Validation of transfusion administrations among potential Transfusion-Related Acute Lung Injury (TRALI) patients included in the Sentinel Distributed Database

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1 Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA; 2 HCA Healthcare, Nashville, TN; 3 Duke Clinical Research Institute, Durham, NC; 4 Center for Biologics Evaluation and Research, Food and Drug Administration, Silver Spring, MD; 5 Health Information Systems Consulting, Milton, MA
Disclosures

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- This presentation reflects the views of the authors and not necessarily those of the FDA
Background

- Sentinel Initiative is the U.S. Food and Drug Administration's (FDA) active safety surveillance system that uses routine querying tools and pre-existing electronic healthcare data to monitor safety of medical products.

- FDA’s Center for Biologics Evaluation and Research (CBER) is responsible for ensuring safety of blood products and blood components.

- Blood Safety Surveillance Continuous Active Network (BloodSCAN)
  - Subcomponent of the Sentinel Initiative sponsored by CBER to monitor recipient safety of FDA-regulated blood components and blood-derived products.
Background

- Many blood transfusions occur in inpatient settings
  - Claims data often do not contain transfusion information

- In 2016, inpatient electronic transfusion data were added to the Sentinel network, providing new safety surveillance potential
  - Full-text electronic health records available
  - Facilitates chart review and exposure/outcome validation during inpatient stays
Background

Sentinel Inpatient EMR Data

174 hospitals located in 20 states

~5% of all inpatient care delivered in USA
## Sentinel Common Data Model: Overview

### Administrative
- **Enrollment**
  - Person ID
  - Enrollment start & end dates
  - Drug coverage
  - Medical coverage
  - Medical record availability
- **Demographic**
  - Person ID
  - Birth date
  - Sex
  - Zip code
  - Etc.
- **Dispensing**
  - Person ID
  - Dispensing date
  - National drug code (NDC)
  - Days supply
  - Amount dispensed
- **Encounter**
  - Person ID
  - Service date(s)
  - Encounter ID
  - Encounter type and provider
  - Facility
  - Etc.
- **Diagnosis**
  - Person ID
  - Service dates
  - Encounter ID
  - Encounter type and provider
  - Diagnosis code & type
  - Principal discharge diagnosis
  - Etc.
- **Procedure**
  - Person ID
  - Service date(s)
  - Encounter ID
  - Encounter type & provider
  - Procedure code & type
  - Etc.

### Clinical
- **Lab Result**
  - Person ID
  - Result and specimen collection dates
  - Test type, immediacy & location
  - Logical Observation Identifiers Names and Codes (LOINC®)
  - Test result & unit
  - Etc.
- **Vital Signs**
  - Person ID
  - Measurement date & time
  - Height & weight
  - Diastolic & systolic BP
  - Tobacco use & type
  - Etc.
- **Death**
  - Person ID
  - Death date
  - Source
  - Confidence
  - Etc.
- **Cause of Death**
  - Person ID
  - Cause of death
  - Source
  - Confidence
  - Etc.

### Registry
- **State Vaccine**
  - Person ID
  - Vaccination date
  - Admission type
  - Vaccine code & type
  - Provider
  - Etc.

### Inpatient
- **Inpatient Pharmacy**
  - Person ID
  - Administration date & time
  - Encounter ID
  - National Drug Code (NDC)
  - Route
  - Dose
  - Etc.
- **Inpatient Transfusion**
  - Person ID
  - Administration start & end date & time
  - Encounter ID
  - Transfusion administration ID
  - Transfusion product code
  - Blood type
  - Etc.

Background: Electronic transfusion data

- Sentinel inpatient electronic transfusion data provides information often not available in claims data:
  - Administered transfusions
  - Start/end transfusion dates AND times
  - Product blood type (A, B, O, AB)
  - Rh factor (+, -)
  - # units, potentially large volume transfusion
Background: Electronic transfusion data

- Two transfusion coding systems in use
  - ISBT-128 codes1 (majority >99%)
  - Codabar codes (<1%)

- ISBT-128 and Codabar codes identify:
  - Blood components
  - Processing/Collection methods

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Background: Electronic transfusion data

- Centers for Disease Control and Prevention’s (CDC) National Healthcare Safety Network’s (NHSN) method was used for mapping codes into relevant categories:
  - Blood component (red blood cells [RBC], platelets, plasma, cryoprecipitate)
  - Processing methods (leukocyte-reduction [LR], irradiation [IR])
  - Collection methods (apheresis [AP] or whole blood derived [WBD])
## CDC’s NHSN Mapping

