ASSESSMENT OF TRANSFUSION-RELATED ACUTE LUNG INJURY (TRALI) AFTER RED BLOOD CELL, PLASMA AND PLATELET ADMINISTRATION: INITIAL RESULTS IN THE SENTINEL SYSTEM

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INTRODUCTION

- The Sentinel System is an active surveillance system that uses routine querying tools and pre-existing electronic healthcare data from multiple sources to monitor the safety of regulated medical products.

- The Blood Safety Surveillance Continuous Active Network (BloodSCAN) was created by the Center for Biologics Evaluation and Research (CBER) as a subcomponent of the Sentinel System to monitor recipient safety of FDA-regulated blood components and blood-derived products.

- Most blood transfusions occur in inpatient settings, and the 2016 addition of Hospital Corporation of America (HCA) to the Sentinel network provides new safety surveillance potential for BloodSCAN.

- As part of an assessment of the feasibility of studying blood transfusion safety in Sentinel, FDA conducted an exploratory evaluation of Transfusion-Related Acute Lung Injury (TRALI) frequency using inpatient electronic medical record (EMR) data from HCA.

- HCA's network includes over 165 acute care hospitals.

BACKGROUND

- Transfusion-Related Acute Lung Injury (TRALI) is an adverse event, broadly defined as the onset of respiratory distress during or within 6 hours of blood transfusion.

- TRALI is a leading cause of transfusion-associated fatalities reported to the U.S. Food and Drug Administration.

OBJECTIVE

To describe the frequency of potential TRALI cases recorded in inpatient EMR data included Sentinel database.
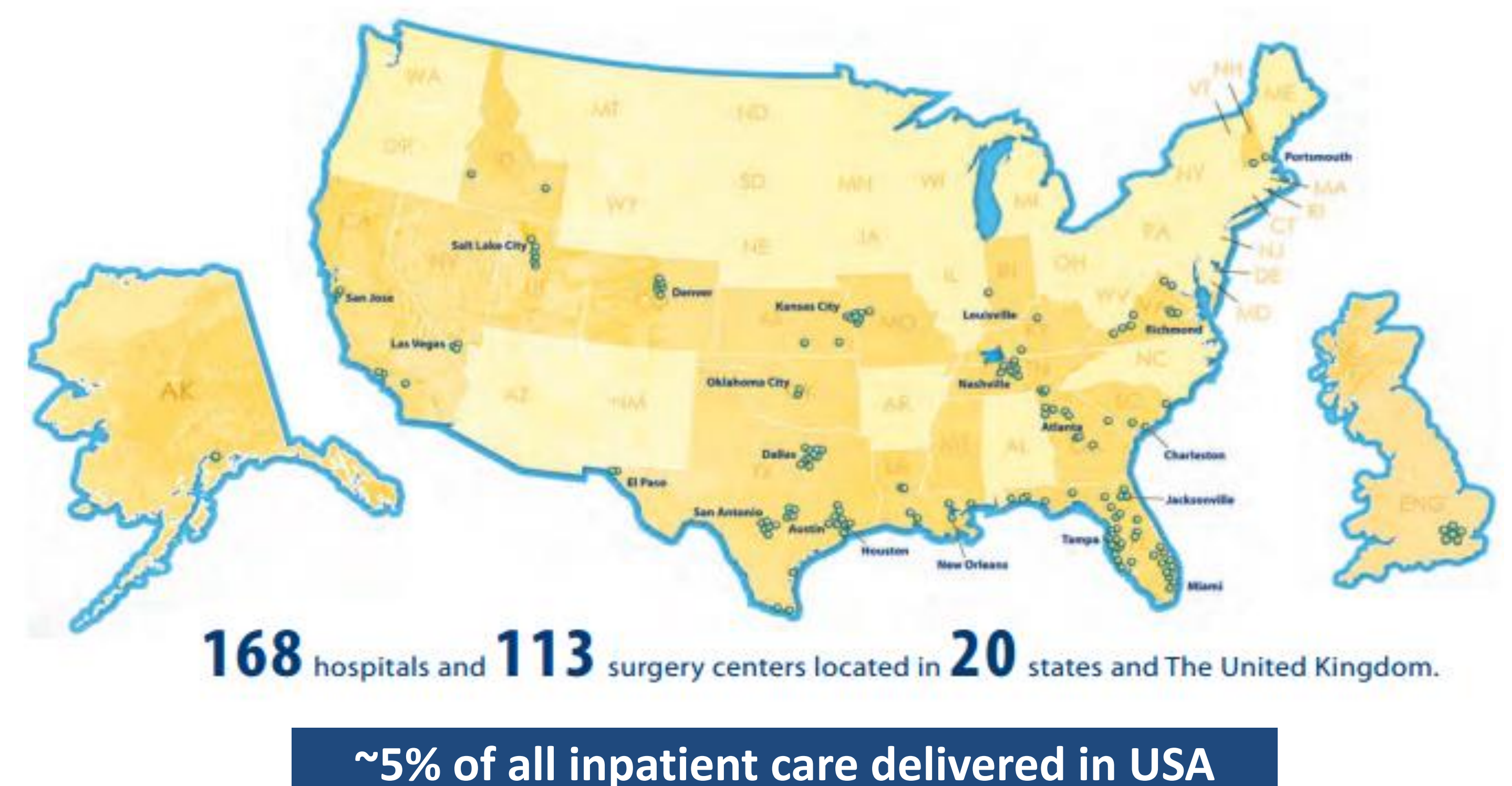
METHODS

Design and population: We conducted a retrospective cohort study examining TRALI occurrence among patients (all ages) diagnosed in a hospital setting between September 2013 and September 2015.

