Blood Banking and Risk Management: Understanding Your Risk and the Tools to Manage It

Maggie L. Neustadt, JD CPHRM
Director of Risk Management
Saint Luke’s Hospital of Kansas City
Agenda

• What is clinical risk and why does it matter to you?
• What tools can we use to mitigate that risk?
What is Risk?

- Quality Improvement
- Patient Safety
- Risk Management
- Regulatory Compliance
Clinical Risk
Institute of Medicine report *To Err is Human: Building as Safer Health System*, 1999.
## The Local Statistics

<table>
<thead>
<tr>
<th>Category of Alleged Medical Error</th>
<th>Occurrences</th>
<th>Paid Occurrences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>31.5%</td>
<td>30.4%</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>17.9%</td>
<td>18.3%</td>
</tr>
<tr>
<td>Treatment (non-surgical)</td>
<td>17.8%</td>
<td>17.8%</td>
</tr>
<tr>
<td>Patient Safety / Ethical Lapses</td>
<td>14.4%</td>
<td>14.4%</td>
</tr>
<tr>
<td>Medication Related</td>
<td>8.9%</td>
<td>8.8%</td>
</tr>
<tr>
<td>Pregnancy &amp; Childbirth</td>
<td>6.1%</td>
<td>6.6%</td>
</tr>
<tr>
<td>Anesthesia</td>
<td>1.9%</td>
<td>1.7%</td>
</tr>
<tr>
<td>IV &amp; Blood Products</td>
<td>1.5%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Reported</th>
<th>Closed</th>
<th>Closed with Payment</th>
<th>Total Indemnity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Banks</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>$80,000</td>
</tr>
<tr>
<td>General Physician / Surgeon</td>
<td>110</td>
<td>132</td>
<td>23</td>
<td>$4,124,126</td>
</tr>
<tr>
<td>Pharmacists / Pharmacies</td>
<td>21</td>
<td>19</td>
<td>23</td>
<td>$2,214,366</td>
</tr>
<tr>
<td>Nursing Homes</td>
<td>8</td>
<td>13</td>
<td>12</td>
<td>$1,151,180</td>
</tr>
<tr>
<td>Hospitals</td>
<td>268</td>
<td>303</td>
<td>153</td>
<td>$32,719,486</td>
</tr>
</tbody>
</table>
The Local Statistics

## Allegations by Category 2003 to 2015
### Compilations of IV & Blood Products

<table>
<thead>
<tr>
<th>Allegation</th>
<th>Claimants</th>
<th>Claimants With Payment</th>
<th>Average Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect blood type</td>
<td>9</td>
<td>8</td>
<td>$835,875</td>
</tr>
<tr>
<td>Inappropriate temperature in local application</td>
<td>2</td>
<td>2</td>
<td>$77,500</td>
</tr>
<tr>
<td>Excessive amount of blood or other fluid</td>
<td>1</td>
<td>1</td>
<td>$275,000</td>
</tr>
</tbody>
</table>

The Local Statistics

- Average Case Indemnity: $318,200
- Incorrect Blood Type Indemnity: $835,875

2015 Missouri Department of Insurance, Financial Institutions and Professional Registration, Medical Professional Liability Insurance report, published Sept 2016 at p. 25
How lay-people see blood transfusion
How Blood Bankers see transfusion
Blood Bank Danger Zones

Unnecessary transfusions leading to adverse events
Transfusion reactions
Out-dated reagents
Failure to validate product prior to issuing
Issuing outdated product
Refrigeration malfunction
Mislelabeling
Massive transfusion protocols
Improper storage
HIV/ID
Urgent needs from national rare donor registry
Special populations
Closing a program
EMR downtime
An estimated 5 million people will require a blood transfusion each year in the United States. Blood transfusions take healthy blood (or blood components) from a donor and give it to a patient who needs additional. Transfusions are used to treat a number of conditions, including emergency situations in which the patient has lost a large amount of blood. Blood transfusions may also be used for people with sickle-cell diseases, for infants with Rh incompatibility, or for the treatment of other blood-related illnesses. Doctors are
BLOOD TRANSFUSION MISTAKES

TOP BALTIMORE MEDICAL MALPRACTICE ATTORNEYS

There's no doubt about it—blood transfusions provide life-saving benefits to those who need them. They may be used to treat a patient who has experienced blood loss due to injury or surgery. They may be necessary to treat conditions ranging from severe anemia and clotting disorders to hemophilia or sickle-cell anemia.

