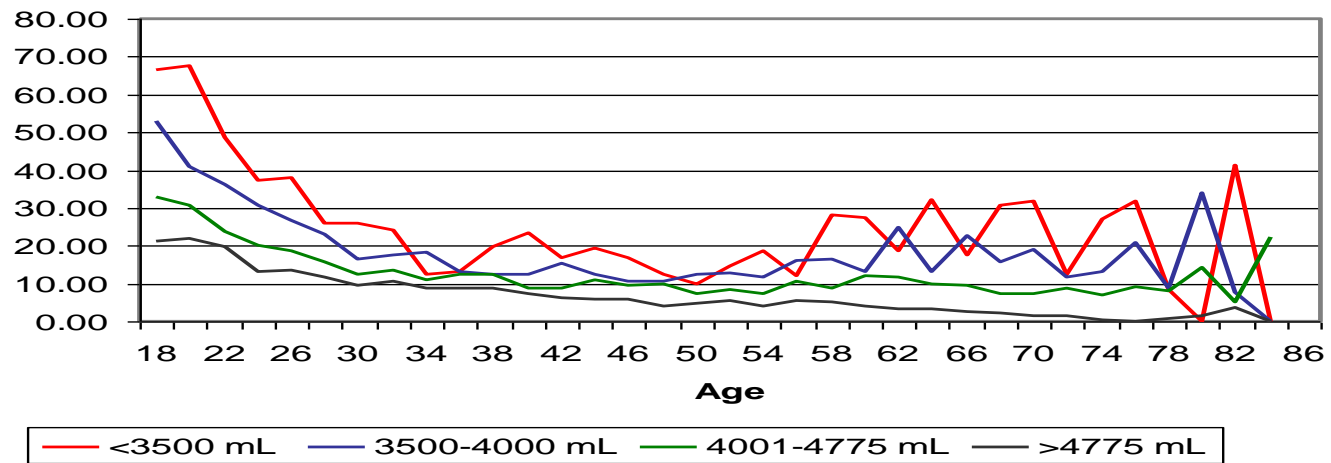


age and
gender


Reaction Rate per 1000



age and
blood
volume
groups



Four Factors

- 1) Youth 2) being female 3) being a first time donor and 4) low EBV  higher VVR rates
- But, youth is associated with low EBV and being a first time donor
- Being female is associated with low EBV

How do we know which factor is most important and how do we know whether there is a fifth factor with which our 4 factors are linked?

Which factors are linked with injury?

Rate of Adverse Events by Donation Type

Collection Procedure	Whole Blood 555,186	2 RBCs 165,064	Multi-Comp 18,895	Plts +Plasma 55,002
N	/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

Donor vigilance system must support analysis of data by procedure type

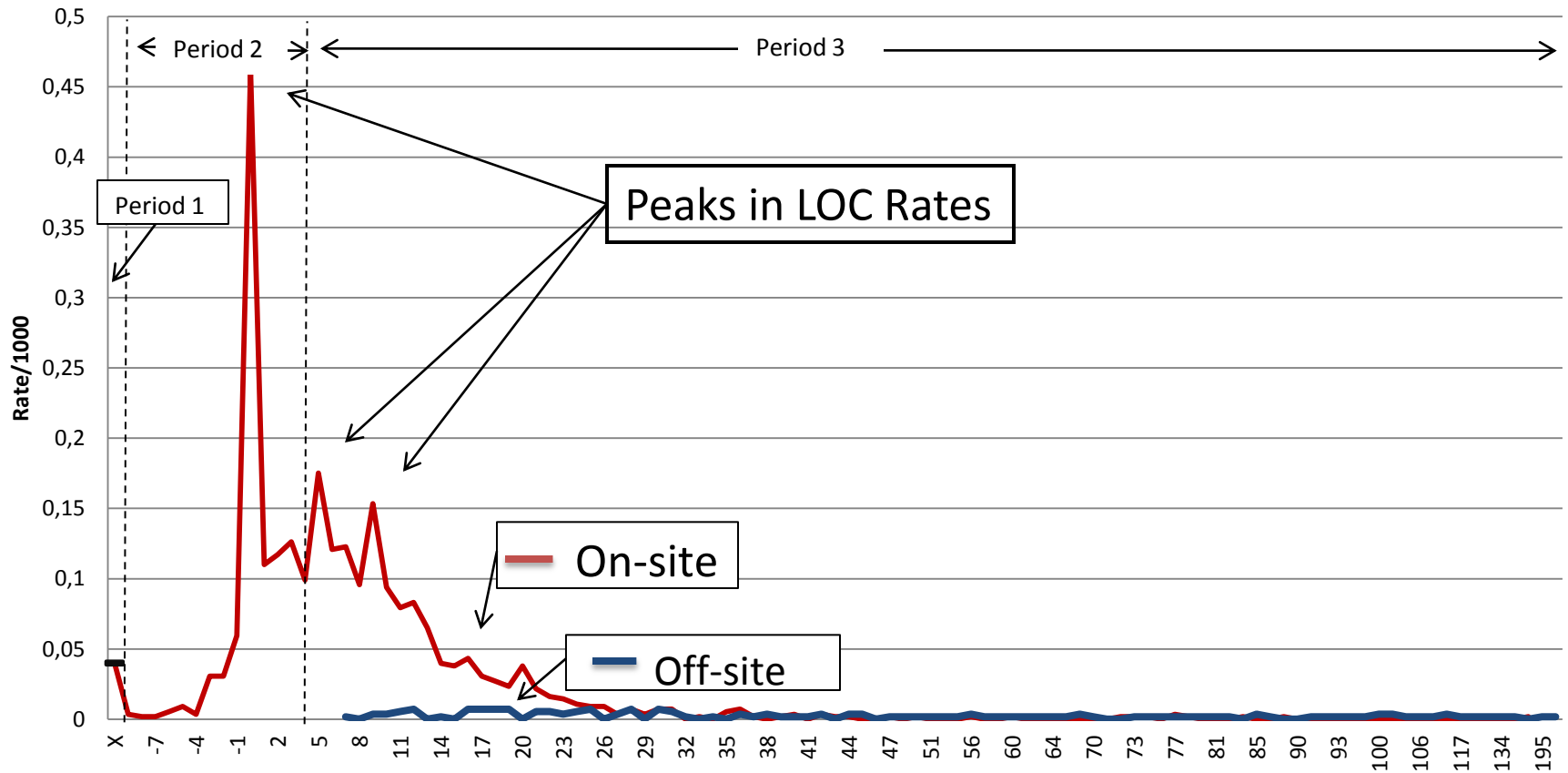
Focus on Whole Blood Donation

We know now that analysis has to be procedure specific.