Data: TRALI patients with inpatient hospital stays (i.e., encounters) coded with TRALI ICD-9-CM codes were identified (Criterion A). As TRALI is likely under-diagnosed, we also identified possible cases with certain respiratory failure codes in combination with an ICD-9 code for a transfusion reaction (Criteria B and C).

Analyses: We conducted descriptive analyses (SAS 9.4), including estimating the frequency of potential TRALI events.

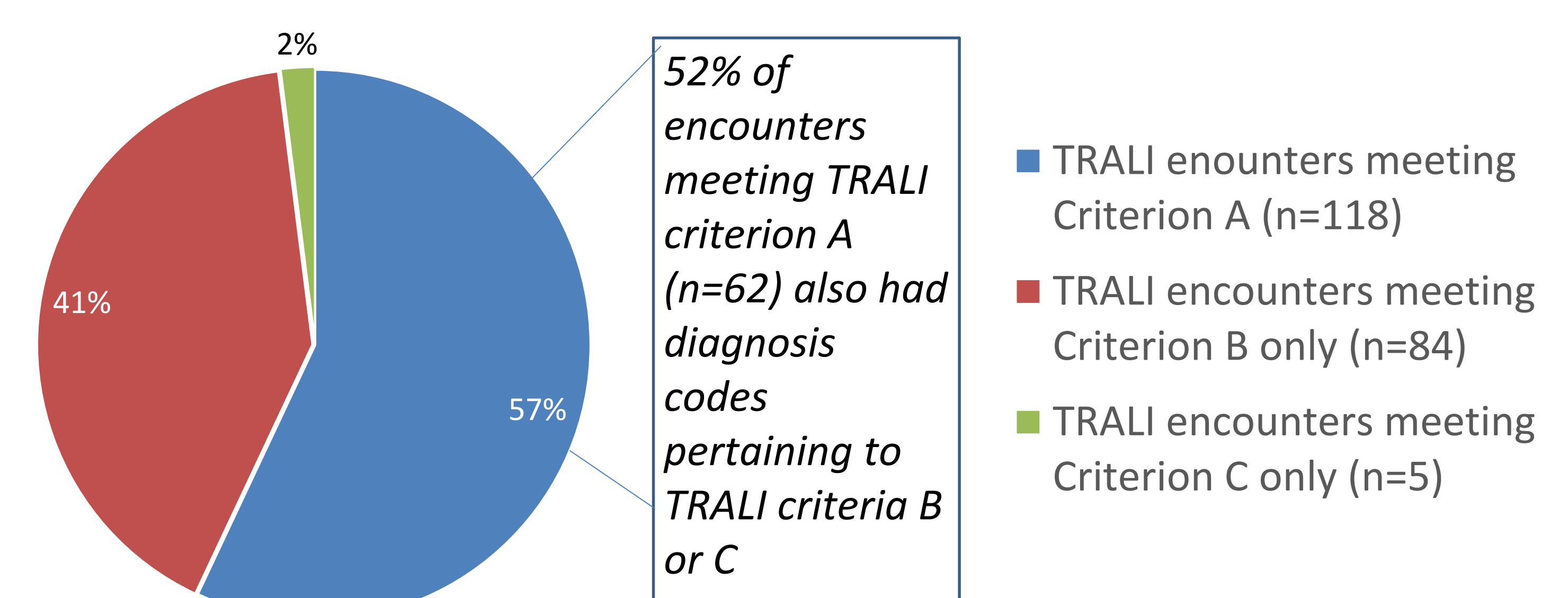| Criteria	ICD-9-CM Code(s)
Criterion A	TRALI, ICD-9-CM code in any position (518.7)
Criterion B	Acute respiratory failure ICD-9-CM code in any position (518.81), WITH code for a blood transfusion reaction (999.80 or 999.89 or E934.7)
Criterion C	Other pulmonary insufficiency (518.82), WITH code for a blood transfusion reaction (999.80 or 999.89 or E934.7)
Any TRALI Criteria	Criteria A, and/or B, and/or C listed above

Electronic Medical Record (EMR) Based Sentinel Partner

168 hospitals and **113** surgery centers located in **20** states and The United Kingdom.

**~5% of all inpatient care delivered in USA**

RESULTS

- We identified 207 potential TRALI inpatient encounters [Criterion A=118 (57%), B only=84 (41%), C only=5 (2%)] among over four million inpatient encounters captured in Sentinel inpatient EMR data during the study time period.

