



*Blood Systems*

# Donor Vigilance: Five-Year Journey of Continuous Process Improvement

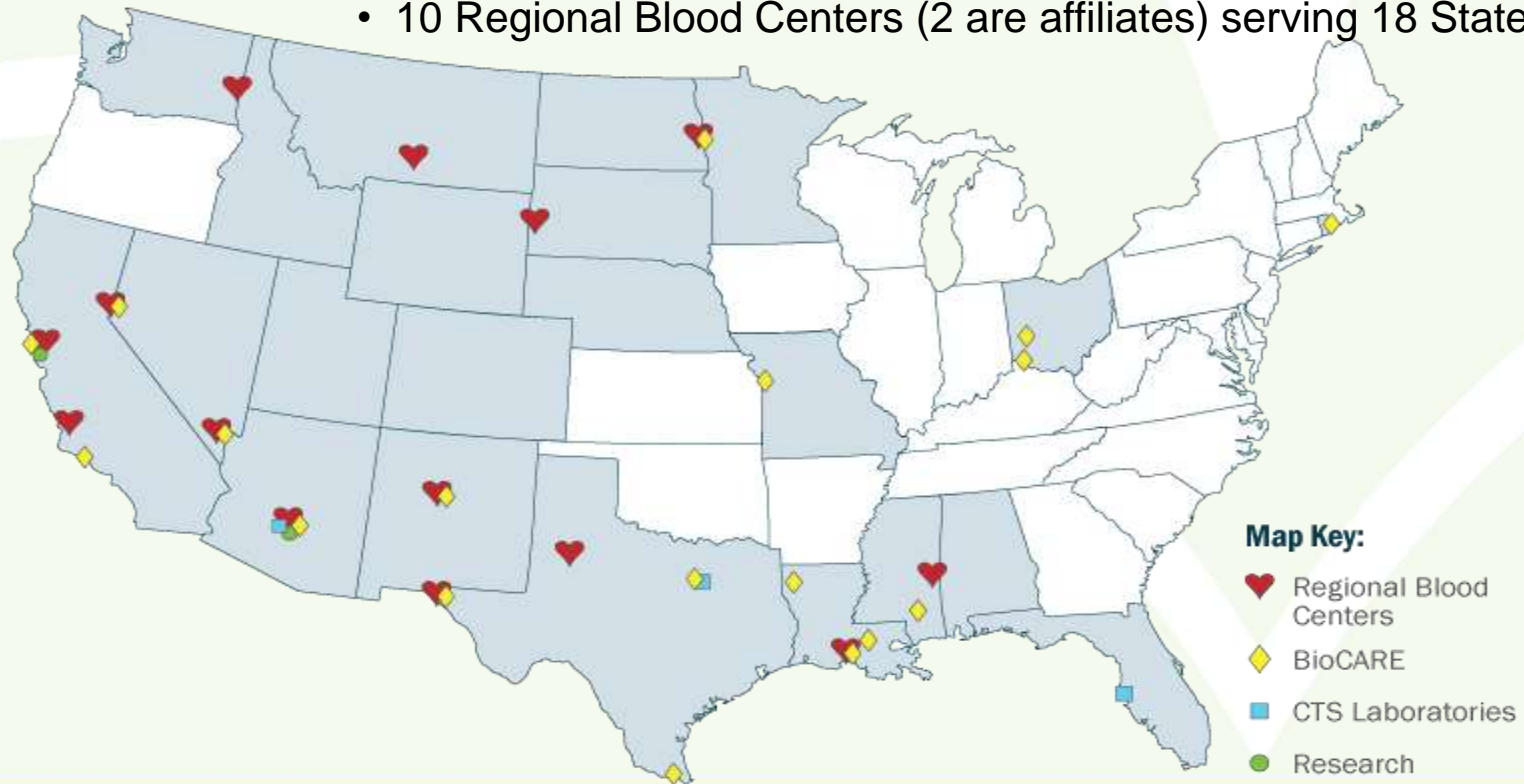
Hany Kamel, MD  
Marjorie Bravo, MD  
Brian Custer, PhD  
Peter Tomasulo, MD

# Background

- Donor Vigilance Program at Blood Systems, Inc. (BSI) began in 2007
- Resulted in multiple refereed publications that have influenced policies
- Led to implementation of intervention measures that reduced vasovagal reactions in donors.

# Organization Background

- Established 1943
- Non-profit 501 (c) (3) Organization
- National Headquarters is Blood Systems (Scottsdale, Arizona)
- 10 Regional Blood Centers (2 are affiliates) serving 18 States



# Aim

- To describe actions taken in data collection to enhance analysis and reporting on blood donor adverse events (AEs) aimed to inform appropriate intervention strategies.



# BSI's Donor Vigilance Timeline

2007

2008

2009

2010

2011

present

## CONTINUOUS PROCESS IMPROVEMENT

Data Collection Forms

Database

Vasovagal Reactions Classification

Supplemental Donor Testing

BECS changes to accommodate external reporting

- Mild Reactions
- Donor Association
- Intended Collection Type



# Data Collection Forms

2007

2008

2009

2010

2011

present

- Rev 5 (up to 6/3/07)
  - Rev 6 (6/4/07 to 12/2/07)
    - Rev 7 (12/3/07 to 4/24/08)
      - Rev 8 (4/25/08 to 7/27/08)
        - Rev 9 (7/28/08 to 10/26/08)
          - Rev 10 (10/27/08 to 3/29/09)
            - Rev 11 (3/30/09 to 11/27/2011)
              - Rev 12 (11/28/2011 to present)
  - Revisions 5 to 12 (2007 to present) - periodic reviews allowed inclusion of data elements evaluated as important in donor vigilance
  - NOTE: participation in national reporting allowed for stabilization of data collection form, i.e. Rev. 11 (3/30/2009 to 11/27/2011)



# BS 336 – Donor Reactions and Incidents (Paper Form)



United Blood Services

CENTER INFORMATION:

## DONOR REACTION/INCIDENT REPORT

Donor Name: \_\_\_\_\_ SS \_\_\_\_\_

First Middle Last

Phone: (H) \_\_\_\_\_ (W) \_\_\_\_\_ (ext.) \_\_\_\_\_ Birth date: \_\_\_\_\_

Address: \_\_\_\_\_  
Street City State Zip

Donor Type: ☐ Allogeneic (homologous) ☐ Autologous ☐ Directed ☐ Therapeutic

Sex: ☐ Male ☐ Female ☐ First time donor or ☐ Repeat donor Donation No: \_\_\_\_\_

Donation Site: ☐ Fixed site ☐ Mobile

Process Code: ☐ W ☐ A ☐ C ☐ P ☐ Q ☐ R ☐ Z ☐ X ☐ T ☐ D ☐ S ☐ M ☐ N ☐ O

Was collection completed? ☐ Yes ☐ Short - Volume removed \_\_\_\_\_

INSTRUMENT TYPE: ☐ Baxter/ Fenwal - CS 3000 ☐ Baxter/ Fenwal - Amicus ☐ Baxter/ Fenwal - Auto-C  
☐ COBE BCP-TRIMA ☐ COBE BCP-Spectra ☐ Haemonetics MCS+ 8150 ☐ Haemonetics MCS+ 9000

