Practical Approaches to Reduce Risk of Transfusion
Wednesday, July 16, 2014
2:00 p.m. – 3:30 p.m. (ET) / 6:00p.m.-7:30 p.m. (GMT)

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Practical Approaches to Reduce the Risk of Transfusion

Moderator: Colleen Aronson, MT(ASCP)SBB
Speakers: Megan Shetterly, RN, MS; Suzanne Butch, MLS(ASCP), SBB, DLM
Objectives

• Describe the more common causes of transfusion error and some of the options to reduce these risks.

• Evaluate a practical and proven approach to reduce specimen labeling errors and errors related to patient identification (ID) checks at the bedside.
Types of Transfusion Errors

- Misidentification
- Special needs to met – antigen negative, irradiation, volume reduction, leukocyte-reduction
- Wrong products transfused
- Under or over transfusion
- Documentation - Failure of complete forms or incorrect documentation
Transfusion Fatal Errors

• Misidentification - at specimen collection

• Misidentification - in the lab

• Misidentification - at transfusion
Contributing Factors

- Complacency
- Urgency
- Hand-offs
- Lack of/unclear communication

- User unfamiliar with new software
- Ignored warning message because lack of faith in the computer system
Joint Commission National Patient Safety Goal

#1 Improve the accuracy of patient identification.

– NPSG.01.01.01

Use at least two patient identifiers when providing care, treatment, and services.

– NPSG.01.03.01

Eliminate transfusion errors related to patient misidentification
1. Use at least two patient identifiers when administering medications, blood, or blood components; when collecting blood samples and other specimens for clinical testing; and when providing treatments or procedures. The patient's room number or physical location is not used as an identifier. (See also MM.05.01.09, EPs 8 and 11; NPSG.01.03.01, EP 1)
NPSG.01.01.01

2. **Label** containers used for blood and other specimens in the presence of the patient. (See also NPSG.01.03.01, EP 1)
1. Before initiating a blood or blood component transfusion:

- Match the blood or blood component to the order.
- Match the patient to the blood or blood component.
NPSG.01.03.01

- Use a two-person verification process or a one-person verification process accompanied by automated identification technology, such as bar coding. (See also NPSG.01.01.01, EPs 1 and 2)
2. When using a two-person verification process, one individual conducting the identification verification is the qualified transfusionist who will administer the blood or blood component to the patient.

3. When using a two-person verification process, the second individual conducting the identification verification is qualified to participate in the process, as determined by the hospital.
• TRM.40230 Compatibility Specimen Labeling Phase II
• All blood samples used for compatibility testing are labeled at the time of specimen collection in the presence of the patient with:
  – 1. Patient's first and last name
  – 2. Unique identification number
  – 3. Date of collection
  – 4. A method to identify the phlebotomist.
• **TRM.30550 Misidentification Risk Phase II**
  The facility has a documented program to ensure that the risk of pretransfusion sample misidentification and other causes of mistransfusion are monitored and subjected to continual process improvement.

• **TRM.40235 Patient Identification Phase II**
  The patient is asked to verbally verify his/her identity, whenever practical, at the time of specimen collection.
The facility has a plan to implement a system to reduce the risk of mistransfusion for non-emergent red cell transfusions.
AABB Biovigilance

- Report transfusion events
- Information was not available to the public on the AABB Biovigilance web page
FDA

• FDA 21 CFR 606.151
• Standard operating procedures for compatibility testing shall include the following:
• (a) a method of collecting and identifying the blood samples of recipients to ensure positive identification
# FDA Transfusion Deaths