- Is rate constant from start to end of donation?
- Is trigger for reactions constant?
- Is cause of all VVR the same?
- Is cause the same in men and women?
- Do all reactions have equal potential for injury?
- Will 1 intervention be effective for all VVR?

(Need large amounts of specific data to know answers)

Fainting Rates Across Time Course of Whole Blood Donation: 2007 Data



Rate not constant – complex process

PERIOD 2, REMOVING THE NEEDLE

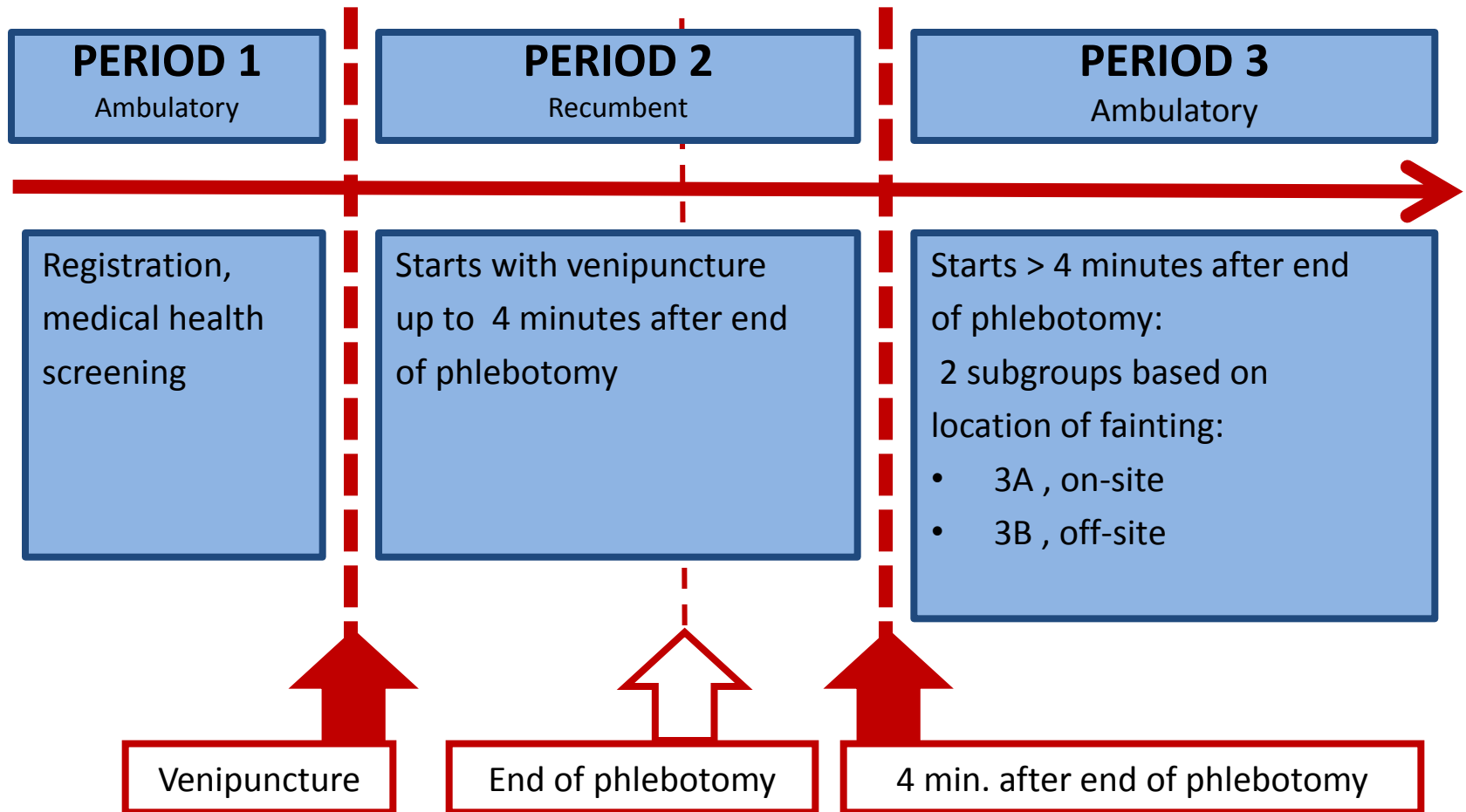
Instrumentation during relative hypovolemia

- USAF pilots 10% → 50%
- 6-16 year old 10% → 40%

Stevens PM. Cardiovascular dynamics during orthostasis and the influence of intravascular instrumentation. Am.J.Cardiol. 1966;17):211-8..

de Jong-de Vos van Steenwijk CC et al Incidence and hemodynamic characteristics of near-fainting in healthy 6- to 16-year old subjects. J.Am.Coll.Cardiol. 1995 25:1615-21.