Repeated needle adjustment required ☐ Yes ☐ No

Reaction occurred at: ☐ Screening area ☐ Donor chair ☐ Canteen ☐ Other

Time of reaction: \_\_\_\_\_ ☐ Prior to donation ☐ During donation ☐ After donation - Date \_\_\_\_\_

If donor is diabetic, how treated? ☐ With insulin ☐ With oral hypoglycemics

### FOR REACTIONS ONLY

- |   |  |   |
|---|--|---|
| <input type="checkbox"/> Pallor   | <input type="checkbox"/> Weakness                      | <input type="checkbox"/> Vomiting             |
| <input type="checkbox"/> Sweating   | <input type="checkbox"/> Nausea                        | <input type="checkbox"/> Tetany               |
| <input type="checkbox"/> Nervousness  | <input type="checkbox"/> Tingling/numbness lip/fingers | <input type="checkbox"/> Difficulty breathing |
| <input type="checkbox"/> Hyperventilation   | <input type="checkbox"/> Slow pulse                    | <input type="checkbox"/> Convulsions          |
| <input type="checkbox"/> Rapid, thready pulse   | <input type="checkbox"/> Hypotension                   | <input type="checkbox"/> Incontinence         |
| <input type="checkbox"/> Lightheadedness  | <input type="checkbox"/> Twitching movements           | <input type="checkbox"/> Chest pain           |
| <input type="checkbox"/> Fainting/unresponsiveness to commands _____ sec/min (circle one) |  |   |

### FOR INCIDENTS ONLY

Donor complaint: ☐ at time of phlebotomy ☐ later \_\_\_\_\_ Date \_\_\_\_\_

☐ Hematoma \_\_\_\_\_  
specify size and location

☐ Excessive pain at needle site ☐ pain elsewhere in arm: \_\_\_\_\_  
specify site

☐ Numbness ☐ tingling ☐ redness \_\_\_\_\_  
specify site

☐ Infiltration \_\_\_\_\_

☐ Possible arterial puncture

☐ Fall - ☐ No apparent injury ☐ Head trauma ☐ Possible injury

Description of incident, actions taken, donor examination: \_\_\_\_\_


Property damage ☐ No ☐ Yes

BS 336 (Rev. 9/02)



Blood Systems

# BS 336 – Donor Reactions and Incidents (Paper Form)




Donor  
Phone  
Address  
Donor  
Sex:  
Donor  
Process  
Was co  
INSTR  
Repeat  
Readio  
Time of  
If donor

☐ Pol  
☐ Sw  
☐ Ne  
☐ Hy  
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☐ Lig  
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Donor  
☐ He  
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Descri  
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BS 336 (Rev 4)  
MED-300



Blood Systems

Center Information:

## Donor Reaction/Incident Report

Donation # \_\_\_\_\_ Date \_\_\_\_\_ Reaction/Incident Start Time \_\_\_\_\_

Reaction Location ☐ Waiting Area ☐ Screening ☐ Donor Room ☐ Canteen ☐ Off Site

Donor Name \_\_\_\_\_  
Last First Middle

For minor donors, name of Parent or Guardian \_\_\_\_\_ Daytime phone number (work or cell) \_\_\_\_\_

**Reaction Signs/Symptoms**

<input type="checkbox"/> Pallor	<input type="checkbox"/> Nausea	<input type="checkbox"/> Tetany
<input type="checkbox"/> Sweating	<input type="checkbox"/> Vomiting	<input type="checkbox"/> Convulsions
<input type="checkbox"/> Nervousness/Anxiety	<input type="checkbox"/> Twitching movements	<input type="checkbox"/> Difficulty breathing
<input type="checkbox"/> Hyperventilation	<input type="checkbox"/> Fainting/loss of consciousness	<input type="checkbox"/> Incontinence
<input type="checkbox"/> Light-headedness/Dizziness	_____ sec/min (circle one)	<input type="checkbox"/> Chest pain
<input type="checkbox"/> Weakness		<input type="checkbox"/> Other _____
<input type="checkbox"/> Tingling/numbness lips/fingers		

**Treatment**

<input type="checkbox"/> Feet elevated	<input type="checkbox"/> Breathing into paper bag
<input type="checkbox"/> Advised to take slow, deep breaths	<input type="checkbox"/> Saline infused Volume _____
<input type="checkbox"/> Cool compress applied	<input type="checkbox"/> Blood components returned Volume _____
<input type="checkbox"/> Fluid intake encouraged	<input type="checkbox"/> Other (see comments)

**Monitoring**

Pre-donation Vital Signs      Phlebotomy Stop Time

Time												
BP												
Pulse												
Emesis	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N
Position												

**Monitoring (continued)**

Time													Discharge
BP													
Pulse													
Emesis	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	
Position													

Position Key: R=lying flat or feet elevated; S=sitting with feet on the bed; D=sitting with feet over the side; T=standing

**Release from Collection Site**

<input type="checkbox"/> Home with discharge instructions	Time released from site: _____
<input type="checkbox"/> Home with instructions to follow up with personal physician	Donor care transferred to: _____
<input type="checkbox"/> 911, Paramedics	Name/Relationship _____
<input type="checkbox"/> Medical Director notified	Time _____ EC _____

**Procedure Problems and Incidents**

<input type="checkbox"/> Hematoma	<input type="checkbox"/> Pain in arm	Right / Left	<input type="checkbox"/> Fall
<input type="checkbox"/> Excessive pain at needle site	<input type="checkbox"/> Numbness	Right / Left	<input type="checkbox"/> No apparent injury
<input type="checkbox"/> Infiltration	<input type="checkbox"/> Tingling	Right / Left	<input type="checkbox"/> Head trauma (see comments)
<input type="checkbox"/> Possible arterial puncture	<input type="checkbox"/> Redness	Right / Left	<input type="checkbox"/> Other injury (see comments)
<input type="checkbox"/> Other incidents _____			

**Treatment**

☐ Pressure bandage ☐ Other (See Comments)


Comments \_\_\_\_\_

Completed by: \_\_\_\_\_





# BS 336 – Donor Reactions and Incidents (Paper Form)



**Blood Systems**  
57521

Donation # \_\_\_\_\_  
Reaction Location \_\_\_\_\_  
Donor Name \_\_\_\_\_  
Phone \_\_\_\_\_  
Address \_\_\_\_\_  
Donor Sex: ☐ Male ☐ Female  
Donation Process: ☐ Whole Blood ☐ Platelets ☐ Plasma ☐ Cryoprecipitate  
Repeat: ☐ Yes ☐ No  
Reason: \_\_\_\_\_  
Time of day: \_\_\_\_\_  
If donor: ☐ Pallor ☐ Sweating ☐ Nausea ☐ Hyperventilation ☐ Rash ☐ Light-headedness ☐ Faint

