

U.S. Bio**vigilance** Network

Investing in patient safety and donor health

Preliminary Validation of AABB subset of CDC-NHSN Biovigilance data

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On behalf of AABB Biovigilance
Data QC and Validation Working Group

Members of the QC & Validation Working Group

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QC & Validation Working Group Goals

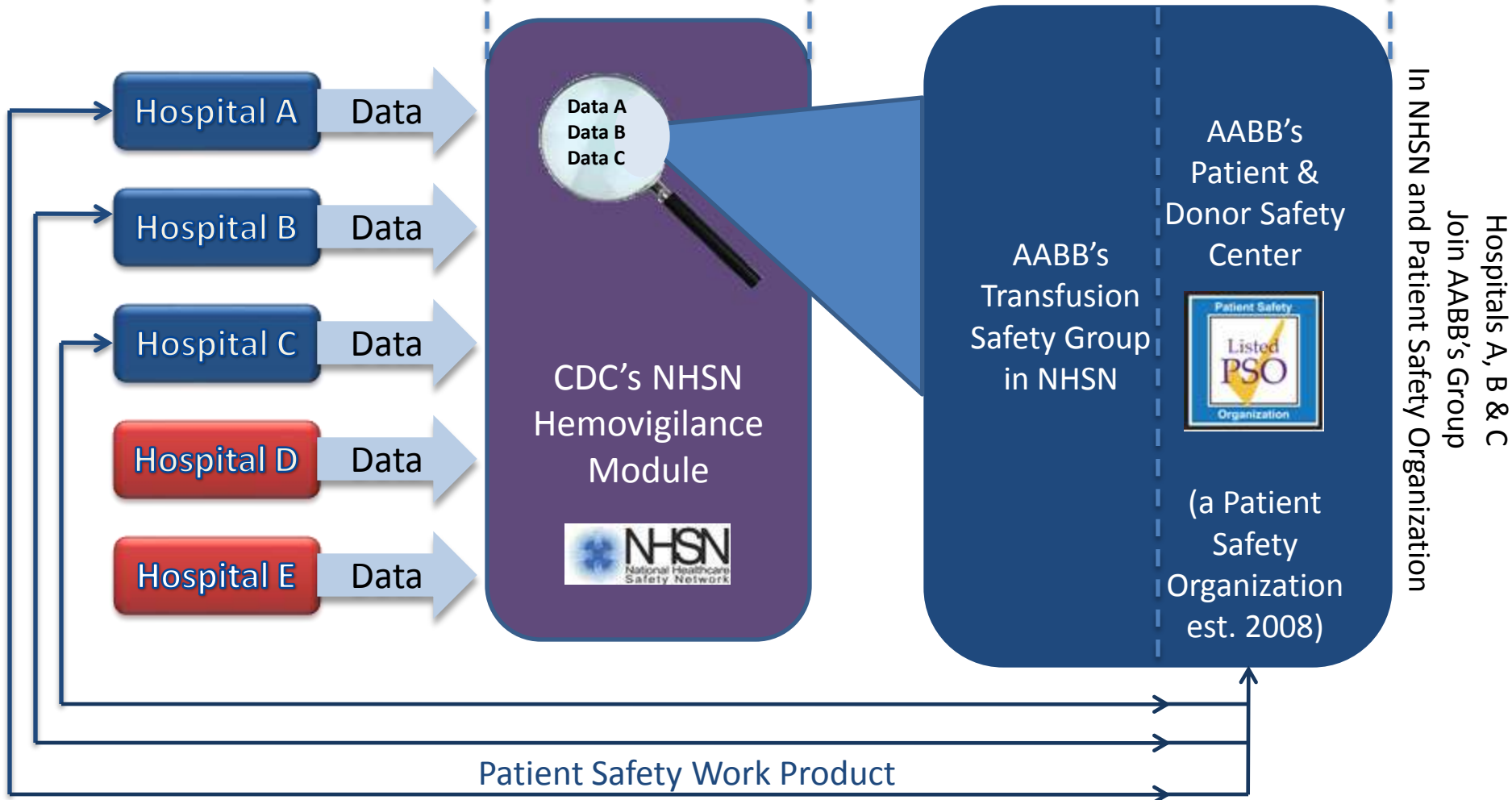
- Evaluate quality of data reported to AABB through CDC's NHSN
- Develop a supplemental tool that can be used for data validation
- Determine need for additional user training and support

AABB's Patient and Donor Safety Center Data Protection Diagram

Data Protection:
*State Peer Review
Protections*

Data Protection:
*Public Health
Service Act*

Data Protection: *Patient Safety and
Quality Improvement Act of 2005*



Data Protection: *HIPAA and the Patient Safety Act*

Note: Reports, benchmarking, analysis, etc. cannot be returned to participating facility without the HIPAA Business Agreement and AABB's Participation & Confidentiality Agreement in place.