<table>
<thead>
<tr>
<th>Broad Categorization</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Plasma</strong></td>
<td>APHPLASMA - Apheresis plasma</td>
</tr>
<tr>
<td></td>
<td>WBDPLASMA - Whole blood derived plasma</td>
</tr>
<tr>
<td><strong>Platelets</strong></td>
<td>APHPLAT - Apheresis platelets</td>
</tr>
<tr>
<td></td>
<td>IRAPPHPLAT - Irradiated apheresis platelets</td>
</tr>
<tr>
<td></td>
<td>IRRAPPHPLAT - Irradiated leukocyte reduced apheresis platelets</td>
</tr>
<tr>
<td></td>
<td>IRLRWBDPLAT - Irradiated leukocyte reduced whole blood derived platelets</td>
</tr>
<tr>
<td></td>
<td>IRWBDPLAT - Irradiated whole blood derived platelets</td>
</tr>
<tr>
<td></td>
<td>LRSHPHPLAT - Leukocyte reduced apheresis platelets</td>
</tr>
<tr>
<td></td>
<td>LRRWBDPLAT - Leukocyte reduced whole blood derived platelets</td>
</tr>
<tr>
<td></td>
<td>WBDPLAT - Whole blood derived platelets</td>
</tr>
<tr>
<td><strong>Red Blood Cells</strong></td>
<td>APHRBC - Apheresis red blood cells</td>
</tr>
<tr>
<td></td>
<td>IRAPHRBC - Irradiated apheresis red blood cells</td>
</tr>
<tr>
<td></td>
<td>IRLRAPHRC - Irradiated leukocyte reduced apheresis red blood cells</td>
</tr>
<tr>
<td></td>
<td>IRLRWBDRBC - Irradiated leukocyte reduced whole blood derived RBC</td>
</tr>
<tr>
<td></td>
<td>IRWBDRBC - Irradiated whole blood derived red blood cells</td>
</tr>
<tr>
<td></td>
<td>LRRAPHRBC - Leukocyte reduced apheresis red blood cells</td>
</tr>
<tr>
<td></td>
<td>LRRWBDRBC - Leukocyte reduced whole blood derived red blood cells</td>
</tr>
<tr>
<td></td>
<td>WBDRCB - Whole blood derived red blood cells</td>
</tr>
<tr>
<td><strong>Whole Blood</strong></td>
<td>WB - Whole blood</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>CRYO – Cryoprecipitate</td>
</tr>
<tr>
<td></td>
<td>GRAN – Granulocytes</td>
</tr>
<tr>
<td></td>
<td>LEUK – Leukocytes</td>
</tr>
<tr>
<td></td>
<td>LYMPH – Lymphocytes</td>
</tr>
<tr>
<td></td>
<td>MNC - Mononuclear cells</td>
</tr>
<tr>
<td></td>
<td>SERUM - Serum</td>
</tr>
</tbody>
</table>

[https://www.cdc.gov/nhsn/index.html](https://www.cdc.gov/nhsn/index.html)
Background

- This sub-study was part of a protocol based assessment:

  [Image]

  **Sentinel ASSESSMENT PROTOCOL**

  TRANSFUSION RELATED ACUTE LUNG INJURY AFTER RED BLOOD CELL, PLASMA AND PLATELET ADMINISTRATION 2013-2015

- Assessment identified potential TRALI cases with diagnosis codes in Sentinel data, and validated outcomes and transfusion exposures captured in the Sentinel electronic database with medical charts

Objectives

- To determine through medical chart review the positive predictive value of reported blood transfusion exposures in potential TRALI cases captured in the Sentinel electronic database, specifying:
  - Blood component (RBC, platelets, plasma, cryoprecipitate)
  - Processing methods (LR, IR)
  - Collection methods (AP or WBD)
Methods

Potential TRALI cases with transfusion information in Sentinel electronic data were identified between September 2013-September 2015

Medical chart review: Physicians with critical care expertise confirmed transfusions potentially associated with TRALI

PPV analyses: Transfusion data in Sentinel database compared with transfusion information confirmed by the adjudicators (chart confirmed transfusions used as gold standard for validation)
Methods

- Potential TRALI inpatient stays identified with diagnosis codes:

  **TRALI Criterion A**
  
  - TRALI ICD-9-CM code (518.7)

  **TRALI Criterion B**
  
  - Acute respiratory failure ICD-9-CM code (518.81), AND code for a blood transfusion reaction (999.80 or 999.89 or E934.7)

  **TRALI Criterion C**
  
  - Other pulmonary insufficiency (518.82), AND code for a blood transfusion reaction (999.80 or 999.89 or E934.7)
Methods