Donor: ☐ Hematoma ☐ Excessive bleeding ☐ Infiltration ☐ Possible ☐ Other incident

Describe: \_\_\_\_\_  
Proper: \_\_\_\_\_

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**Donor**

Reaction/Incident Start Date \_\_\_\_\_ Time \_\_\_\_\_

Reaction During: ☐ Pre-screening ☐ Medical Screening ☐ Collection ☐ Canteen ☐ Off Site

Donor Name \_\_\_\_\_

For minor donors, name of Parent or Guardian \_\_\_\_\_

Daytime phone number \_\_\_\_\_ Evening phone number \_\_\_\_\_

**Donor Reaction/Incident Report**

**Part I – Assessment and Management**

**Reaction Signs/Symptoms**

☐ Pallor  
☐ Sweating  
☐ Feeling warm or chilled  
☐ Nervousness/Anxiety  
☐ Hyperventilation  
☐ Light-headedness/Dizziness  
☐ Weakness  
☐ Tingling/numbness/tingling  
☐ Nausea  
☐ Vomiting  
☐ Twitching movements (Tremors)  
☐ Muscle tightness or cramping (Tetany)  
☐ Incontinence  
☐ Fainting/loss of consciousness  
-Length of Time \_\_\_\_\_ seconds (circle one)  
☐ Convulsions  
☐ Difficulty breathing  
☐ Chest pain  
☐ Accident/Fall  
☐ No apparent injury  
☐ With injury (see Comments)  
☐ Other reaction (see Comments)

**Procedure Problems/Incidents**

☐ Hematoma  
-Size \_\_\_\_\_  
☐ Infiltration  
-Volume \_\_\_\_\_  
☐ Pain or pressure at needle site  
☐ Possible arterial puncture  
☐ Redness at needle site  
☐ Rash/itching/hives at needle site  
☐ Generalized rash/itching/hives  
☐ Needle adjustment  
☐ Pain the sternal/axillary down the forearm  
☐ Numbness/tingling of fingers, hand or arm  
☐ Weakness of arm or hand  
☐ Pain anywhere in affected arm  
☐ Other incident (see Comments)

**Treatment**

☐ Feet elevated  
☐ Cool compress applied  
☐ Advised to take slow, deep breaths  
☐ Pressure bandage  
☐ Breathing into paper bag  
☐ Fluid intake encouraged  
☐ Saline infused  
-Volume \_\_\_\_\_  
☐ Other treatment (see Comments)

**Monitoring**


Phlebotomy Start Time: \_\_\_\_\_  
Phlebotomy Stop Time: \_\_\_\_\_

		(circle one)			
		BP	Pulse	Emesis	Position
<b>During Reaction (mark as appropriate)</b>	Time _____	BP _____	Pulse _____	Emesis Y N	Position _____
	Time _____	BP _____	Pulse _____	Emesis Y N	Position _____
	Time _____	BP _____	Pulse _____	Emesis Y N	Position _____
	Time _____	BP _____	Pulse _____	Emesis Y N	Position _____
	Time _____	BP _____	Pulse _____	Emesis Y N	Position _____
	Time _____	BP _____	Pulse _____	Emesis Y N	Position _____
	Time _____	BP _____	Pulse _____	Emesis Y N	Position _____
	Time _____	BP _____	Pulse _____	Emesis Y N	Position _____
<b>Discharge Time and Vital Signs</b>		Time _____	BP _____	Pulse _____	

Position Key: R=lying or feet elevated; S=sitting with feet on the bed; D=sitting with feet over the side; T=standing

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MED300


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**Blood Systems**


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# BS 336 – Donor Reactions and Incidents (Paper Form)




Donor # \_\_\_\_\_  
 Reaction Location \_\_\_\_\_  
 Donor Name \_\_\_\_\_  
 Phone \_\_\_\_\_  
 Address \_\_\_\_\_  
 Donor Sex: ☐ Male ☐ Female  
 Donor Age \_\_\_\_\_  
 Process \_\_\_\_\_  
 Was collected in \_\_\_\_\_  
 INSTR \_\_\_\_\_  
 Repeat \_\_\_\_\_  
 Reaction \_\_\_\_\_  
 Time of day \_\_\_\_\_  
 If donor \_\_\_\_\_  
☐ Pale  
☐ Swelling  
☐ Nausea  
☐ Hypertension  
☐ Rash  
☐ Light-headed  
☐ Faint  
 Donor \_\_\_\_\_  
☐ Hematoma  
☐ Excessive  
☐ Infiltration  
☐ Possible  
☐ Other incident  
 Describe \_\_\_\_\_  
 Proper \_\_\_\_\_




Donation # \_\_\_\_\_  
 Reaction Location \_\_\_\_\_  
 Donor Name \_\_\_\_\_  
 Phone \_\_\_\_\_  
 Address \_\_\_\_\_  
 Donor Sex: ☐ Male ☐ Female  
 Donor Age \_\_\_\_\_  
 Process \_\_\_\_\_  
 Was collected in \_\_\_\_\_  
 INSTR \_\_\_\_\_  
 Repeat \_\_\_\_\_  
 Reaction \_\_\_\_\_  
 Time of day \_\_\_\_\_  
 If donor \_\_\_\_\_  
☐ Pale  
☐ Swelling  
☐ Nausea  
☐ Hypertension  
☐ Rash  
☐ Light-headed  
☐ Faint  
 Donor \_\_\_\_\_  
☐ Hematoma  
☐ Excessive  
☐ Infiltration  
☐ Possible  
☐ Other incident  
 Describe \_\_\_\_\_  
 Proper \_\_\_\_\_




Donor # \_\_\_\_\_  
 Reaction Location \_\_\_\_\_  
 Donor Name \_\_\_\_\_  
 Phone \_\_\_\_\_  
 Address \_\_\_\_\_  
 Donor Sex: ☐ Male ☐ Female  
 Donor Age \_\_\_\_\_  
 Process \_\_\_\_\_  
 Was collected in \_\_\_\_\_  
 INSTR \_\_\_\_\_  
 Repeat \_\_\_\_\_  
 Reaction \_\_\_\_\_  
 Time of day \_\_\_\_\_  
 If donor \_\_\_\_\_  
☐ Pale  
☐ Swelling  
☐ Nausea  
☐ Hypertension  
☐ Rash  
☐ Light-headed  
☐ Faint  
 Donor \_\_\_\_\_  
☐ Hematoma  
☐ Excessive  
☐ Infiltration  
☐ Possible  
☐ Other incident  
 Describe \_\_\_\_\_  
 Proper \_\_\_\_\_