Preliminary Review of AHTR and Allergic Reactions: Appropriateness of Reaction Criteria Chosen

	Matched	Did not Match	Used N/A Category
Total AHTR	2	3	1
Percent	40%	60%	20%
Total Severe Allergic	47	16	3
Percent	74.6%	25.4%	4.8%
Total Life Threatening Allergic	1	2	0
Percent	33.3%	66.7%	0

Acute hemolytic transfusion reaction (AHTR): Rapid death after, or within 24 hours of **cessation of** transfusion. Clinical signs are present. No single criterion exists to definitively diagnose this antibodies associated with AHTR.

Case Definition Criteria		Severity
Signs/Symptoms	Laboratory/Radiology	
Definitive: Occurs during, immediately after, or within 24 hours of cessation of transfusion with ANY of the following: <ul style="list-style-type: none"> • Chills/rigors • Fever • Back/flank pain • Hypotension • Hemoglobinuria occurring during or shortly after cessation of transfusion • Epistaxis • Oliguria/anuria • Renal failure • Disseminated intravascular coagulation (DIC) • Pain and/or oozing at IV site AND EITHER ABO incompatibility or other allotypic RBC antigen incompatibility OR Clerical check indicates that the patient's name and blood group on the blood unit are different than the recipient's name and blood group.	Definitive: Positive direct antiglobulin test (DAT) for anti-IgG or anti-C3 AND Positive elution test with alloantibody present on the transfused red blood cells AND 2 or more of the following: <ul style="list-style-type: none"> • Elevated LDH • Elevated bilirubin • Low haptoglobin • Hemoglobinuria • Low fibrinogen • Elevated plasma hemoglobin 	Use grade in /
Probable: Same as definitive case criteria.	Probable: Incomplete laboratory confirmation to meet definitive case definition criterion.	
Possible: N/A	Possible: N/A	

Allergic reaction: The result of an interaction of instances, infusion of antibodies from an atopic (mucocutaneous signs and symptoms).

Case Definition Criteria	
Signs/Symptoms	Laboratory/Radiology
Definitive: 2 or more of the following occurring during or within 4 hours of cessation of transfusion: <ul style="list-style-type: none"> • Maculopapular rash • Urticaria (hives) • Pruritus (itching) • Generalized flushing • Localized angioedema • Edema of lips, tongue and uvula • Erythema and edema of the periorbital area • Conjunctival edema • Respiratory distress; bronchospasm • Hypotension 	Definitive: N/A
Probable: ANY 1 of the following occurring during or within 4 hours of cessation of transfusion : <ul style="list-style-type: none"> • Maculopapular rash • Urticaria (hives) • Pruritus (itching) • Localized angioedema • Edema of lips, tongue and uvula • Erythema and edema of the periorbital area • Conjunctival edema 	Probable: N/A
Possible: N/A	Possible: N/A

Preliminary Review of AHTR and Allergic Reactions: Appropriateness of Reaction Grade Chosen

	Matched	Did not Match	Did not report enough information to confirm
Total AHTR	3	2	0
Percent	60%	40%	0%
Total Severe Allergic	45	14	0
Percent	71.4%	28.6%	0%
Total Life Threatening Allergic	1	2	0
Percent	33.3%	66.7%	0

Definitions of Reaction Severity Grade

Severity

Grade 1 (Non-Severe):

- Medical intervention (e.g. symptomatic treatment) required but lack of such would not result in permanent damage or impairment of a body function.

Grade 2 (Severe):

- Inpatient hospitalization or prolongation of hospitalization directly attributable to the event and/or:
 - Persistent or significant disability or incapacityOR
 - A medical or surgical intervention that is necessary to preclude permanent damage or impairment of a body function.