- Sentinel inpatient electronic transfusion data are labeled with ISBT-128 and Codabar codes
- Mapped codes to blood components using CDC’s National Healthcare Safety Network’s method
- Classified the codes into relevant categories:
  - Blood component (RBC, platelets, plasma, cryoprecipitate)
  - Processing methods (LR, IR)
  - Collection methods (AP or WB)
Methods: Chart review

- Requested medical charts for all potential TRALI cases through the electronic medical records (EMR) platform
  - Requested all charts with a potential TRALI diagnosis code, even if there was no transfusion documented in electronic data
  - Adjudicators were provided with the medical chart of the entire hospitalization for each potential TRALI case
  - Adjudicators abstracted and adjudicated every potential TRALI case and verified the transfusion exposure
  - Blood bank feeds were often not available on the standard EMR platform, but if they were available they were provided to adjudicators for review
Methods: Chart review

- Physicians with critical care expertise confirmed transfusions potentially associated with TRALI, including:
  - blood component, processing, and collection methods

- When transfusion information was not available in charts, physicians described reasons for the omission
  - i.e., transfusion occurred in another hospital, outpatient setting, etc.
Methods: Positive Predictive Value (PPV) calculation

We quantified the PPV for transfusions identified in the Sentinel electronic database, as compared to transfusion exposures confirmed with chart review (gold standard).

- Positive predictive value was calculated as the proportion of transfusions in Sentinel electronic data that was confirmed by medical chart review.
  - PPV = \( \frac{A}{A+C} \)
Methods

- We examined the PPV of electronic Sentinel transfusion data as compared to medical chart review, and focused on:
  - Any transfusion
  - Blood component (i.e., RBC, plasma, platelet, cryoprecipitate)
  - Processing method (LR, IR)
  - Collection method (i.e., AP or WBD)

- For all analyses, chart confirmed transfusion exposures was the gold standard
Methods

- Exploratory analyses:
  - We located TRALI cases with documentation of processing and collection methods in the medical charts.
  - In this subgroup, we quantified the PPV for processing/collection methods identified in the Sentinel electronic database as compared to medical charts.
  - Gold standard: chart confirmed transfusion exposures
  - Limitation: few medical charts contained documentation of processing and collection methods
Results

- During the study period (September 2013-September 2015) there were almost 4 million inpatient stays in 169 hospitals and approximately 350,000 inpatient stays with transfusions

- Among 208 potential TRALI cases that were identified (all TRALI diagnosis codes)
  - Medical charts were available for 195 (94%) of these 208 potential cases
Results

Potential TRALI inpatient encounters identified in Sentinel electronic data (n=208)

- n=13, unable to be retrieved

Potential TRALI cases, charts retrieved and adjudicated (n=195, 94%)

- n=13, no electronic transfusion data, adjudicators reviewed reasons for lack of information

Potential TRALI cases, with charts and any transfusion captured in electronic transfusion data (n=182, 88%)

- n=3, transfusion associated with TRALI administered during a different hospital stay, or in outpatient setting

Potential TRALI cases, transfusion of interest** confirmed by adjudicators with medical charts (n=179*, 86%)

*Gold standard - chart confirmed transfusion exposures

**Transfusion of interest is transfusion potentially associated with TRALI
Results

*Multiple blood components were often administered during a transfusion event*

** Chart confirmed transfusions was gold standard for validation.
## Results

<table>
<thead>
<tr>
<th>Transfusions by blood component and processing/collection method</th>
<th>Transfusions confirmed in charts**</th>
<th>Transfusions recorded in Sentinel database</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Any transfusion*</td>
<td>179</td>
<td>182</td>
</tr>
<tr>
<td>Red blood cells</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LR RBC</td>
<td>143</td>
<td>143</td>
</tr>
<tr>
<td>IR RBC</td>
<td>62</td>
<td>130</td>
</tr>
<tr>
<td>AP RBC</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>WB RBC</td>
<td>23</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>118</td>
</tr>
<tr>
<td>Plasma ¥</td>
<td>36</td>
<td>37</td>
</tr>
<tr>
<td>AP Plasma</td>
<td>4</td>
<td>10</td>
</tr>
<tr>
<td>WB Plasma</td>
<td>1</td>
<td>27</td>
</tr>
<tr>
<td>Platelets ¥</td>
<td>43</td>
<td>43</td>
</tr>
<tr>
<td>LR Platelets</td>
<td>15</td>
<td>38</td>
</tr>
<tr>
<td>IR Platelets</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>AP Platelets</td>
<td>16</td>
<td>39</td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td>11</td>
<td>12</td>
</tr>
</tbody>
</table>