Donor # \_\_\_\_\_  
 Reaction Location \_\_\_\_\_  
 Donor Name \_\_\_\_\_  
 Phone \_\_\_\_\_  
 Address \_\_\_\_\_  
 Donor Sex: ☐ Male ☐ Female  
 Donor Age \_\_\_\_\_  
 Process \_\_\_\_\_  
 Was collected in \_\_\_\_\_  
 INSTR \_\_\_\_\_  
 Repeat \_\_\_\_\_  
 Reaction \_\_\_\_\_  
 Time of day \_\_\_\_\_  
 If donor \_\_\_\_\_  
☐ Pale  
☐ Swelling  
☐ Nausea  
☐ Hypertension  
☐ Rash  
☐ Light-headed  
☐ Faint  
 Donor \_\_\_\_\_  
☐ Hematoma  
☐ Excessive  
☐ Infiltration  
☐ Possible  
☐ Other incident  
 Describe \_\_\_\_\_  
 Proper \_\_\_\_\_



Donor # \_\_\_\_\_  
 Reaction Location \_\_\_\_\_  
 Donor Name \_\_\_\_\_  
 Phone \_\_\_\_\_  
 Address \_\_\_\_\_  
 Donor Sex: ☐ Male ☐ Female  
 Donor Age \_\_\_\_\_  
 Process \_\_\_\_\_  
 Was collected in \_\_\_\_\_  
 INSTR \_\_\_\_\_  
 Repeat \_\_\_\_\_  
 Reaction \_\_\_\_\_  
 Time of day \_\_\_\_\_  
 If donor \_\_\_\_\_  
☐ Pale  
☐ Swelling  
☐ Nausea  
☐ Hypertension  
☐ Rash  
☐ Light-headed  
☐ Faint  
 Donor \_\_\_\_\_  
☐ Hematoma  
☐ Excessive  
☐ Infiltration  
☐ Possible  
☐ Other incident  
 Describe \_\_\_\_\_  
 Proper \_\_\_\_\_



DIN \_\_\_\_\_ Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Center Information:

## Donor Reaction/Incident Report

Reaction/Incident Start Date \_\_\_\_/\_\_\_\_/\_\_\_\_ Time \_\_\_\_:\_\_\_\_:\_\_\_\_ Completed by \_\_\_\_\_

Reaction During ☐ Pre-screening ☐ Medical Screening ☐ Collection ☐ Canteen ☐ Off Site

Donor Name \_\_\_\_\_

### Part I – Assessment and Management

Reaction/Incident Start Date \_\_\_\_/\_\_\_\_/\_\_\_\_ Time \_\_\_\_:\_\_\_\_:\_\_\_\_

Reaction During ☐ Pre-screening ☐ Medical Screening ☐ Collection ☐ Canteen ☐ Off Site

Donor Name \_\_\_\_\_

For minor donor  
Daytime phone \_\_\_\_\_

**Reaction Signs/Symptoms**

☐ Pallor  
☐ Sweating  
☐ Feeling warm or chilled  
☐ Nervousness/Anxiety  
☐ Hyperventilation  
☐ Light-headedness/Dizziness  
☐ Weakness  
☐ Tingling/numbness in fingers  
☐ Nausea  
☐ Vomiting  
☐ Twitching movements (Tremors)  
☐ Muscle tightness or cramping (Tetany)  
☐ Incontinence  
☐ Fainting/loss of consciousness  
☐ Length of Time \_\_\_\_ sec/min (circle one)  
☐ Convulsions  
☐ Difficulty breathing  
☐ Chest pain  
☐ Accident/Fall  
☐ No apparent injury  
☐ With injury (see Comments)  
☐ Other reaction (see Comments)

**Procedure Problems/Incidents**

☐ Hematoma ☐ smaller than 2 in. ☐ larger than 2 in.  
☐ Infiltration  
☐ Volume ☐ <1 in. ☐ >1 in.  
☐ Pain or pressure at needle site  
☐ Possible arterial puncture  
☐ Redness at needle site  
☐ Rash/itching/hives at needle site  
☐ Generalized rash/itching/hives  
☐ Pain that shoots/radiates down the forearm  
☐ Numbness/tingling of fingers, hand or arm  
☐ Weakness of arm or hand  
☐ Pain anywhere in affected arm  
☐ Other incident (see Comments)

**Treatment**

☐ Feet elevated  
☐ Cool compress applied  
☐ Warm compress applied  
☐ Advised to take slow, deep breaths  
☐ Pressure bandage  
☐ Breathing into paper bag  
☐ Fluid intake encouraged  
☐ Saline infused  
☐ Volume \_\_\_\_\_  
☐ Other treatment (see Comments)

**Reaction Monitoring**

Phlebotomy Start Time: \_\_\_\_:\_\_\_\_:\_\_\_\_ ☐ RN Supervising Reaction  
 Phlebotomy Stop Time: \_\_\_\_:\_\_\_\_:\_\_\_\_

Pre-donation Vital Signs		(circle one)		(circle one)	
Time	BP	Pulse	Symptoms	Y	N
Time	BP	Pulse	Symptoms	Y	N
Time	BP	Pulse	Symptoms	Y	N
Time	BP	Pulse	Symptoms	Y	N
Time	BP	Pulse	Symptoms	Y	N
Time	BP	Pulse	Symptoms	Y	N
Time	BP	Pulse	Symptoms	Y	N
Time	BP	Pulse	Symptoms	Y	N
Time	BP	Pulse	Symptoms	Y	N

**Discharge Time and Vital Signs**

Time \_\_\_\_:\_\_\_\_:\_\_\_\_ BP \_\_\_\_/\_\_\_\_/\_\_\_\_ Pulse \_\_\_\_ Position \_\_\_\_

Position Key: R-lying or feet elevated, S-sitting with feet on the bed, O-sitting with feet over the side, T-standing