## Table 1: Transfusion-Related Fatalities by Complication, FY2009 through FY2013

<table>
<thead>
<tr>
<th>Complication</th>
<th>FY09 No.</th>
<th>FY09 %</th>
<th>FY10 No.</th>
<th>FY10 %</th>
<th>FY11 No.</th>
<th>FY11 %</th>
<th>FY12 No.</th>
<th>FY12 %</th>
<th>FY13 No.</th>
<th>FY13 %</th>
<th>Total No.</th>
<th>Total %</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRALI*</td>
<td>13</td>
<td>30%</td>
<td>18</td>
<td>45%</td>
<td>10</td>
<td>33%</td>
<td>17</td>
<td>45%</td>
<td>14</td>
<td>37%</td>
<td>72</td>
<td>38%</td>
</tr>
<tr>
<td>HTR (non-ABO)</td>
<td>8</td>
<td>18%</td>
<td>5</td>
<td>13%</td>
<td>6</td>
<td>20%</td>
<td>5</td>
<td>13%</td>
<td>5</td>
<td>13%</td>
<td>29</td>
<td>15%</td>
</tr>
<tr>
<td>HTR (ABO)</td>
<td>4</td>
<td>9%</td>
<td>2</td>
<td>5%</td>
<td>3</td>
<td>10%</td>
<td>3</td>
<td>8%</td>
<td>1</td>
<td>3%</td>
<td>13</td>
<td>7%</td>
</tr>
<tr>
<td>Microbial Infection</td>
<td>5</td>
<td>11%</td>
<td>2</td>
<td>5%</td>
<td>4</td>
<td>13%</td>
<td>3</td>
<td>8%</td>
<td>5</td>
<td>13%</td>
<td>19</td>
<td>10%</td>
</tr>
<tr>
<td>TACO</td>
<td>12</td>
<td>27%</td>
<td>8</td>
<td>20%</td>
<td>4</td>
<td>13%</td>
<td>8</td>
<td>21%</td>
<td>13</td>
<td>34%</td>
<td>45</td>
<td>24%</td>
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<tr>
<td>Anaphylaxis</td>
<td>1</td>
<td>2%</td>
<td>4</td>
<td>10%</td>
<td>2</td>
<td>7%</td>
<td>2</td>
<td>5%</td>
<td>0</td>
<td>0%</td>
<td>9</td>
<td>5%</td>
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<tr>
<td>Other</td>
<td>1**</td>
<td>2%</td>
<td>1**</td>
<td>3%</td>
<td>1**</td>
<td>3%</td>
<td>0</td>
<td>0%</td>
<td>0</td>
<td>0%</td>
<td>3</td>
<td>2%</td>
</tr>
<tr>
<td>Totals</td>
<td>44</td>
<td>100%</td>
<td>40</td>
<td>100%</td>
<td>30</td>
<td>100%</td>
<td>38</td>
<td>100%</td>
<td>38</td>
<td>100%</td>
<td>190</td>
<td>100%</td>
</tr>
</tbody>
</table>

*These numbers include both “TRALI” and “possible TRALI” cases\(^9,10\)

**Other:
- FY2009: Hypotensive Reaction\(^11\)
- FY2010: Graft vs. Host Disease (GVHD)
- FY2011: GVHD
### Hemolytic Reactions

<table>
<thead>
<tr>
<th>Complication</th>
<th>FY09</th>
<th>FY09</th>
<th>FY10</th>
<th>FY10</th>
<th>FY11</th>
<th>FY11</th>
<th>FY12</th>
<th>FY12</th>
<th>FY13</th>
<th>FY13</th>
<th>Total</th>
<th>Total</th>
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<td>13%</td>
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<td>10%</td>
<td>3</td>
<td>8%</td>
<td>1</td>
<td>3%</td>
<td>13</td>
<td>7%</td>
</tr>
</tbody>
</table>

**Table 1: Transfusion-Related Fatalities by Complication, FY2009 through FY2013**

- **HTR (non-ABO)**: 29 total fatalities (15%)
- **HTR (ABO)**: 13 total fatalities (7%)
Serious Hazards of Transfusion (SHOT)

• Collects all types of errors related to transfusion
• Looks for trends
• Annual Reports
• Recommendations made

• http://www.shotuk.org/home/
Figure 1: Cumulative data for SHOT categories 1996/7-2012 (n=11,570)

- CS: Cell salvage and autologous transfusion
- TTI: Transfusion-transmitted infection
- PTP: Post-transfusion purpura
- UCT: Unclassifiable complications of transfusion
- ATR: Acute transfusion reaction
- TAD: Transfusion-associated dyspnoea
- HTR: Haemolytic transfusion reaction
- ALLO: Alloimmunisation
- TA-GvHD: Transfusion-associated graft vs host disease
- TRALI: Transfusion-related acute lung injury
- TACO: Transfusion-associated circulatory overload
- Anti-D: Anti-D errors
- HSE: Handling & storage errors
- ADU: Avoidable, delayed or undertransfusion
- IBCT: Incorrect blood component transfused

- Pathological reactions which may not be preventable
- Probably or possibly preventable by improved practice and monitoring
- Adverse events caused by error

Number of reports
UK Transfusion Errors in 2011

• 2.3 per cent of patients were not wearing an identity band at the time of the audit despite the fact that a blood transfusion was in progress

• 85 per cent of patients had all four pre-transfusion observations recorded

• 87 per cent had observations within 30 minutes following the start of the transfusion

• 84 per cent had the required observations at the end of the transfusion.