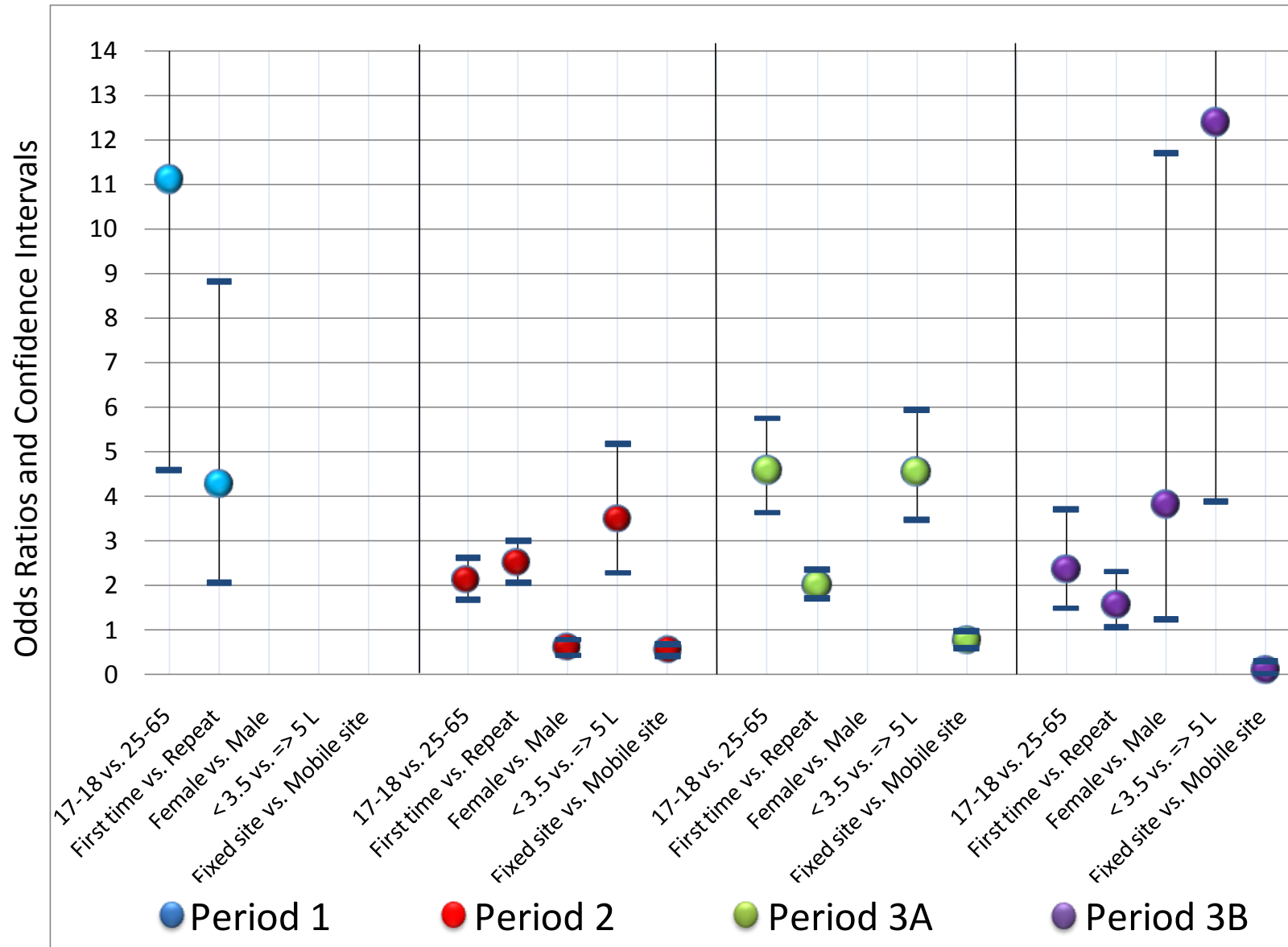
Time Course of WB Donation



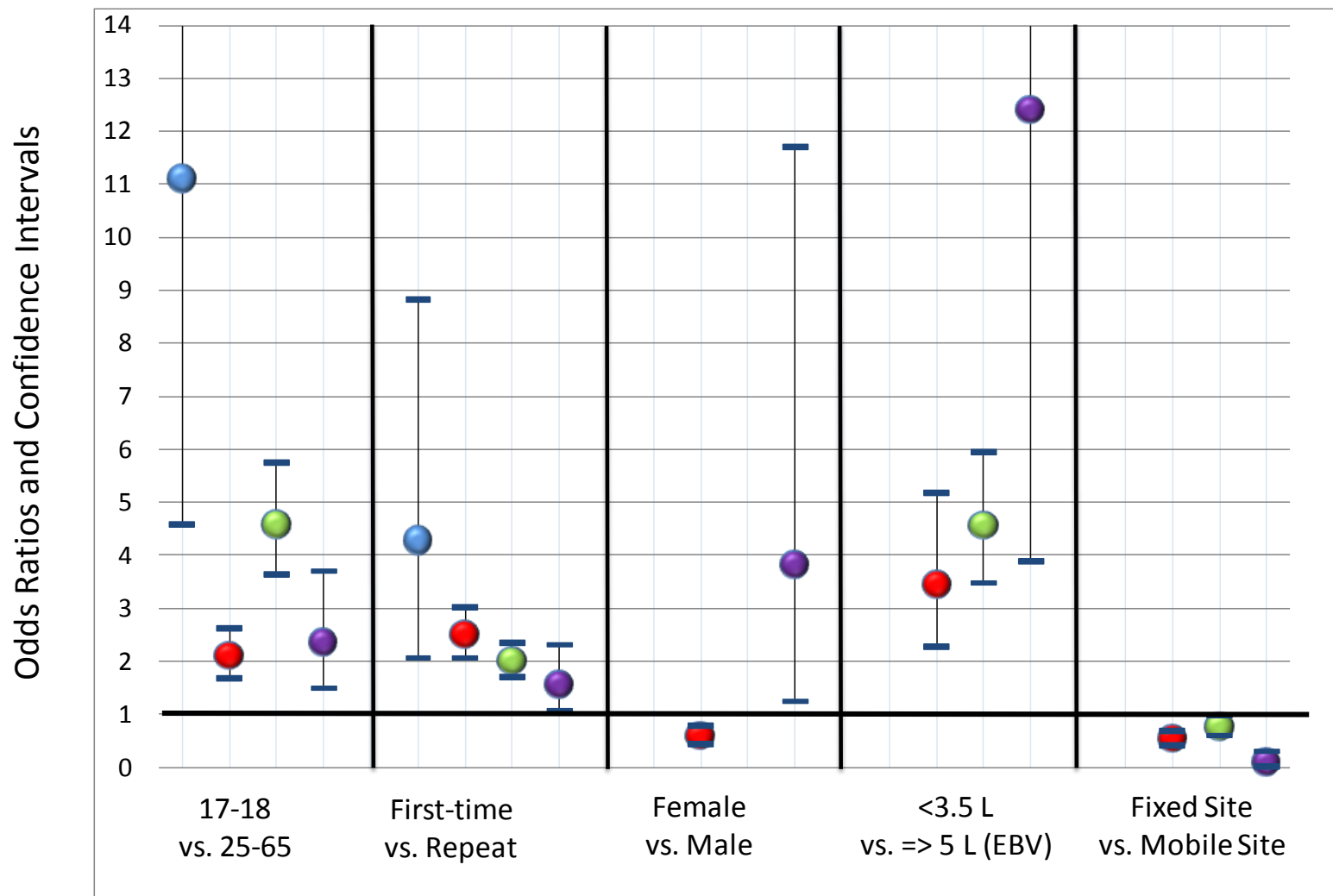
Multivariable logistic regression analysis to identify factors associated with fainting / injury