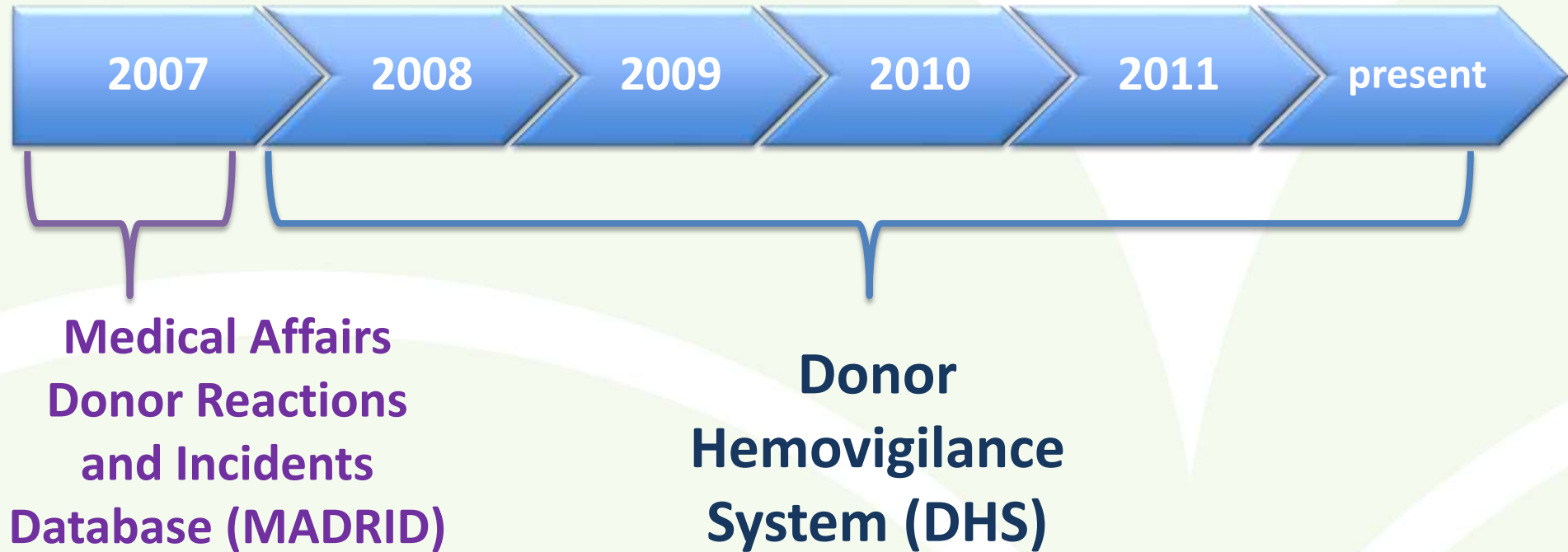
## BS 336 – Donor Reactions and Incidents (Paper Form)

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# Database

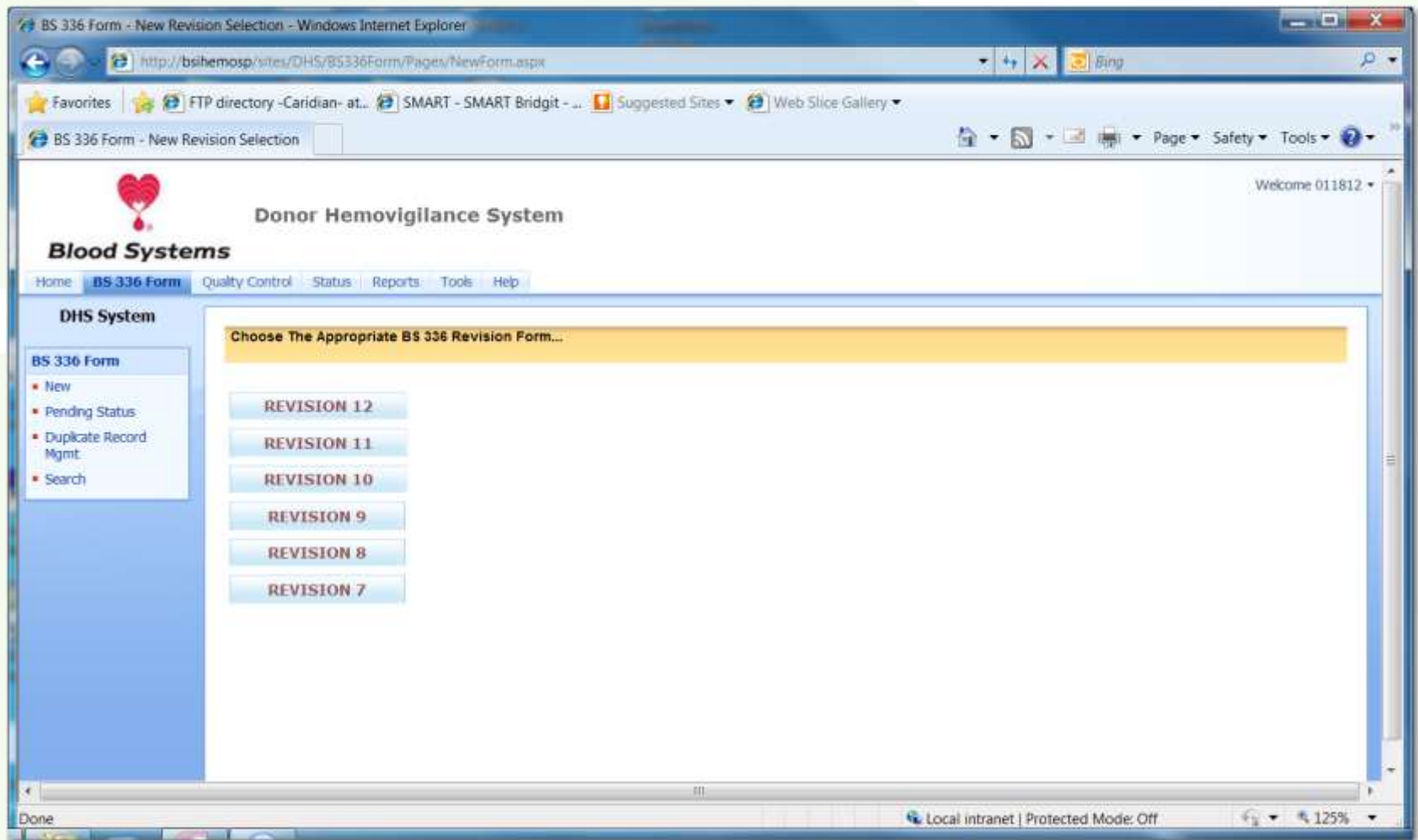




# Medical Affairs Donor Reactions and Incidents Database (MADRID)

Medical Affairs Donor Reaction and Incident Database (MADRID)v.2		
<b>Center</b> 22 <b>Donation #</b> 6097614 <b>Date on BS 336:</b> 6/20/2007 <b>Reaction Location</b> D <b>Reaction/ Incident Start Time:</b> 16:40 <b>Donor ID</b> 2549859	<b>Entry Date:</b> 11/20/2007  <b>Supervisor/ Designee Review</b> <b>Class. of Reaction 1</b> Moderate <b>Reaction 2</b> <b>Phlebotomy Type:</b> pls/rbc  <b>First time Donor</b> <input type="checkbox"/> <b>Collection Complete</b> <input checked="" type="checkbox"/> <b>Needle Adjustment</b> <input type="checkbox"/>  <b>Follow-up Treatment</b> <b>ER</b> <input type="checkbox"/> <b>Admitted</b> <input type="checkbox"/> <b>Risk Management Notified</b> <input type="checkbox"/>  <b>Medical Director Review</b> May donate	<b>D R R</b> <b>Donation # on DRR</b> 6097614 <b>Donor ID on DRR</b> 2549659 <b>Gender</b> M <b>DOB:</b> 9/29/1944 <b>Donation Date:</b> 6/20/2007 <b>Collection Site</b> 22C01 <b>Donation Type</b> B <b>Bag Type</b> TC  <b>Weight (in pounds)</b> 185 <b>Height (in inches)</b> 69 <b>Blood Pressure</b> <b>Systolic</b> 138 <b>Diastolic</b> 84 <b>Pulse</b> 64  <b>Donor Reaction Time:</b> <b>Phlebotomy</b> <b>Start Time:</b> <b>End Time:</b>
<b>Reaction Signs/ Symptoms</b> <input type="checkbox"/> Fainting/unresponsive to commands <input type="checkbox"/> Vomiting <input type="checkbox"/> <input type="checkbox"/> Tetany <input type="checkbox"/> <input type="checkbox"/> Convulsions <input type="checkbox"/> <input type="checkbox"/> Incontinence  <b>Release from Collection Site</b> <b>911, Paramedics Called</b> <input type="checkbox"/> <b>Time released from site:</b> 17:28  <b>Procedure Problems and Incidents</b> <input type="checkbox"/> Hematoma <input type="checkbox"/> Tingling <input type="checkbox"/> Excessive pain at needle <input type="checkbox"/> Redness <input type="checkbox"/> Infiltration <input type="checkbox"/> Fall <input type="checkbox"/> Possible arterial puncture <input type="checkbox"/> No apparent injury <input type="checkbox"/> Pain in arm <input type="checkbox"/> Head trauma <input type="checkbox"/> Numbness <input type="checkbox"/> Other injury		
<b>Comments:</b>		