*Multiple blood components were often administered during a transfusion event

** Chart confirmed transfusions was gold standard for validation

¥ No LR or IR plasma and WB platelet transfusions were documented in medical charts
PPV analyses: Transfusion data in Sentinel database compared with transfusion information confirmed by the adjudicators*

*Gold standard - transfusion exposures confirmed with medical charts
## Results – Main analyses

<table>
<thead>
<tr>
<th>Blood component</th>
<th>Electronic transfusion data</th>
<th>Confirmed in Medical charts</th>
<th>PPV (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LR RBCs</td>
<td>130</td>
<td>62</td>
<td>47.7% (38.9%, 56.6%)</td>
</tr>
<tr>
<td>LR platelets</td>
<td>38</td>
<td>15</td>
<td>39.5% (24%, 56.6%)</td>
</tr>
</tbody>
</table>

*Gold standard - chart confirmed transfusion exposures
## Results – Exploratory analyses

### Leukocyte-reduced (LR) blood components in Sentinel electronic transfusion data vs. medical charts*

<table>
<thead>
<tr>
<th>Blood component</th>
<th>Electronic transfusion data</th>
<th>Confirmed in Medical charts</th>
<th>PPV (95% CI)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>LR RBCs</td>
<td>62</td>
<td>62</td>
<td>100% (94.2%, 100%)</td>
</tr>
<tr>
<td>LR platelets</td>
<td>15</td>
<td>15</td>
<td>100% (78.2%, 100%)</td>
</tr>
</tbody>
</table>

*Gold standard - chart confirmed transfusion exposures

** Exploratory analyses compared electronic transfusion data with transfusions in charts only for cases in which adjudicators located processing/collection method in charts
## Results – Main analyses

<table>
<thead>
<tr>
<th>Blood component</th>
<th>Electronic transfusion data</th>
<th>Confirmed in Medical charts</th>
<th>PPV (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IR RBCs</td>
<td>12</td>
<td>5</td>
<td>41.7% (15.2%, 72.3%)</td>
</tr>
<tr>
<td>IR platelets</td>
<td>10</td>
<td>6</td>
<td>60% (26.2%, 87.8%)</td>
</tr>
</tbody>
</table>

*Gold standard - PPV=100%, chart confirmed transfusion exposures*
Results – Exploratory analyses

Irradiated blood components in Sentinel electronic transfusion data vs. medical charts*

<table>
<thead>
<tr>
<th>Blood component</th>
<th>Electronic transfusion data</th>
<th>Confirmed in Medical charts</th>
<th>PPV (95% CI)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>IR RBCs</td>
<td>5</td>
<td>5</td>
<td>100% (47.8%, 100%)</td>
</tr>
<tr>
<td>IR platelets</td>
<td>6</td>
<td>6</td>
<td>100% (54.1%, 100%)</td>
</tr>
</tbody>
</table>

*Gold standard - PPV=100%, chart confirmed transfusion exposures

**Exploratory analyses compared electronic transfusion data with transfusions in charts only for cases in which adjudicators located processing/collection method in charts
## Results – Main analyses

### Apheresis derived (AP) blood components in electronic transfusion data vs. medical charts*

<table>
<thead>
<tr>
<th>Blood component</th>
<th>Electronic transfusion data</th>
<th>Confirmed in Medical charts</th>
<th>PPV (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AP RBCs</td>
<td>38</td>
<td>23</td>
<td>60.5% (43.4%, 76%)</td>
</tr>
<tr>
<td>AP platelets</td>
<td>39</td>
<td>16</td>
<td>41% (25.6%, 57.9%)</td>
</tr>
<tr>
<td>AP plasma</td>
<td>10</td>
<td>4</td>
<td>40% (12.2%, 73.8%)</td>
</tr>
</tbody>
</table>

*Gold standard - PPV=100%, chart confirmed transfusion exposures
Results – Exploratory analyses

Apheresis derived (AP) blood components in electronic transfusion data vs. medical charts*

<table>
<thead>
<tr>
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<th>Electronic transfusion data</th>
<th>Confirmed in Medical charts</th>
<th>PPV (95% CI)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>AP RBCs</td>
<td>23</td>
<td>23</td>
<td>100% (85.2%, 100%)</td>
</tr>
<tr>
<td>AP platelets</td>
<td>16</td>
<td>16</td>
<td>100% (79.4%, 100%)</td>
</tr>
<tr>
<td>AP plasma</td>
<td>4</td>
<td>4</td>
<td>100% (39.8%, 100%)</td>
</tr>
</tbody>
</table>