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

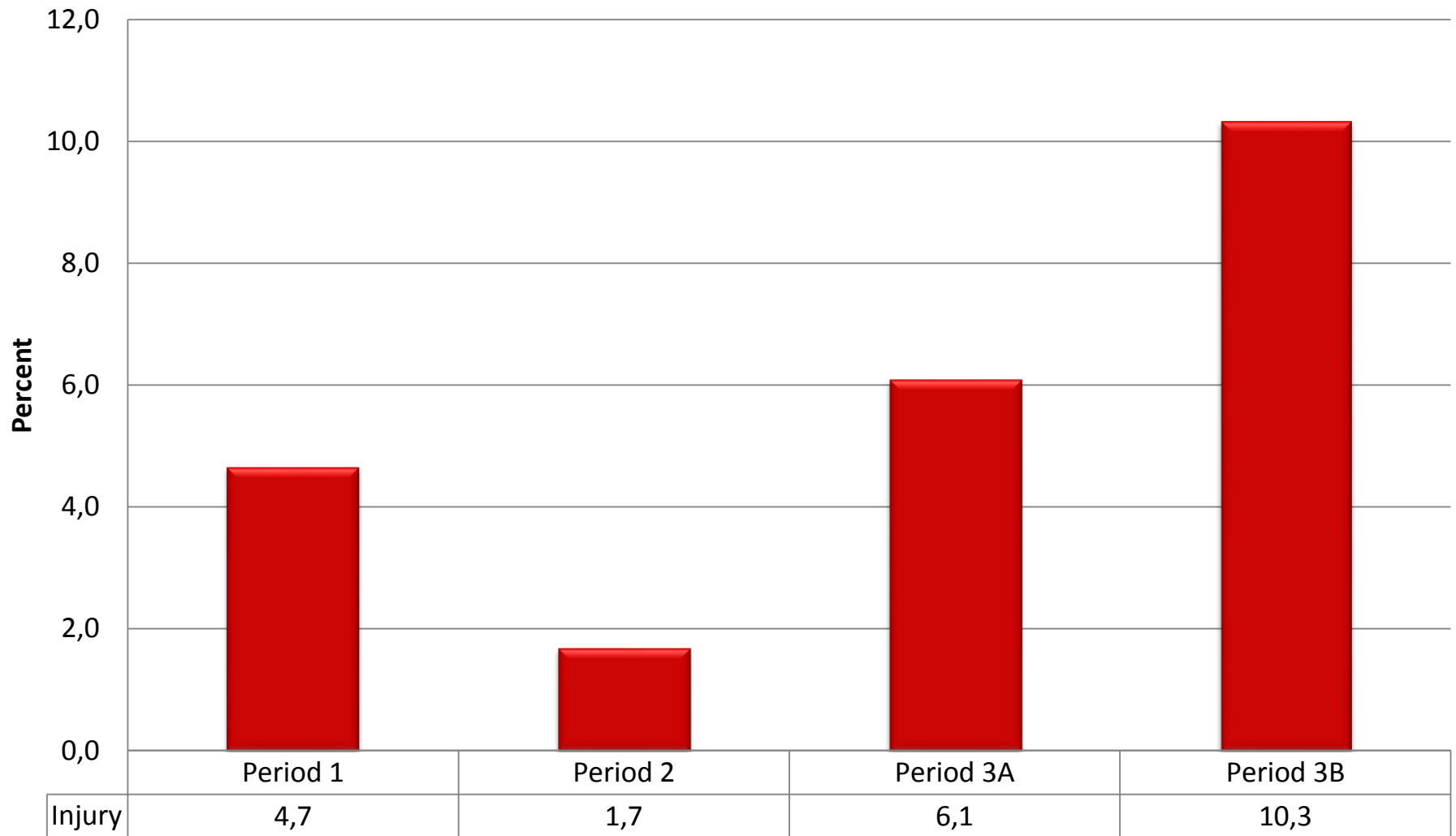
Possibilities (Whole Blood Donation)

Period	Fainting Rate/ 1000 donations*	Cause (?)	% Injury among Fainting Events
1	0.04	Uncertainty, fear of needles	4.7
2	1.1	Relative hypovolemia, needle removal	1.7
3A	1.4	Relative hypovolemia, low EBV, failure to compensate for position change	6.1
3B	0.3	Relative hypovolemia, being female (cardiac filling), low EBV, failure to compensate for position change	10.3