# Donor Hemovigilance System (DHS)



# Donor Hemovigilance System (DHS)

BS 336 Form - Revision 11 Form - Windows Internet Explorer  
http://bsihemosp/sites/DHS/BS336Form/Pages/Rev12Detail.aspx

BS 336 Form - Revision 11 Form

Welcome 011812

**Blood Systems**

Home **BS 336 Form** Quality Control Status Reports Tools Help

**DHS System**

BS 336 Form

- New
- Pending Status
- Duplicate Record Mgmt
- Search

BS336FormRev12WebPart

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**Donor Reaction/Incident Report: Part I, Section A – Assessment and Management**

DIN  \* Date  \* Center Information:  Select One \* Permanent Donor ID

Donor Name Last  First

Donor Phone#  Guardian Phone

Reaction/Incident Start Date  Incident Time  If time not known, select  
☐ 0001-0600 ☐ 0601-1200 ☐ 1201-1800 ☐ 1801-2400 ☐ N/A

Reaction Time  If time not known, select  
☐ 0001-0600 ☐ 0601-1200 ☐ 1201-1800 ☐ 1801-2400 ☐ N/A

Completed by

Reaction During  Select One

[Back To Revision Selection](#) [Next Page](#) [Save For Later](#)

BS 336(Rev. 12) MED300

DIN is a required field.  
Date is a required field.  
Center Information is a required field.

Local intranet | Protected Mode: Off 125%

# Donor Hemovigilance System (DHS)

BS 336 Form - Revision 11 Form - Windows Internet Explorer

http://bsihemosp/sites/DHS/BS336Form/Pages/Rev12Detail.aspx

BS 336 Form - Revision 11 Form

Welcome 011812

## Donor Hemovigilance System

### Blood Systems

Home BS 336 Form Quality Control Status Reports Tools Help

#### DHS System

BS 336 Form

- New
- Pending Status
- Duplicate Record Mgmt
- Search

BS336FormRev12WebPart

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**Donor Reaction/Incident Report: Part I, Section A – Assessment and Management**

**Reaction Signs/Symptoms**

<input type="checkbox"/> Pallor	<input type="checkbox"/> Light-headedness/Dizziness	<input type="checkbox"/> Convulsions
<input type="checkbox"/> Sweating	<input type="checkbox"/> Weakness	<input type="checkbox"/> Difficulty breathing/shortness of breath
<input type="checkbox"/> Nervousness/Anxiety	<input type="checkbox"/> Nausea	<input type="checkbox"/> Chest pain
<input type="checkbox"/> Feeling warm	<input type="checkbox"/> Vomiting	<input type="checkbox"/> Accident/Fall
<input type="checkbox"/> Chills or shivering	<input type="checkbox"/> Continued Vomiting	
<input type="checkbox"/> Tingling/numbness lips/fingers	<input type="checkbox"/> Twitching movements (Tremors)	<input type="radio"/> No apparent injury
<input type="checkbox"/> Muscle tightness, cramping, spasms, Tetany	<input type="checkbox"/> Incontinence Diarrhea	<input type="radio"/> With injury (see Comments)
<input type="checkbox"/> Hyperventilation	<input type="checkbox"/> Fainting/Loss of Consciousness	<input type="checkbox"/> Other reaction (see Comments)

Length of Time  Sec ☐ Min  
(select one)