But, a blood transfusion is risky, and if precise safety standards are not adhered to, serious infections, diseases, or death could occur. If this has happened to you or a loved one, turn to the medical malpractice attorneys at Murphy, Falcon & Murphy. For more than 70 years, our firm has become a symbol of how the law can speak up for those who are injured and hurt by powerful institutions. If your injuries have gone unanswered by your healthcare providers, we can fight for you.

Seek justice with our firm—call 410.983.6266 for a free legal consultation today.

WHAT CAUSES A BLOOD TRANSFUSION-RELATED INJURY OR
Incompatible Blood Transfusion Complication Lawyer

Attorneys For Patients Injured By Incompatible Blood Transfusions in Chicago, Illinois

According to the Agency for Healthcare Research and Quality, there are almost 3 million blood transfusions done each year in the U.S., averaging 1 out of 10 hospital stays.

Blood transfusions are a necessary and often life saving procedure, however, if handled improperly, it can also be deadly. Hospitals and medical facilities are expected to take extreme care when administering any type of blood product to their patients. The National Quality Forum has listed any error that happens involving administration of incompatible blood products as a “never event” that is completely preventable and should not ever occur in a healthcare setting.

Blood Transfusion
Two key components to clinical risk management
Two key components to clinical risk management

Risk prevention

Risk Mitigation
Key Tools for Risk Prevention

- Education/annual competencies
- Drills
- Policies
- Procedures
- Professional standards
- Reporting near misses
Key Tools to Mitigate Risk

Documentation/record keeping
Disclosure
Golden Rule of Documentation and Record Keeping...
If it isn't documented—it didn't happen
Why document?

Regulatory reasons

Refrigeration logs/alarms
Equipment QA checks
Reagent expirations
Why document?

Communication

• To ourselves to insure safe care
  • Communicate what happened, what you did about it and what the response was
    • Refrigerator alarms going off; reported to maintenance, maintenance cannot resolve so new equipment is on order to arrive within 2 hours

• To others for safe hand off
  • ICU requested Factor VII; issuance of product pending approval from Blood Bank Medical Director
Did I mention communication?

An estimated **80%** of serious medical errors involved miscommunication between caregivers during the transfer of patients.

- Joint Commission Center for Transforming Patient Care as cited in CRICO Malpractice Risks in Communication Failures, 2015 Annual Benchmarking Report
Did I mention Communication?
Disclosure

noun dis·clo·sure  
\( \text{dis-} \ ' \text{klō-} \text{zhər} \)

• The act of making something known

• The act or process of revealing or uncovering.

Disclosure of serious unanticipated outcomes

http://www.merriam-webster.com/dictionary/disclosure
Old model

“Deny and Defend”
New Model

“Disclose and Resolve”
Why disclose?

- Ethical—patient centered response
- Regulatory (TJC)
- It may be the law
  - Ten states have laws mandating disclosure of medical errors
  - Most states have apology laws
Missouri’s Apology Law

A caregiver’s expression of empathy and compassion for a patient after an adverse event cannot be used as evidence of liability in a civil suit against that caregiver.

Missouri Revised Statute 538.229
Data shows that pt more often sue because of the handling of the error not the error itself.

Key piece of disclosure is showing how you will prevent the event from happening to others.
Why disclose: impact on lawsuits

Contrary to common perception, being honest and open with patients may help prevent a lawsuit down the road.

The need for an explanation – plaintiffs wanted to know how the injury happened and why

Compensation for actual losses, pain, and suffering or to provide care in the future for an injured person

Accountability – plaintiffs believed that the staff or organization should be accountable for their actions

Questions
**New technicians:** Nursery requested 16 ml of packed cells infant who was group O Rh negative. The new technologist working night shift found no O negative pack available in house. He called his community blood bank who also had none available. He then found an O positive CPDA-1 CMV negative quad pack in the refrigerator and split out the volume needed for the transfusion and issued it to the nursery. When he tried to dispense the unit in the computer, it gave him an error message, but he issued it anyway. When the day shift arrived, he asked one of the Blood Bank Coordinators to help issue the unit since he had not been able to issue it in the computer.

**Post-transfusion events:** Patient was given multiple transfusion in trauma situation in April. Hospital blood bank notified by the community blood bank ten months later that donor of blood given had reactive anti-HBc test. Coordinated follow up testing at no cost to patient, then follow up with the trauma surgeon. Fortunately, patient's hepatitis serology was consistent with her previous Hepatitis B vaccination, and no evidence of acute or chronic Hepatitis B infection.