*except for Period 1 – per 1000 presentations

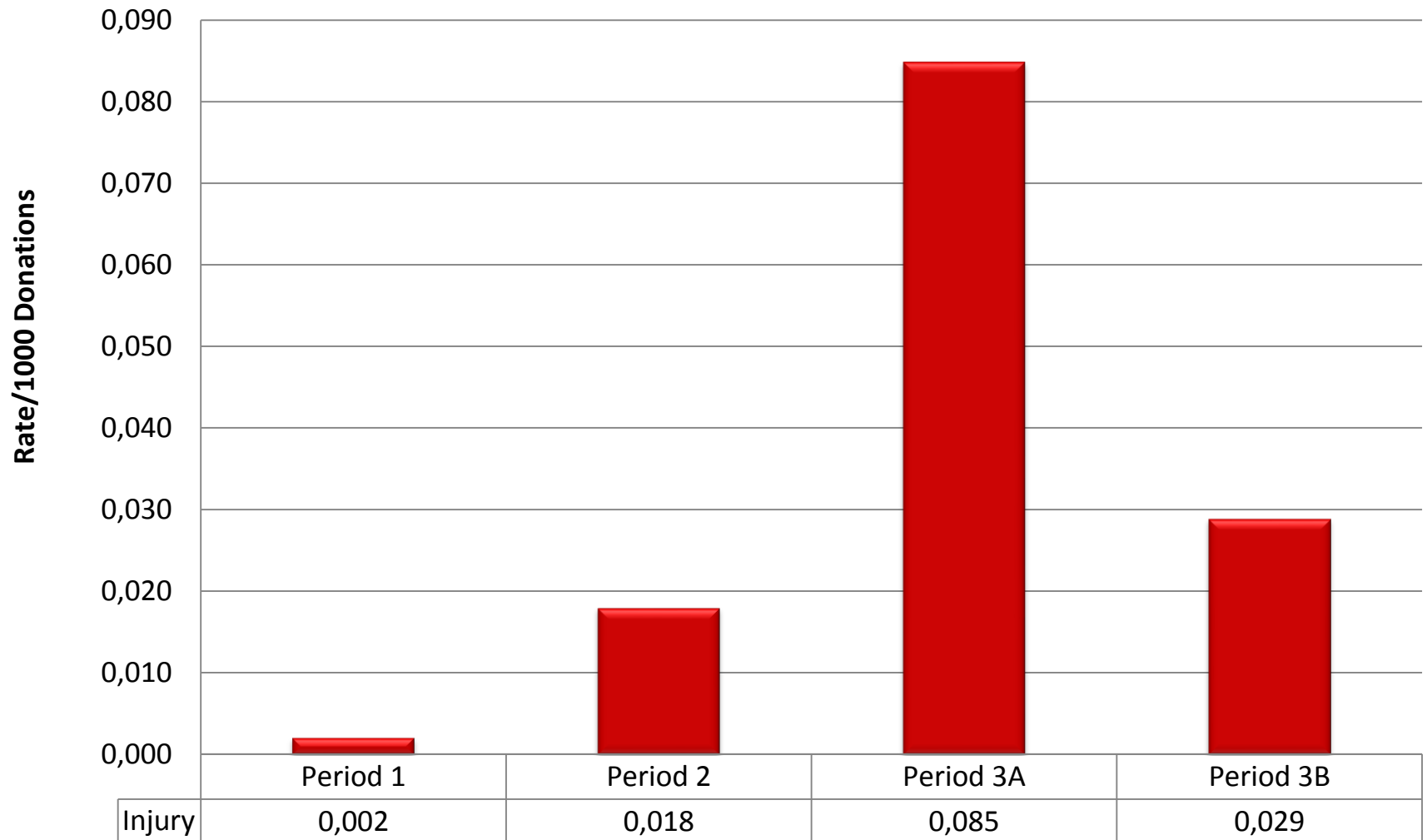
Injury / 100 Faints

(Males and Females)



Injury / 1000 Donations

(Males and Females)



Injury from Whole Blood Donation

- Injury most associated with LOC after standing up
- Fainting while upright is most associated with % EBV donated and with female gender (late VVR)
- Cardiac filling and female [stiffer] heart
- Lack of compensation for orthostatic changes 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?

Reducing Risk of Injury from VVR

What Interventions? When Apply?

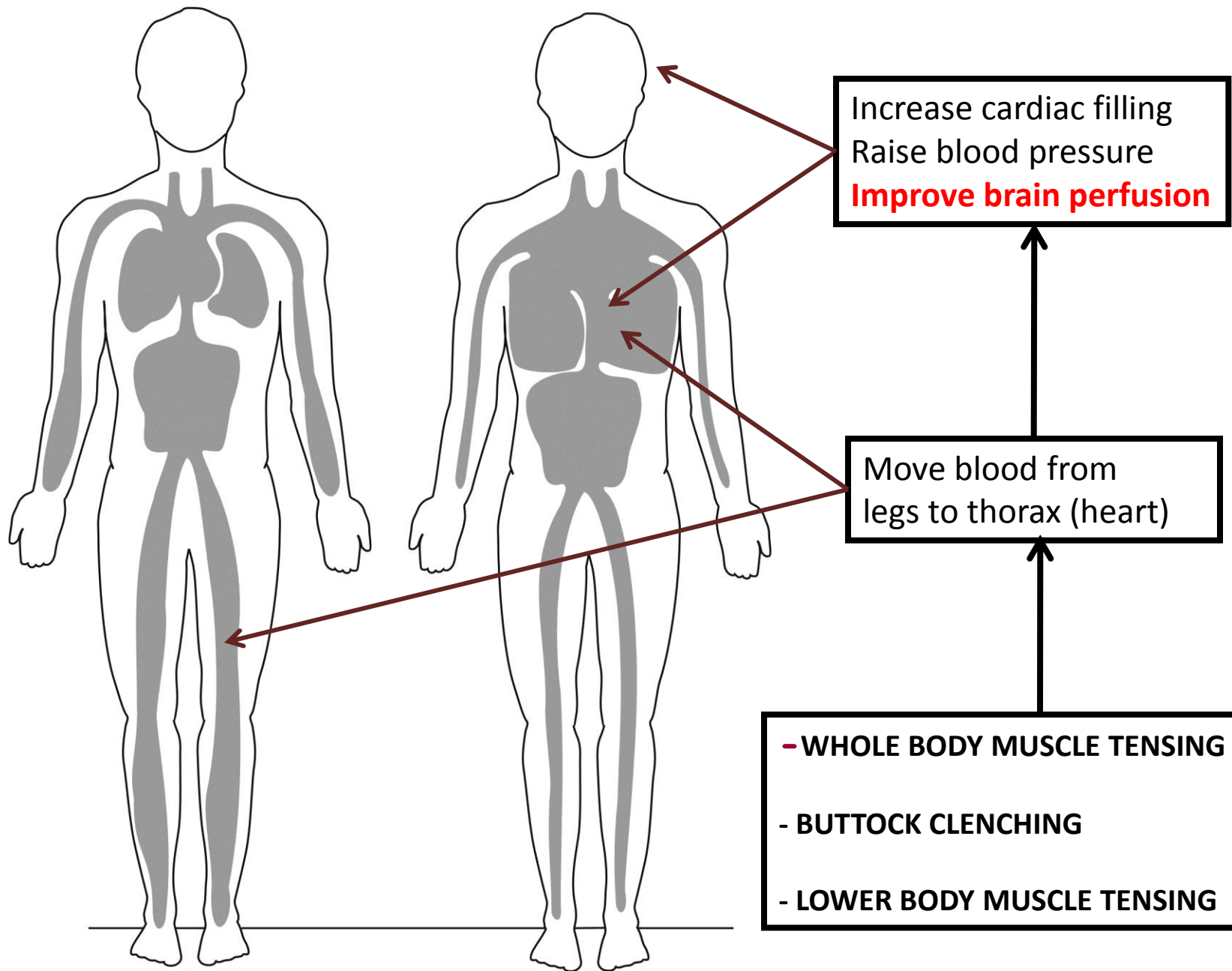
- **Interventions**
 - Limit % EBV donated
 - Reassurance
 - Reduce needle manipulation
 - Increase cardiac filling
 - Restore blood volume
 - Muscle tension
 - Electrolyte replacement
 - Restrict activity after donation
- **Periods**
 - Period 1 (before venipuncture)
 - Period 2 (donor recumbent, phlebotomy)
 - Period 3A (donor on-site, ambulatory, ~protection)
 - Period 3B (donor off-site, ambulatory, out of area of protection)