Previous Page Next Page Save For Later

BS 336(Rev. 12) MED300

Local intranet | Protected Mode: Off 125%

# Donor Hemovigilance System (DHS)

BS 336 Form - Revision 11 Form - Windows Internet Explorer

http://bsihemosp/sites/DHS/BS336Form/Pages/Rev12Detail.aspx

BS 336 Form - Revision 11 Form

Home BS 336 Form Quality Control Status Reports Tools Help

**DHS System**

BS 336 Form

- New
- Pending Status
- Duplicate Record Mgmt
- Search

BS336FormRev12WebPart

Page 3 of 10

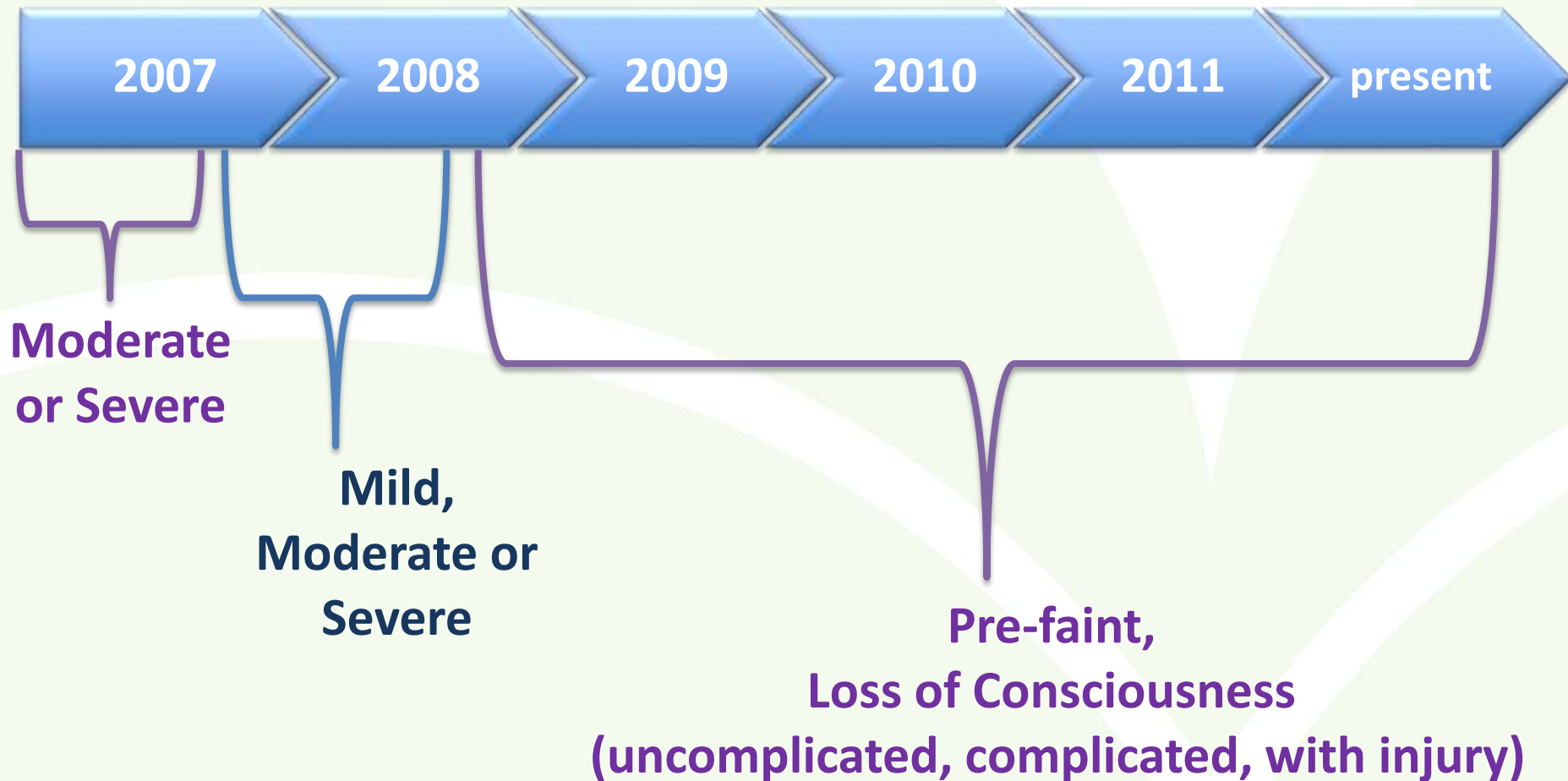
**Donor Reaction/Incident Report: Part I, Section A – Assessment and Management**

Procedure Problems/Incidents	Treatment
<input type="checkbox"/> Hematoma - Size: <input type="text" value="Select One"/>	<input type="checkbox"/> Advised to perform AMT exercises
<input type="checkbox"/> Infiltration	<input type="checkbox"/> Feet elevated
<input type="checkbox"/> Pain or Pressure at needle site	<input type="checkbox"/> Cool compress applied
<input type="checkbox"/> Possible arterial puncture Pulse: <input type="radio"/> Y <input type="radio"/> N	<input type="checkbox"/> Warm compress applied
<input type="checkbox"/> Redness at needle site	<input type="checkbox"/> Advised to take slow, deep breaths
<input type="checkbox"/> Rash/itching/hives at needle site	<input type="checkbox"/> Pressure bandage
<input type="checkbox"/> Generalized rash/itching/hives	<input type="checkbox"/> Breathing into paper bag
<input type="checkbox"/> Pain that shoots/radiates down the forearm - Volume: <input type="text"/> Measurement: <input type="text"/> <input type="text" value="Select One"/>	<input type="checkbox"/> Fluid intake encouraged
<input type="checkbox"/> Numbness/tingling of fingers, hand or arm	<input type="checkbox"/> Saline infused
<input type="checkbox"/> Weakness of arm or hand	<input type="checkbox"/> Other treatment (see Comments)
<input type="checkbox"/> Pain anywhere in affected arm	<input type="text"/>
<input type="checkbox"/> Other incident (see Comments)	
<input type="text"/>	

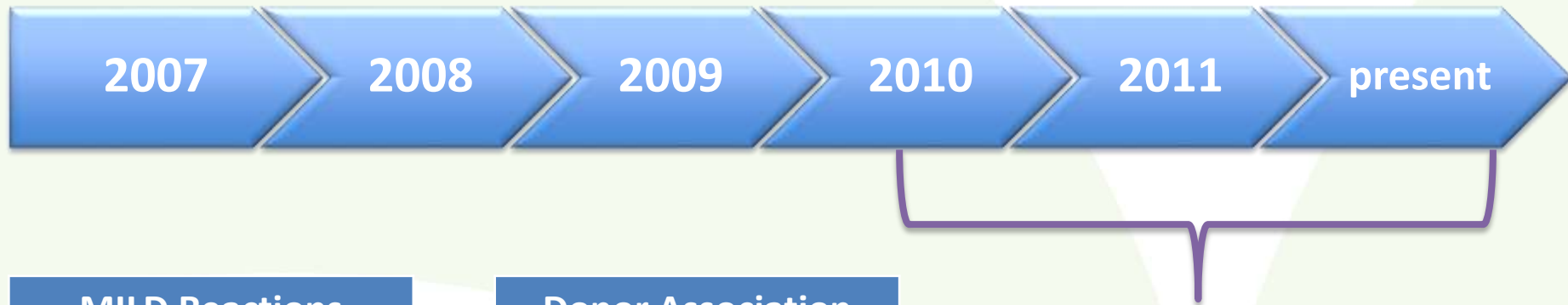
BS 336 (Rev. 12) MED300

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# Vasovagal Reactions Classification