Reference: Right blood, right patient, right time, Royal College of Nursing, 2013
Who Makes The Errors

- 40% medical staff
- 40% nursing and midwifery
- <5% by phlebotomy staff
SHOT 2012

“Ten ABO incompatible transfusions were reported to SHOT in 2012, three of which resulted in major morbidity. It is this risk that led to clear recommendations for full sample labelling for transfusion samples which are well accepted. “

Dr Paula Bolton-Maggs, Medical Director Serious Hazards of Transfusion Scheme (SHOT), Manchester Blood Centre Zero tolerance for labelling of all pathology specimens: a recommendation from SHOT 2013. The Bulletin of The Royal College of Pathologists, Number 165, January 2014.
SHOT Errors 2014

• Near miss – ID error found before transfusion
  – Near miss reports 980
  – Sample errors 534
  – Wrong blood in tube 505
SHOT 2013

• The leading error remains transfusion of an incorrect blood component. This has been the most frequent transfusion hazard reported to SHOT since the scheme started in 1996.

Why do these ERRORS occur?
• Attention lapses (being distracted/interrupted during a task)
• Deliberate non-compliance (taking short cuts and failing to follow SOP)
• Genuine errors (intention of carrying out correct procedure but failed)
• Misperceptions (what the task involves)
• Misplaced priorities (mixed messages over clinical priorities)
Cause of Transfusion Errors

• “It is clear from 16 years of SHOT reporting that most transfusion incidents are caused by human error. Failure to identify the patient correctly at the time of blood sampling and at the time of transfusion remain the most common causes, and many reports have evidence of multiple errors.”

• Dr Paula Bolton-Maggs, Medical Director Serious Hazards of Transfusion Scheme (SHOT), Manchester Blood Centre Zero tolerance for labelling of all pathology specimens: a recommendation from SHOT 2013. The Bulletin of The Royal College of Pathologists, Number 165, January 2014.
SHOT Recommendations

• The key recommendation from the 2011 and 2012 Reports are:

• Correct patient identification is essential. Patients should be positively identified (asked to say their name and date of birth, and not prompted with a question that requires a yes/no answer)
Policy Change Needed

“Transfusion is particularly well regulated and it is likely that similar errors affect all branches of pathology. SHOT therefore recommends improved (zero tolerance) sample labelling for all pathology specimens to ensure the core identifiers are used. Pathology laboratory managers need to implement this recommendation, with support from their chief executives.”

Dr Paula Bolton-Maggs, Medical Director Serious Hazards of Transfusion Scheme (SHOT), Manchester Blood Centre Zero tolerance for labelling of all pathology specimens: a recommendation from SHOT 2013. The Bulletin of The Royal College of Pathologists, Number 165, January 2014.
SHOT Recommendations

• Communication and handover templates need to be improved. Patients are particularly vulnerable with increased shared care, movement within hospitals across different shifts.

• The use of a transfusion checklist is recommended and a model template can be found on the SHOT website.

• Knowledge of transfusion medicine and prescribing of blood components are essential core requirements for all prescribers.
SHOT Laboratory Issues

• Lessons for Transfusion Laboratory Staff Update 2013 incorporating guidance from SHOT Annual Reports 2011 and 2012

Figure 1. Laboratory incidents 2011–2012

- Miscellaneous: 8
- Component labelling, availability & handling and storage: 383
- Component selection: 111
- Testing: 87
- Sample receipt and registration: 66

Number of reports: 0, 50, 100, 150, 200, 250, 300, 350, 400
SHOT 2009 Recommendation

• Empower the patient to ask “Do you know who I am?”
• Campaign launched in 2012

• [Link to website](http://www.transfusionguidelines.org.uk/uk-transfusion-committees/national-blood-transfusion-committee/transfusion-awareness/do-you-know-who-i-am)
Needed

• Clear policies about patient identification
• Support for enforcement from upper management

• Implementation of automation when feasible
References

LESSONS FOR CLINICAL TRANSFUSION STAFF
Update 2013 incorporating guidance from SHOT
Annual Reports 2011 and 2012

Specimen Labeling Collaboration Northeast Pennsylvania

Megan Shetterly, RN, MS
Senior Patient Safety Liaison, Pennsylvania Patient Safety Authority
Pennsylvania Patient Safety Authority

Background

Act 13 (March 2002)

- 11-member Board appointed by the Governor and General Assembly
- Independent Agency
- Non-regulatory
- Dedicated funding stream
- Contract with outside entity to collect, analyze and evaluate reports of Serious Events and Incidents and identify trends
- Advise and issue recommendations for changes and improvements in healthcare practices (Advisories)
- Focused education, research and collaborations
# PA - Reporting Components

## Who Reports
- Hospitals
- Ambulatory Surgical Facilities
- Birthing Centers
- Certain Abortion Facilities
- Nursing Homes (June 2009)

## Types of Events
- Near-Misses ("Incidents")
- Adverse Events ("Serious Events")
- Infrastructure Failures

## Other Considerations
- Mandatory
- No Individual Identifying Data
- Confidentiality Provisions
- Non-discoverable
- Whistleblower Protections
- Facility assessment
- Written Patient Notification
- Anonymous Reports
Where Do The Reports Go?