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

Sodium Balance

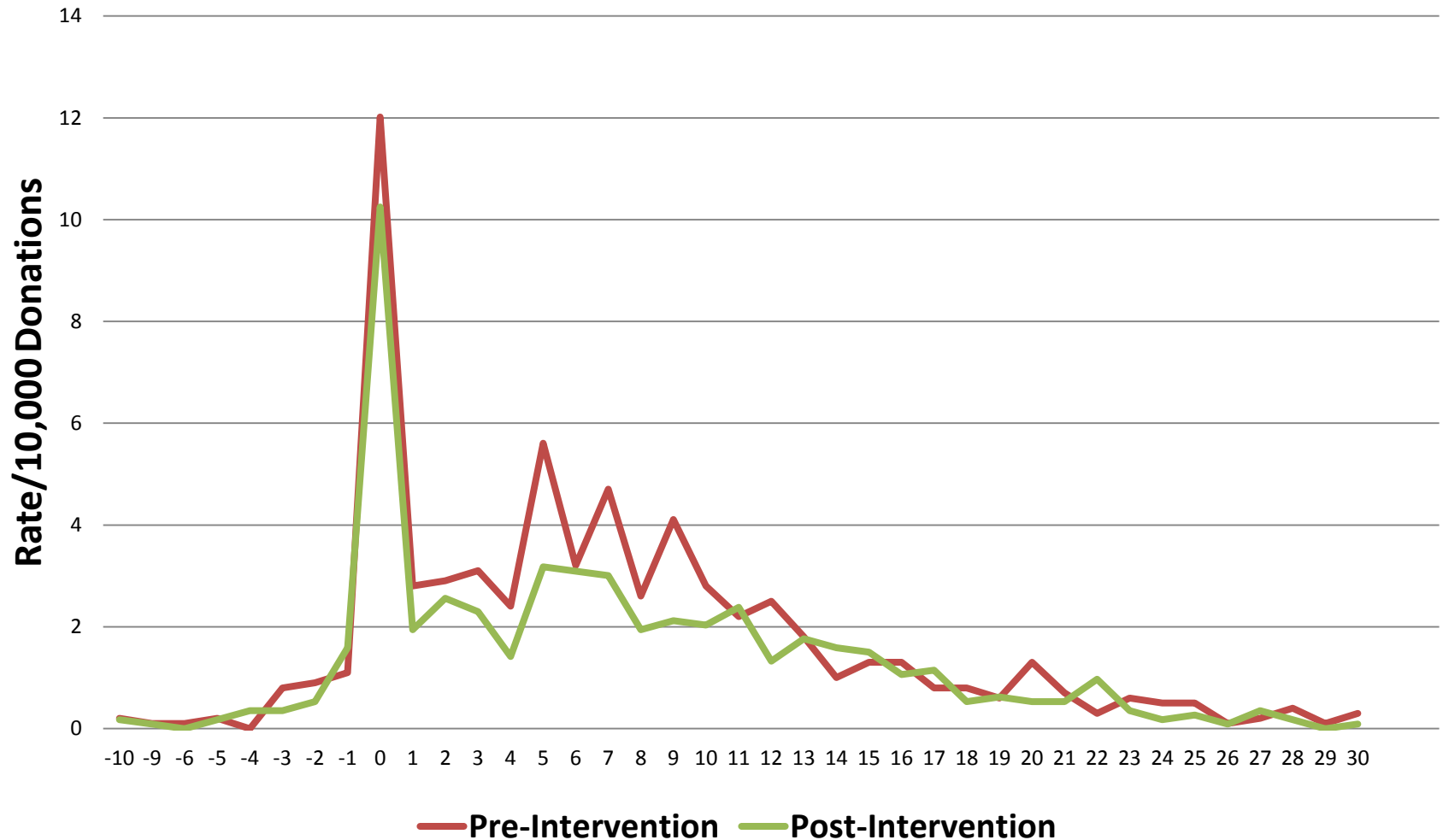
- Salt load increases plasma Na^{++} and thereby thirst sensation. Water and salt retention (isotonic) increase plasma volume
- 50 % of a salt load in a subject on a low-sodium diet will be retained on the first day
- Positive effect of interventions that increase plasma volume – patients with autonomic nervous system disorders
- If blood donors replace salt, recovery from hypovolemia should be more rapid



Interventions 2008 – Young Donors

- Limit donation to $< 15\%$ EBV
- 500 ml water offered < 30 minutes before donation
- Muscle tensing encouraged during phlebotomy