# BECS changes to accommodate external reporting



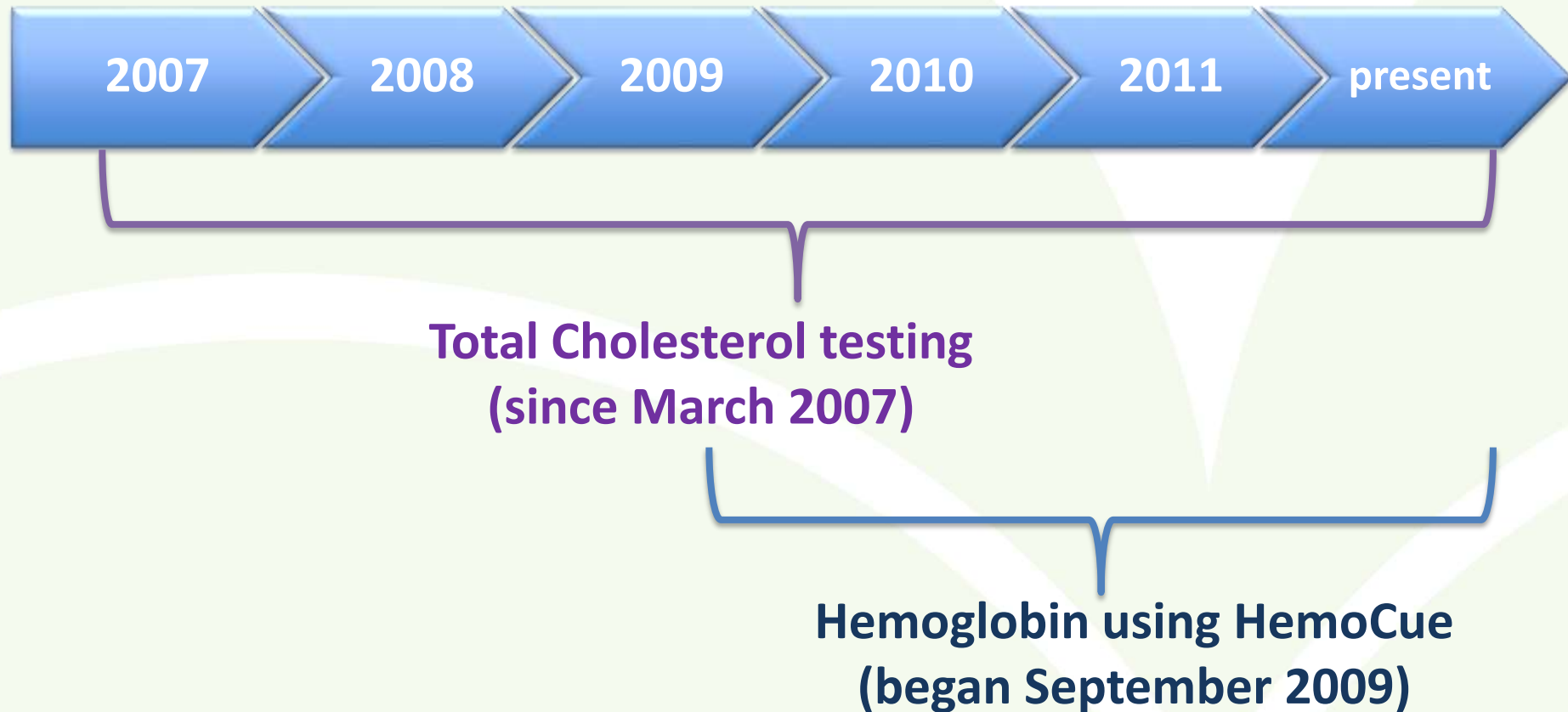
**as of  
18 January 2010**

MILD Reactions
Allergic
Citrate
Hematoma (small)
Infiltration (small)
Multiple
Other
Vasovagal (mild)

Donor Association
High School
College
Military
Others

Intended Collection Type
Specification of collection type among donors with incomplete or unsuccessful donation

# Supplemental Donor Testing





# External Reporting



**Beginning April 2009 data - AABB - Donor Hemovigilance System**

**Submitted 2010 data - International Surveillance of Transfusion-Associated Reactions and Events (ISTARE)**

# Timeline - Overview

Blood Systems, Inc. Donor Vigilance: 5 years of centralized donor reactions and incidents data collection																																																															
		2007												2008												2009												2010												2011												2012	
Months		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12		
Research	1st Intervention	Pre-Intervention												1st Post-Intervention																																																	
	2nd Intervention	2nd Pre-Intervention																																														2nd Post-Intervention															
	Donor Survey	none																																														Donor Survey using Survey															
Reaction Data Collection	BS 336 form revisions	Rev 5 (up to 6/3/07)				Rev 6 (6/4/07 to 12/2/07)				Rev 7 (12/3/07 to 4/24/08)				Rev 8 (4/25/08 to 7/27/08)				Rev 9 (7/28/08 to 10/26/08)				Rev 10 (10/27/08 to 3/29/09)				Rev 11 (3/30/09 to 11/27/2011)																		Rev 12 (11/28/2011 to present)																			
	Centralized BS 336 data entry - Data Collection Tools	MADRID- Access database selected BS 336 fields entered								BSI Donor Hemovigilance System - validated in-house developed BS 336 data entry tool most BS 336 fields entered (launched in May 2009, backlog data entry performed for BS 336 from 2008, current SOPs in place for centers to send BS 336s to COMA for data entry into the DHS )																																																					
External Reporting	BS 336/ Reaction Data Compliance with AABB Donor Reaction Requirements	NO												YES (except for Mild reactions)												Available (including Mild reactions - as of 1/18/2010) (Data in test environment due to errors needing resolution)																		pending BS 336 data entry																			
	ISTARE Donor Advers Reactions Data	No																		2010 data submitted on March 1, 2012												pending submission once data for 2011 is completed																															
Reaction Data	<a href="#">Mild Reactions captured in BECS</a>	<a href="#">MILD reaction in BECS to include all types, mild vasovagal or other mild procedure problems.</a>																		<a href="#">MILD Reactions to match AABB classification (as of 1/18/2010) - Allergic, Citrate, Hematoma (small), Infiltration (small), Multiple, Other, Vasovagal (mild)</a>																																											
	BS 336 Vasovagal Reactions Classification	Moderate or Severe						Mild, Moderate or Severe						Vasovagal Categories (pre-faint, LOC, uncomplicated, complicated, with injury)																																																	
	BS 336 Incidents Classification	Incident						Incident (matches AABB Reaction type/ category except for Allergic Anaphylaxis)						Incidents (matches AABB Reaction type/ category including Allergic Anaphylaxis)				Local Injury Related to Needle Apheresis Allergic																																													
	Can be mapped to AABB Reaction Type/ Category	pre-AABB Donor Hemovigilance categories																		can be matched to AABB reaction types and categories (excluding MILD reactions)												can be matched to AABB reaction types and categories (including MILD reactions)																															
Supplemental Donor Testing	Hemoglobin testing	none																		HemoCue testing																																											
	Cholesterol Testing	none		Began testing on March 5, 2007																																																											
	Donor Association Data	based on use of external association table from Hemosphere , merged to data using the site description																														Direct Association fields option available for staff within BECS: HS, College, Military and Others added as a question in the DRR (implemented on 1/18/2010)																															



## Blood Systems

# Results

## Continuous process improvement (CPI) allowed:

1. Improved capabilities to classify AEs in a manner that allow comparisons with the national and international standards:
  - U.S. Donor Hemovigilance System, and
  - International Surveillance of Transfusion-Associated Reactions and Events (ISTARE),
2. The use of appropriate statistical analyses, e.g. multivariable regression, thus overcoming the limited usefulness of simple rate comparisons or uni-variate analyses, and
3. The evaluation of additional factors' contribution to the likelihood of vasovagal reactions and/or needle related injuries in blood donors

# Summary

- Donor vigilance is an evolving field.
- Gained knowledge may generate new inquiries.
- Only through a continuous improvement process, an optimum donor vigilance program can be achieved.



# Questions



***Blood Systems***

# BSI's Commitment to Quality

- Quality is providing an uncompromised quality of work life, while continuing to ensure the quality and safety of our products and services to ensure a positive outcome for patients and donors
- Blood Systems is dedicated to quality, continuous performance improvement, and implementation of new quality initiatives.