Hemovigilance: A Quality Tool for Blood Transfusion

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Introduction

Hemovigilance

- Haema: Greek for “blood”
- Vigilans: Latin for “watchful”

According to the International Hemovigilance Network:

- “A set of surveillance procedures covering the whole transfusion chain, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.”
The Transfusion Chain

Blood Donation → Blood Component Preparation → Blood Administration and Monitoring → Physician Ordering Practices

- Blood ID and quality Testing
- Issuing and transport of blood to hospitals and to the patient
Hemovigilance should be everywhere

Hemovigilance is a quality system that can exist at 3 levels.

- Local
- National
- International

Any Hemovigilance system, at any level, needs to:

- Document any issues with a blood transfusion chain
- Use lessons learned to reduce these issues
Hemovigilance is not everywhere

Current Challenges:

• Delays in entry and reporting
• Limited data granularity
• Limited system flexibility
• Limited system breadth and depth
• Resource and financial pressures
Examples of hemovigilance success: TRALI reduction using all male plasma donors

Figure: Number of suspected cases (yellow) and deaths (red) at least possibly related to TRALI by year or report

Organized National Hemovigilance Networks

Established and centralized hemovigilance networks around the world (not exhaustive).

• Europe
  - France (1994)
  - United Kingdom (1996)
  - Netherlands (2003)
  - Ireland (1999)

• Africa
  - Namibia (2010)
  - South Africa (2010)

• North America
  - Canada (2007)
  - United States (2006)

• Asia
  - Japan (1993)
  - Singapore (2003)
  - India (2012)

• Australia (2007)
National Hemovigilance Networks: United States

**Mandatory Hemovigilance Reporting:**
- US Food and Drug Administration
  - Transfusion-related fatalities
  - Product deviations

**Table:** Transfusion-Associated Fatalities by Complication FY2013-FY2017

<table>
<thead>
<tr>
<th>Complications</th>
<th>FY13 No.</th>
<th>FY13 %</th>
<th>FY14 No.</th>
<th>FY14 %</th>
<th>FY15 No.</th>
<th>FY15 %</th>
<th>FY16 No.</th>
<th>FY16 %</th>
<th>FY17 No.</th>
<th>FY17 %</th>
<th>Total No.</th>
<th>Total %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaphylaxis</td>
<td>-</td>
<td>0</td>
<td>2</td>
<td>7</td>
<td>2</td>
<td>5</td>
<td>5</td>
<td>12</td>
<td>3</td>
<td>8</td>
<td>12</td>
<td>6</td>
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<tr>
<td>Contamination</td>
<td>5</td>
<td>13</td>
<td>1</td>
<td>3</td>
<td>5</td>
<td>14</td>
<td>5</td>
<td>12</td>
<td>7</td>
<td>19</td>
<td>23</td>
<td>12</td>
</tr>
<tr>
<td>HTR (ABO)</td>
<td>1</td>
<td>3</td>
<td>4</td>
<td>13</td>
<td>2</td>
<td>5</td>
<td>4</td>
<td>9</td>
<td>1</td>
<td>3</td>
<td>12</td>
<td>7</td>
</tr>
<tr>
<td>HTR (non-ABO)</td>
<td>5</td>
<td>13</td>
<td>4</td>
<td>13</td>
<td>4</td>
<td>11</td>
<td>1</td>
<td>2</td>
<td>6</td>
<td>16</td>
<td>20</td>
<td>11</td>
</tr>
<tr>
<td>Hypotensive Reaction</td>
<td>-</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>TACO</td>
<td>13</td>
<td>34</td>
<td>5</td>
<td>17</td>
<td>11</td>
<td>30</td>
<td>19</td>
<td>44</td>
<td>11</td>
<td>30</td>
<td>59</td>
<td>32</td>
</tr>
<tr>
<td>TRALI</td>
<td>14</td>
<td>37</td>
<td>13</td>
<td>43</td>
<td>12</td>
<td>32</td>
<td>8</td>
<td>19</td>
<td>9</td>
<td>24</td>
<td>56</td>
<td>30</td>
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</tbody>
</table>

National Hemovigilance Networks: United States

Reporting is **not mandatory** for anything else:

- Non-fatal transfusion reactions (infectious and non-infectious, acute and delayed)
- Non-fatal donor reactions
- Process or procedure errors that do not lead to product deviations

...So, how do we learn and monitor anything nationally???
National Hemovigilance Networks: United States

The National Healthcare Safety Network (NHSN).

- Started in 2010 by the CDC
- Secure, free, web-based reporting system
- Collects data about transfusion-related adverse events: incidents (e.g., errors and near misses) and patient adverse reactions
- Created standardized definitions to allow for the potential to compare between sites
- Allows hospitals to monitor their own data, and to share data with external groups at the individual hospitals discretion
- As of 2016, 277/4600 (6.0%) of hospitals were enrolled
# National Hemovigilance Networks: United States

## The National Healthcare Safety Network (NHSN).

<table>
<thead>
<tr>
<th>Reaction Type</th>
<th>Case-definition</th>
<th>Severity</th>
<th>Imputability</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Transfusion-related acute lung injury (TRALI)</td>
<td></td>
<td>2. Severe</td>
<td>2. Probable</td>
</tr>
<tr>
<td>3. Transfusion-associated dyspnea (TAD)</td>
<td></td>
<td>3. Life-threatening</td>
<td>3. Possible</td>
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<tr>
<td>5. Hypotensive transfusion reaction</td>
<td></td>
<td>5. Not determined</td>
<td>5. Ruled Out</td>
</tr>
<tr>
<td>6. Febrile non-hemolytic transfusion reaction (FNHTR)</td>
<td></td>
<td></td>
<td>6. Not Determined</td>
</tr>
<tr>
<td>7. Acute hemolytic transfusion reaction (AHTR)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Delayed hemolytic transfusion reaction (DHTR)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Delayed serologic transfusion reaction (DSTR)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>10. Transfusion-associated graft vs. host disease (TAGVHD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Post-transfusion purpura (PTP)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Transfusion-transmitted infection (TTI)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
National Hemovigilance Networks: United States

The National Healthcare Safety Network (NHSN).

Transfusion-related adverse reactions reported to the National Healthcare Safety Network Hemovigilance Module, United States, 2010 to 2012

Alexis R. Harvey, Sridhar V. Basavaraju, Koo-Whang Chung, and Matthew J. Kuehnert

Transfusion-Transmitted Infections Reported to the National Healthcare Safety Network Hemovigilance Module

Kathryn A. Haass a,⁎, Mathew R.P. Sapiano b, Alexandra Savinkina a,c, Matthew J. Kuehnert a, Sridhar V. Basavaraju a

…It’s working, and we are learning stuff!
National Hemovigilance Networks: United States

Other National Monitoring options.

- AABB
  - Center for Patient Safety (no longer available)
  - Donor Hemovigilance and Reporting Tool (DonorHART)

- Collaborative independent research initiatives
  - American Red Cross
  - Blood Systems Research Institute
  - NIH - Retrovirus Epidemiology Donor Study (REDS-II)
  - NIH - Recipient Epidemiology and Donor Study (REDS-III)
National Hemovigilance Networks: United States

The future...

...is up to us.
National Hemovigilance Networks: United States

Conclusions.

• Hemovigilance efforts are critically important

• Public health initiatives informed by national hemovigilance monitoring activities has saved lives

• The US hemovigilance system is still emerging, and is showing promise
Suggested References


Disclosures/Potential Conflicts of Interest

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