- Of potential TRALI patients(n=207 encounters, among 206 patients), 53% were female, and the median age was 63 years (range, less than 1 to 97 years).

- A transfusion was recorded in 92% of these TRALI encounters (n=191).

Proportion of identified TRALI encounters meeting each TRALI criterion (n=207), and multiple TRALI criteria (n=62)

52% of encounters meeting TRALI criterion A (n=62) also had diagnosis codes pertaining to TRALI criteria B or C

- TRALI enounters meeting Criterion A (n=118)
- TRALI encounters meeting Criterion B only (n=84)
- TRALI encounters meeting Criterion C only (n=5)

Proportion of potential TRALI encounters with a transfusion

- TRALI encounters with transfusion (n=191)
- TRALI encounters without transfusion (n=15)
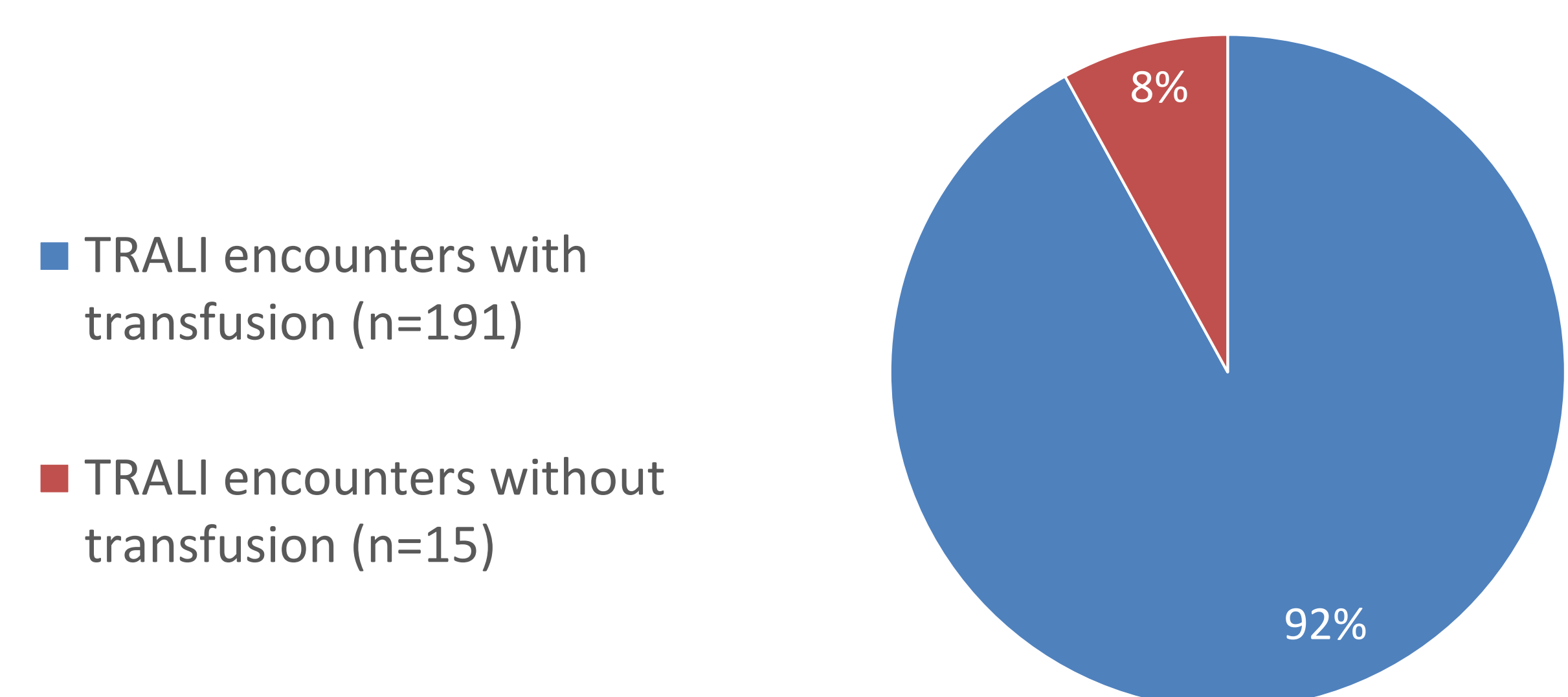
Of the 118 encounters that met Criterion A, 62(52%) also met B and/or C; a transfusion was recorded in 95% (n=59) of these encounters.

CONCLUSION

- Identifying TRALI cases in Sentinel inpatient EMR data appears to be feasible but validation is necessary.
- Future work includes:
  - description validation of the TRALI outcome and transfusion exposure with medical records
  - of TRALI risk factors
  - calculation of TRALI incidence rates subsequent to plasma, platelet and red blood cell administration
- Validation of blood transfusions and TRALI outcomes in a large EMR-based system will provide a solid foundation for future blood component surveillance activities.