Incoming Reports → Triage → Analytics → Patient Safety Review Meeting

Program Outputs
- Toolkits
- Facilities’ own analyses
- Advisories/Recommendations
- Facility Contacts re: individual events
- Patient Safety Liaisons
- Online & live education
- Web sites
- Collaborative Learning

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How It All Began

- **Opportunity recognized** (2007 PA-PSRS data)
  - Errors related to Procedure/Test/Treatment (23%)
    - Most frequent event type
    - 41% Lab test problems

- **Pursuit of Regional Collaborative through Patient Safety Liaison (PSL)**
  - Invitations for participation sent to Hospitals in Northeast (NE) Pennsylvania
It Can Happen To You

- Hospital fined after deadly blood transfusion error

http://medicalmalpracticelawblog.com/2009/05/18/hospital-fined-after-deadly-blood-transfusion-error/
Human, Financial, Emotional COST

- 70% of all information used by clinicians to diagnose conditions and treat patients comes from the laboratory setting.

- 17 to 29 billion dollars spent annually on preventable adverse events.

- Clinicians leaving health care.

(DOC; IOM)
## Cost Analysis Example

### Specimen Identification Errors 0.1% to 6.5%

<table>
<thead>
<tr>
<th></th>
<th>High End</th>
<th>Low End</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Error Rate</strong></td>
<td>6.5%</td>
<td>0.1%</td>
</tr>
<tr>
<td><strong>Monthly Blood Tests Performed</strong></td>
<td>100,000</td>
<td>100,000</td>
</tr>
<tr>
<td><strong>Errors/Month</strong></td>
<td>6,500</td>
<td>100</td>
</tr>
<tr>
<td><strong>Monthly Cost @ $10 per redraw</strong></td>
<td>$65,000</td>
<td>$1,000</td>
</tr>
</tbody>
</table>

(AuBuchon et al: Renner; Howanitz)
9 Hospitals With 1 Common Goal

The right blood specimen is correctly labeled for the right patient every time
Joint Commission National Patient Safety Goals

- **NPSG.01.01.01**: Use at least two patient identifiers when providing care, treatment and services. [was Goal 1A]

- **NPSG.01.03.01**: Eliminate transfusion errors related to patient misidentification.

- **Goal 13**: Encourage patients’ active involvement in their own care as a patient safety strategy
Slogan
**Culture of Safety Requirement**

**January 2009**

- **LD.03.01.01** “Leaders create and maintain a culture of safety and quality throughout the hospital”
  - Evaluation of culture with valid tool
  - Prioritize and implement changes identified by the tool
  - Everyone in organization should have the opportunity to participate
Where To Start?

- Make the project manageable
  - One care area
  - Select a dedicated team
  - Stay focused
  - Expand to other areas when ready
How Did We Address This Issue?

- Relevant Literature
  - CDC Laboratory Medicine Best Practices
  - Reference Materials
  - Other Supporting Documents

- Networking and Knowledge Sharing
  - Policies/Procedures
  - Redesign Ideas

- Workshops
  - Reliable Design
  - Just Culture
  - Human Factors
  - Event Investigation
    - Theory U
    - Gracious Space

- Site Visits
  - Observations
  - Presentations
How Did We Address This Issue?

- Data Collection and Analysis
  - Statistics
  - Contributing Factors
  - Barriers and Action Items
- Visual Display
  - Theme/Slogan
- Conference Calls
  - Ongoing Support

- Best Practices
  - Guest speakers
- Presentations
  - American Society for Healthcare Risk Management (AHSRM)
  - Continue Survey Readiness (CSR)
  - The Hospital & Healthsystem Association of Pennsylvania (HAP)
Investigation Is The Key!

Team
- Communication
- Change of Shift
- Unplanned work load increase
- Holiday
- Shift Change

Task
- Training
- Emergency situation
- Inexperienced staff
- Inadequate supervision
- Cardiac/Respiratory Arrest
- Order entry system problem

Patient
- Lack of patient compliance
- Lack of patient understanding
- Language barrier
- Lack of family cooperation

Staff
- Float staff
- Agency, temporary, traveling staff
- Staff scheduling issues
- Inadequate system for covering pt care
- Insufficient staffing
- Issue related to proficiency
- Issue related to impairment

Work Environment
- Distractions/Interruptions
- Limited access to pt info
- Poor lighting
- High noise level
- Equipment malfunction

Organization
- No dedicated phlebotomy
- Lack of policies/procedure
- Unclear or ambiguous policies/procedures
- Procedures not followed

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Behavioral Choices
Setting The Stage
The Basics of Event Investigation

- What happened?
- What normally happens?
- What does procedure require?
- Why did it happen?
- How were we managing it?