Grade 3 (Life-threatening):

- Major intervention required following the transfusion (vasopressors, intubation, transfer to intensive care) to prevent death

Grade 4 (Death):

- The recipient died following an adverse transfusion reaction. [**Note:** Grade 4 should be used only if death is possibly, probably or definitely related to transfusion. If the patient died of another cause, the severity of the reaction should be graded as 1, 2 or 3 as appropriate.]

Preliminary review of TACO/TRALI/TAD Criteria chosen

	Matched	Did not Match	Used N/A Category
Total TACO	13	10	5
Percent	56.5%	43.5%	21.7%
Total TRALI	0	10	10
Percent	0%	100%	100%
Total TAD	2	1	1
Percent	66.7%	33.3%	33.3%

Transfusion-associated circulatory overload (TACO): Infusion volume that cannot be effectively processed by the recipient either due to high rate and/or volume of infusion or an underlying cardiac or pulmonary pathology.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	Laboratory/Radiology		
Definitive: New onset or exacerbation of 3 or more of the following within 6 hours of cessation of transfusion: <ul style="list-style-type: none"> • Acute respiratory distress (dyspnea, orthopnea, cough) • Evidence of positive fluid balance • Elevated brain natriuretic peptide (BNP) • Radiographic evidence of pulmonary edema • Evidence of left heart failure • Elevated central venous pressure (CVP) 	Definitive: N/A	Use severity grades as defined in Appendix C.	Definite: No other explanations for volume overload are possible. Probable: Transfusion is a likely contributor to volume overload AND EITHER The patient received other fluids as well OR The patient has a history of cardiac insufficiency that could explain the volume overload. Possible: The patient has a history of pre-existing cardiac insufficiency that most likely explains volume overload.
Probable: N/A	Probable: N/A		
Possible: N/A	Possible: N/A		

Transfusion-related acute lung injury (TRALI): Acute hypoxemia with PaO₂/fraction of inspired oxygen [FIO₂] ratio of 300 mmHg or less combined with chest x-ray showing bilateral infiltrates in the absence of left atrial hypertension (i.e., circulatory overload). Onset of TRALI is abrupt in association with transfusion.

Case Definition Criteria		Severity	Imputability
Signs/Symptoms	Laboratory/Radiology		
<p>Definitive: NO evidence of acute lung injury (ALI) prior to transfusion AND ALI onset during or within 6 hours of cessation of transfusion AND Hypoxemia defined by any of these methods:</p> <ul style="list-style-type: none"> • PaO₂ / FiO₂ less than or equal to 300 mm Hg • Oxygen saturation less than 90% on room air • Other objective evidence <p>AND No evidence of left atrial hypertension (i.e. circulatory overload).</p> <p>Probable: N/A</p> <p>Possible: N/A</p>	<p>Definitive: Bilateral infiltrates on chest radiograph</p> <p>Probable: N/A</p> <p>Possible: N/A</p>	<p>Use severity grades as defined in Appendix C.</p>	<p>Definite: No alternative risk factors for ALI during or within 6 hours of cessation of transfusion.</p> <p>Probable: N/A</p> <p>Possible: Evidence of other risk factors for acute lung injury during or within 6 hours of cessation of transfusion are present, such as:</p> <ul style="list-style-type: none"> • Direct Lung Injury <ul style="list-style-type: none"> • Aspiration • Pneumonia • Toxic inhalation • Lung contusion • Near drowning • Indirect Lung Injury <ul style="list-style-type: none"> • Severe sepsis • Shock • Multiple trauma • Burn injury¹² • Acute pancreatitis • Cardiopulmonary bypass • Drug overdose

Preliminary review of TACO/TRALI/TAD Grade

Appropriateness of reaction grade chosen

	Matched	Did not Match	Did not report enough information to confirm
Total TACO	15	4	4
Percent	78.9%	21.1%	21.1%
Total TRALI	4	6	0
Percent	40%	60%	0%
Total TAD	2	1	0
Percent	66.7%	33.3%	0%