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



Weaknesses of First Implementation

- Limit on % EBV donated was effective
- No effort to restore blood volume rapidly
- No requirement to perform muscle tensing or drink water – staff/donors not engaged
- 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)

New Intervention

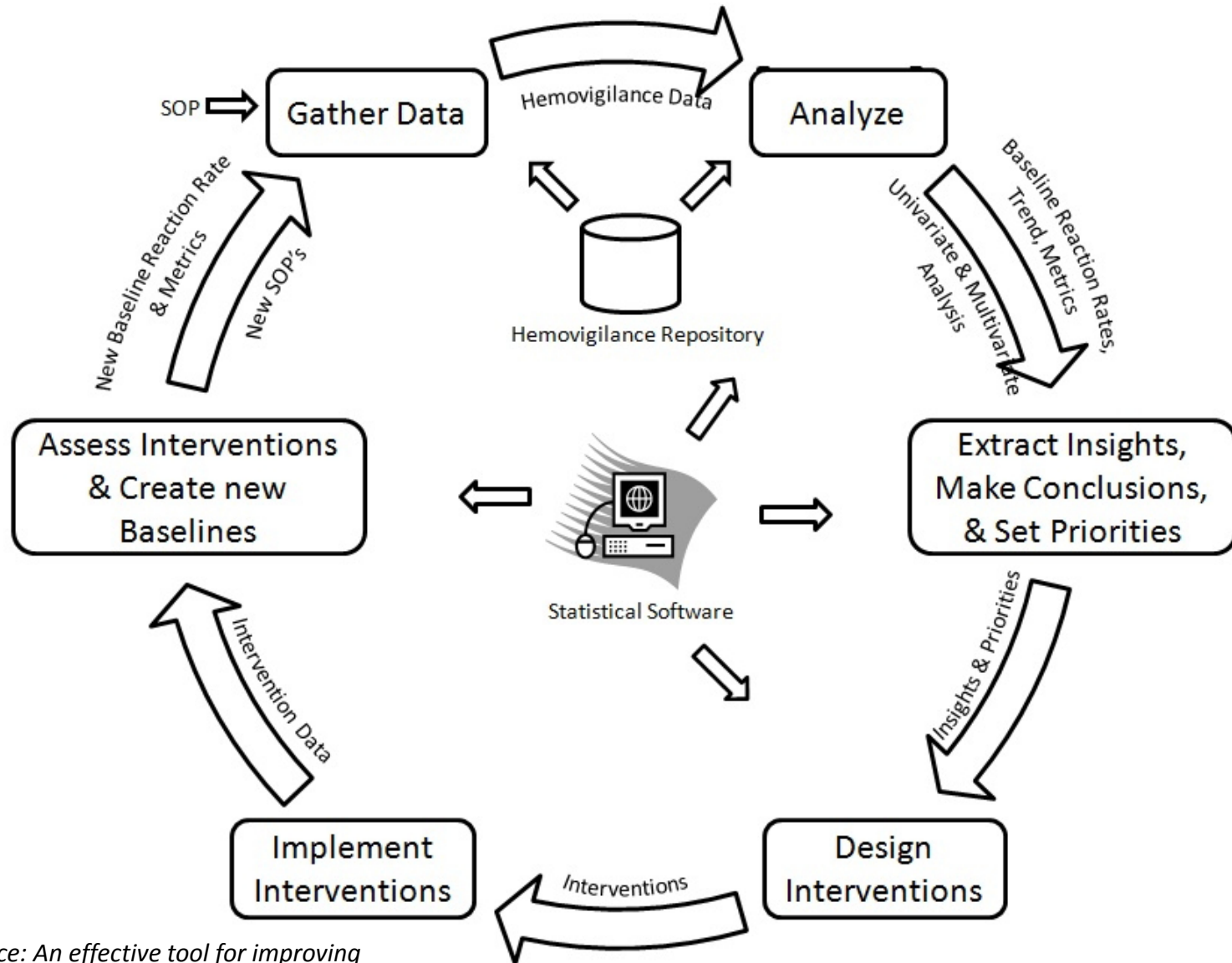
	Period 1	Period 2	Period 3A	Period 3B
Treatment and Prevention	<u>When dizzy or standing up:</u> Muscle Tension Squat Lie Down	<u>When needle removed:</u> Muscle Tension	<u>When dizzy or standing up:</u> Muscle Tension Squat Lie Down	<u>When dizzy or standing up:</u> Muscle Tension Squat Lie Down
Prevention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