Increasing value

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## What Did We Find?

<table>
<thead>
<tr>
<th>Domain</th>
<th>Barriers</th>
</tr>
</thead>
</table>
| Technology | Label printing issues  
No resources for bar coding  
Those with bar coding only have it limited to phlebotomy and not nursing  
Lack of equipment updates  
Wireless signal limited to certain areas |
| Communication | Issues between nursing and phlebotomy  
Lack of teamwork |
| Education  | Lack of knowledge about policies/procedures  
Physicians ordering all labs “stat” |
| Staffing   | High turnover of phlebotomists  
Performing double amount of normal AM draws |
| Workflow   | Lack of care area specific procedures that expedited workflow |
| Leadership | Lack of management support  
Other initiatives with higher priorities took precedence  
Loss of clinical leadership |
Most Frequent Contributing Factors

- Protocol Not Followed
- Distractions/Interruptions
- Increased Workload

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Most Frequent Barriers

- Lack of Leadership Support
- Lack of Resources (Human and Financial)
- No Buy-in From Nursing Staff
- Low or No Reporting of Near Miss Events
Action Items Introduced

- New Equipment
- Standardization
- Involvement by Leadership
- Decreased Workload
- Checklists and Cognitive Aides
- Redundant Processes
- Patient Involvement
- Double Checks
- Visual Aides
- New Policy/Procedure
- Education

Stronger

Intermediate

Weaker
## Actions Introduced

<table>
<thead>
<tr>
<th>Domain</th>
<th>Action Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology</td>
<td>Many labeling changes and technology updates</td>
</tr>
</tbody>
</table>
| Communication | Shared case studies  
                  Involving front line staff                                                |
| Education | Competencies on patient identification, use of equipment  
                   Educated physicians on “stat” orders                                  |
| Staffing  | Leveled workloads                                                           |
| Workflow  | Added printers  
                   Standardized bedside labeling  
                   Standardized hourly batching of labels  
                   New ED process for labeling                                               |
| Leadership| Dashboards  
                   Increased awareness with Authority sponsored pins and posters          |
Statistically Significant Decrease

NE PA Specimen Labeling Collaborative Cumulative Error Rates

Mislabeling rates per 1000 error opportunities

Months (Aug 2009 through June 2010)

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One Facility’s Success with Sustainability

Reduction in Number of Mislabeled Specimens

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What Is The Investment In Collaborative Learning?

<table>
<thead>
<tr>
<th>Activity</th>
<th>Duration</th>
<th>Monthly Commitment</th>
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</thead>
<tbody>
<tr>
<td>Bi-monthly coaching calls</td>
<td>1 hr</td>
<td>2 hr</td>
</tr>
<tr>
<td>Workshops (6 over a 18 month period)</td>
<td>4 hr</td>
<td>1.3 hr</td>
</tr>
<tr>
<td>Literature Review (~ 25 articles)</td>
<td>1 hr</td>
<td>1.5</td>
</tr>
<tr>
<td>Team Meetings (initially may have weekly, then bi-monthly, then monthly)</td>
<td>1 hr</td>
<td>≥ 1 hr (depending on how many meetings held)</td>
</tr>
<tr>
<td>Unit Meetings (Quarterly)</td>
<td>1 hr</td>
<td>0.33 hr</td>
</tr>
<tr>
<td>Investigation (avg 6/month per hosp)</td>
<td>1 hr</td>
<td>6 hr</td>
</tr>
<tr>
<td>Performance Improvement /Implementation Measures (Design, Education, Implementation, Measurement, Reporting)</td>
<td>Varied</td>
<td>Varied depending upon measure(s) introduced</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>10-15 hrs/month</td>
</tr>
</tbody>
</table>
Financial Investment In Collaboration

- Dedicated Resources
  - Project Manager and Team Members
  - Front line staff

- Implementation Measures
  - Equipment/Technology
  - Supplies

- Return on Investment
  - Priceless!
www.patientsafetyauthority.org
We Want To Share What We’ve Learned

http://patientsafetyauthority.org/Educationa
tools/PatientSafetyTools/specimen/Pages/home.aspx
Questions?
References


References


References


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