*Gold standard - chart confirmed transfusion exposures

**Exploratory analyses compared electronic transfusion data with transfusions in charts only for cases in which adjudicators located processing/collection method in charts
## Results – Main analyses

**Whole blood derived (WB) blood components in electronic transfusion data vs. medical charts**

<table>
<thead>
<tr>
<th>Blood component</th>
<th>Electronic transfusion data</th>
<th>Confirmed in Medical charts</th>
<th>PPV (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>WB RBCs</td>
<td>118</td>
<td>10</td>
<td>8.5% (4.1%, 15%)</td>
</tr>
<tr>
<td>WB plasma</td>
<td>27</td>
<td>1</td>
<td>3.7% (0.09%, 18.9%)</td>
</tr>
</tbody>
</table>

*Gold standard - PPV=100%, chart confirmed transfusion exposures*
Results – Exploratory analyses

**Whole blood derived components in electronic transfusion data vs. medical charts***

<table>
<thead>
<tr>
<th>Blood component</th>
<th>Electronic transfusion data</th>
<th>Confirmed in Medical charts</th>
<th>PPV (95% CI)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>WB RBCs</td>
<td>10</td>
<td>10</td>
<td>100% (69.2%, 100%)</td>
</tr>
<tr>
<td>WB plasma</td>
<td>1</td>
<td>1</td>
<td>100% (2.5%, 100%)</td>
</tr>
</tbody>
</table>

*Gold standard - PPV=100%, chart confirmed transfusion exposures

**Exploratory analyses compared electronic transfusion data with transfusions in charts only for cases in which adjudicators located processing/collection method in charts
Results

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*Gold standard- chart confirmed transfusion exposures

**Transfusion of interest is transfusion potentially associated with TRALI
Results

- Reasons transfusion not found in Sentinel inpatient electronic data but captured in a medical chart:
  - Transfusion occurred at a different facility so was noted in the chart but not in electronic data (e.g., transfer, outpatient, emergency department) (n=9)
  - Missing transfusion information (n=3)
  - No transfusion information was available in inpatient electronic data for one potential TRALI case but clinicians suspected intravenous immune globulin to be associated with TRALI (n=1)
Limitations of the study

- Only examined blood transfusions in potential TRALI cases
- Most transfusion codes in Sentinel inpatient electronic data were mapped to a blood component, but approximately 3% could not be mapped (n=6 of 182 potential TRALI cases)
  - Could be due to invalid coding or code not identified using current mapping system
- Only examined processing and collection methods in a subset of potential TRALI cases, as this information often was not available in charts, this limits conclusions that can be drawn
Current Limitations of Sentinel inpatient electronic data

- Limited information about medical conditions/events before/after a hospitalization
  - Rich information about care delivered during in-hospital stay

- Challenges with identifying temporal association between exposures and outcomes
  - Current Sentinel Common Data Model (SCDM) includes admission and discharge dates AND transfusion dates and times but no procedure or diagnosis dates and times
  - A data expansion effort is currently in progress to add these data elements to the SCDM
Conclusions

- Transfusions were well captured in Sentinel’s inpatient electronic transfusion data
  - Included granular information about component type, which matched with medical charts (PPV >90%)
- Processing and collection methods were documented in Sentinel transfusion data but typically not available in charts
  - When processing and collection methods were documented in charts, we observed perfect concordance with electronic transfusion data, however sample sizes were limited
- This validation demonstrated the potential utility of Sentinel inpatient electronic data for future pharmacoepidemiology studies
Acknowledgements

- Sentinel Operations Center staff including Crystal Garcia
- Contributors in the U.S. Food and Drug Administration’s Center for Biologics Evaluation and Research, Office of Biostatistics and Epidemiology
- Data Partner for providing inpatient data and expertise
- Clinical adjudicators at the Data Partner who conducted medical chart review
Optional Slides
Results – back up

<table>
<thead>
<tr>
<th>Transfusion date and time match in charts compared to Sentinel inpatient data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion date match</td>
</tr>
<tr>
<td>Transfusion time match</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>CODABAR</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>18831</td>
</tr>
<tr>
<td>35772</td>
</tr>
<tr>
<td>35773</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ISBT-128</th>
<th>Description</th>
<th>Prod_CDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0135</td>
<td>WHOLE BLOOD</td>
<td>Heparin/450mL/refg</td>
</tr>
<tr>
<td>E1149</td>
<td>Thawed Apheresis FRESH FROZEN PLASMA</td>
<td>ACD-B/XX/refg</td>
</tr>
</tbody>
</table>
Methods

▪ Study Population
  – Potential TRALI cases with electronic transfusion data were identified between September 2013-September 2015