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

Monitor Intervention Effectiveness

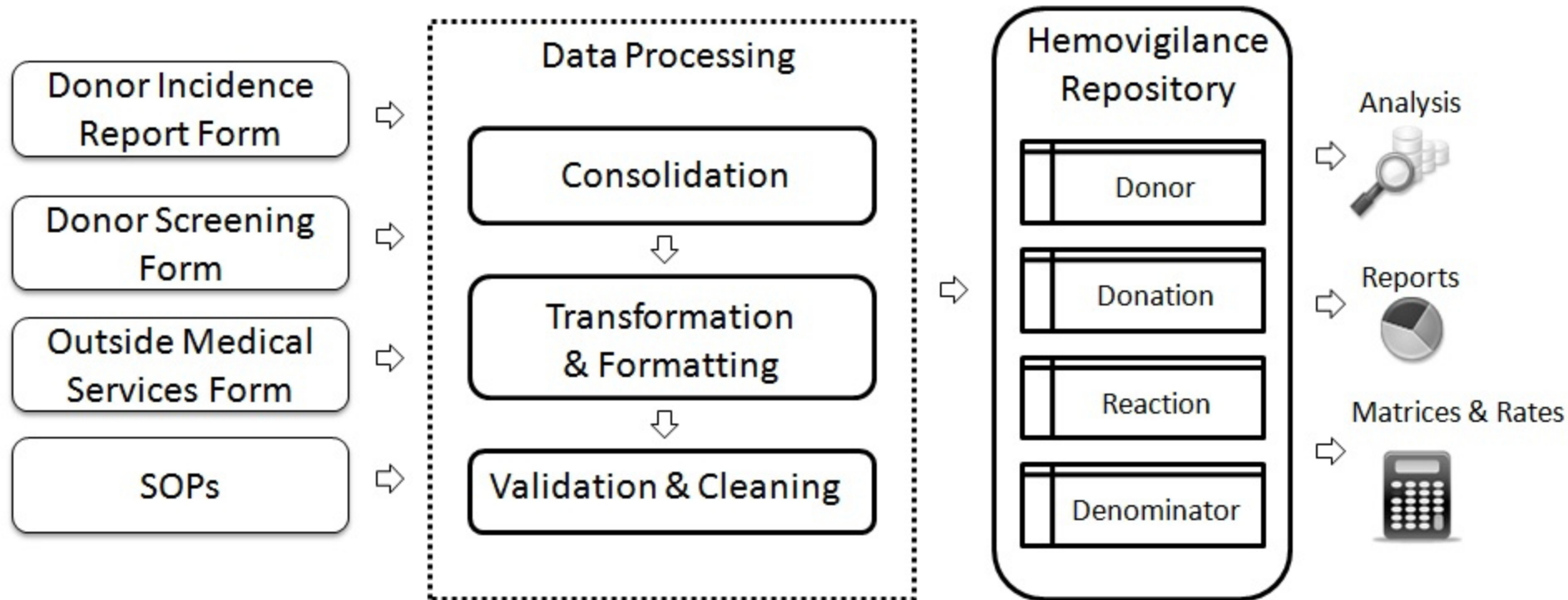
- Rigorous attention to data – continuous
- Implement pilot in half the centers
- Survey control and test donors
 - Did you receive information on muscle tensing
 - Did you receive information on salty snacks
 - Did you tense your muscles
 - Did you eat the snacks
- Stratified post-intervention analysis

Donor Vigilance



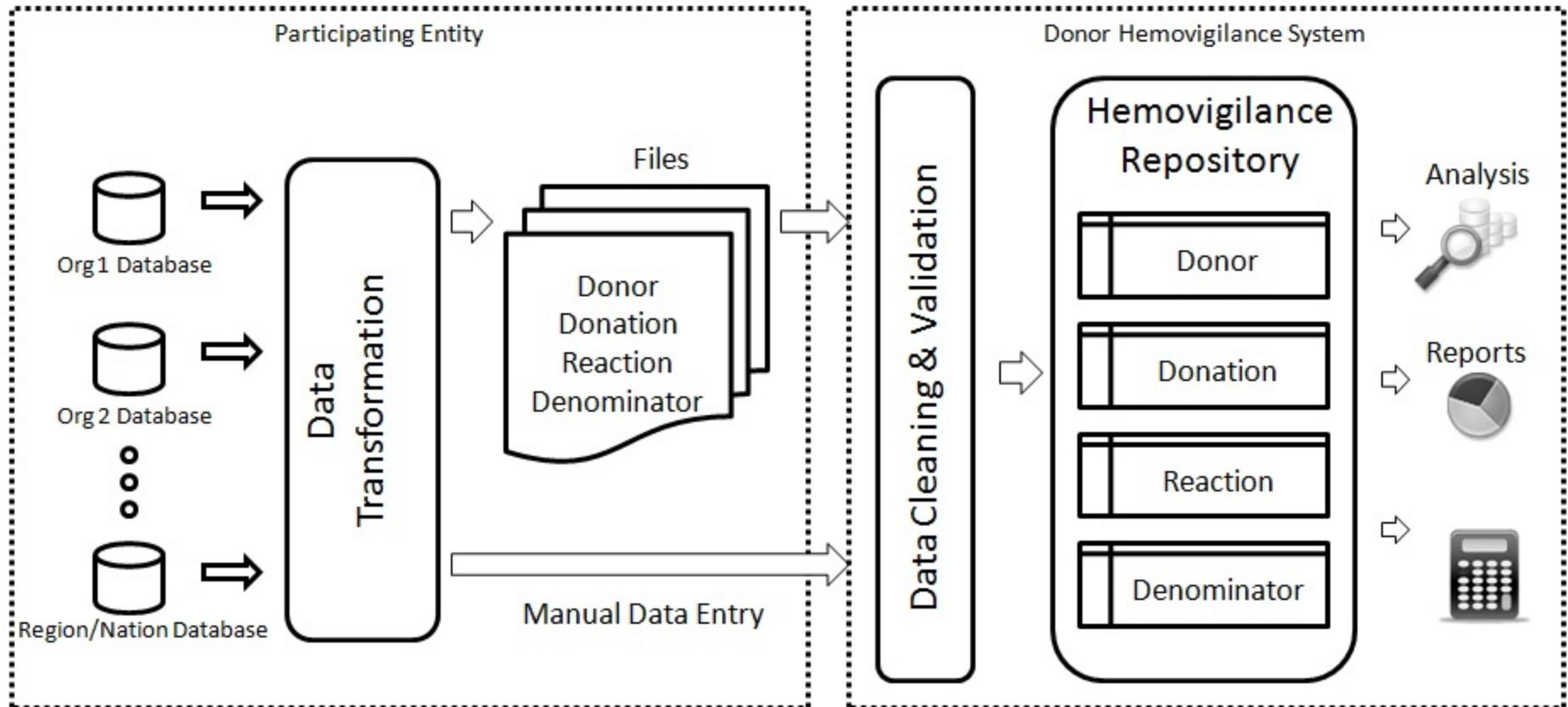
Hemovigilance: An effective tool for improving transfusion safety (ed. R De Vries and J-C Faber)

Data Management at Organization Level



Hemovigilance: An effective tool for improving transfusion safety (ed. R De Vries and J-C Faber)

Data Management Nation Level



Hemovigilance: An effective tool for improving transfusion safety (ed. R De Vries and J-C Faber)

Summary

- Continuous improvement requires detailed metrics, detailed data collection, IT support and monitoring, but does not require comprehensive original research
- Continuous improvement requires knowing what other people are learning about processes
- Continuous improvement requires creating hypotheses for advancement based on data
- Continuous improvement requires interventions for high priority issues

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- Hany Kamel MD
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