Evolution of Supplemental Reporting: Respiratory Reactions

- Creation of Version 1 of supplemental data form based on SHOT UK version
- 5 page form completed by hospitals for TRALI, TACO, TAD included:
 - Time of onset of Rxn
 - S/S with 6 hour details
 - Diagnostic interventions
 - Pre-existing conditions/relationship to ALI
 - Evaluation of Volume Status
 - Course of treatment
 - Components
 - Donor Component investigation/test results
 - HLA/HNA antigen/antibody info
 - Outcomes
- Reviewed forms against NCHS coding for validation
 - Deficiencies identified among known cases and report forms

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Summary of Working Group Expert Analysis: Case Definitions

Case	AE Type	Case Definition Facility	WG Def*	WG Indeterminate*
1	TACO	Definitive	3	
2	TACO	Definitive	3	
3	TACO	Definitive	3	
4	TACO	Definitive	3	
5	TACO	Definitive	1	2
6	TACO	Definitive	2	1
7	TACO	Definitive	1	2
8	TACO	Definitive	1	2
9	TACO	Definitive	2	1
10	TAD	Definitive	2	1

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*Out of 3 people

Summary of Working Group Expert Analysis: Grade

NHSN Case ID	AE Type	Grade Facility	WG NS*	WG S*	WG LT*	WG Indeterminate
1	TACO	Non-Severe	3			
2	TACO	Non-Severe	4*			
3	TACO	Life-Threatening			3	
4	TACO	Non-Severe	3			
5	TACO	Life-Threatening			3	
6	TACO	Life-Threatening			3	
7	TACO	Non-Severe	4*			
8	TACO	Severe	1	1		1
9	TACO	Non-Severe	2	1		
10	TAD	Non-Severe	1	1		1

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* Out of 4 people

** Out of 3 people

Summary of Working Group Expert Analysis: Imputability

NHSN Case ID	AE Type	Imputability Facility	WG Definite***	WG Probable***	WG Indeterminate***
1	TACO	Definite	1	3 ^a	
2	TACO	Definite	3 ^b	1	
3	TACO	Definite	1	3 ^a	
4	TACO	Definite	2	2	
5	TACO	Definite	1	3 ^a	
6	TACO	Definite	4		
7	TACO	Definite	1		3
8	TACO	Definite			4
9	TACO	Definite	2	1	1
10	TAD	Definite	2		2

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***Out of 4 people

^a or possible

^b or probably

Observations

- Despite creation of standardized transfusion reaction definitions, reports did not consistently include all necessary items.
- Selection of N/A categories of case definition, severity, or imputability suggests some reporters may not be using standardized definitions.
- Initial draft of supplemental form used to further confirm proper classification of reactions was not adequate.

Evolution of Supplemental Reporting: Respiratory V2

- Version 2 Supplemental Form
 - Deleted what was already in original reaction report
 - Reduced un-helpful information (eg. antibodies)
 - Included additional narrative, onset of reaction, components transfused and timing of such
 - Specific relevant signs and data values matching
 - Other possible risk factors
- Will use Version 2 in late Spring 2012

Latest Review of 2011 data TRALI

- 1 case with Definite criteria, Definite imputability
- 2 cases with Definite criteria, Probable imputability
- 2 cases with Definite criteria, Possible imputability
- 2 cases with **Possible*** criteria, Possible imputability
- All cases with either shortness of breath, hypoxemia, and/or bilateral infiltrates on CXR

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*Possible is currently not a defined case definition criteria

Latest Review of 2011 data TACO

- 5 cases Definite criteria, Definite imputability
- 14 cases Definite criteria, Probable imputability
- 6 cases Definite criteria, Possible imputability
- 9 cases **Probable*** criteria, Probable imputability
- All except 5 cases reported shortness of breath
- Remainder reported either hypoxemia or bilateral infiltrates on CXR
- Two cases with no respiratory signs/symptoms reported

*Possible is currently not a defined case definition criteria

Challenges encountered with QC validation

- Members of QC working group not reviewing entire patient chart.
- Information requested for NHSN reporting and with supplemental reporting requested by AABB was insufficient for independent reviewer to categorize transfusion reaction.
- Only able to exclude cases as not correct if positive findings are present (findings arguing against transfusion reaction category)

Next steps

- Continue to review data
- Revise supplemental data collection form to specifically match reaction definition requirements
- Creation of “transfusion reaction rounds” for participating AABB facilities to present difficult to categorize cases for group discussion, and to facilitate better understanding of reporting criteria

Thank you!

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