**FDA scientists identified occurrence trends and potential risk factors that suggest that elderly persons in inpatient facilities who receive blood transfusions are potentially at greater risk for developing a serious, transfusion-associated, lung and respiratory disorder called TRALI**

Transfusion-related acute lung injury and potential risk factors among the inpatient U.S. elderly as recorded in Medicare claims data, during 2007 through 2011

Transfusion 28 MAR 2014, DOI: 10.1111/trf.12626


1 Food and Drug Administration, Silver Spring, Maryland; 2Acumen LLC, Burlingame, California; and 3Centers for Medicare & Medicaid Services, Baltimore, Maryland.

**Transfusion-related acute lung injury (TRALI): a leading cause of transfusion-related deaths in the U.S.**

- Damage to the lining of the lungs
  - Pulmonary edema: inhibits breathing and reduces blood oxygen level
  - Respiratory distress
- Occurs within six hours of blood transfusion
- Leading hypothesis suggests the cause is substances released from activated neutrophils

**FDA study of TRALI occurrence and potential risk factors among inpatient U.S. elderly Medicare beneficiaries: Office of Biostatistics and Epidemiology**

**Context**
- Published literature suggests that there is a higher rate of blood transfusions among the elderly than among younger persons and an increased TRALI risk among critically ill inpatients.

**Objective**
- Assess TRALI occurrence and potential risk factors among the inpatient U.S. elderly Medicare beneficiaries, ages 65 and older, during 2007 through 2011.

**Design:** First population-based assessment of TRALI occurrence and potential risk factors among inpatient elderly in the U.S., using large Medicare databases

- Retrospective claims-based study using large Medicare administrative databases
- Transfusions identified by recorded procedure and revenue center codes
- TRALI ascertained by ICD-9-CM diagnosis code
- Evaluation of TRALI rates among inpatient elderly overall and by calendar year, age, sex, race, blood components, and number of units transfused

**Findings**
- 2,556 TRALI diagnoses reported among 11,378,264 inpatient transfusion stays for elderly Medicare beneficiaries: 22.46/100,000 stays
- TRALI rates were higher for platelet- and plasma-containing transfusions
- TRALI rates increased by year of the study (2007-2011) and number of units transfused
- Significantly higher odds of TRALI among specific groups
  - persons 65 to 79 years vs. older than 79 years, with TRALI risk declining with advancing age
  - females vs. males
  - white versus nonwhite
  - certain medical histories
- post-inflammatory pulmonary fibrosis
- cancers of blood forming tissues
- pulmonary insufficiency following trauma or surgery
- tobacco use
- blood transfusion

The findings of the study suggest that underlying recipient health conditions and a history of prior alloimmunizations (e.g., transfusions, pregnancies) can contribute significantly to TRALI occurrence among transfused elderly in the inpatient setting.

This study shows the utility of large administrative databases as an additional epidemiologic tool to assess occurrence and risk factors for TRALI and other rare transfusion-related adverse events.