

Proposed ICD-10-CM Diagnosis Coding for Transfusion-Associated Dyspnea (TAD)

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Introduction

- **The FDA's Center for Biologics Evaluation and Research (CBER's) mission is to ensure the safety and efficacy of biological products, including blood and blood products, and thus to protect and improve public health;**
- **Under the Food and Drug Administration Amendments Act (FDAAA) of 2007, CBER is responsible for conducting the U.S. population-based active surveillance of blood and blood product safety;**
- **CBER uses large private and public (e.g., CMS) medical databases to:**
 - Conduct active safety and utilization surveillance of blood components and products;
 - Evaluate the spread of transfusion-transmissible infections.

Background



- **Transfusion-Associated Dyspnea (TAD) is defined by CDC's National Healthcare Safety Network (NHSN) Hemovigilance Module (HM) as '*Acute respiratory distress occurring within 24 hours of cessation of transfusion and Allergic reaction, TACO, and TRALI definitions are not applicable*' (1);**
- **The 2021 NHSN study by Kracalik et al.(2) suggests that TAD is:**
 - Rare and potentially severe transfusion-related complication, with the overall rate of about 4.1 per 100,000 units transfused;
 - During 2013-2018 study period, of all reported reactions (N=23,083) to NHSN, 2.0% (N=456) were TAD, with 74.3% satisfying case definition and imputability criteria, and 22.4% being serious reactions with one fatality;
- **Massachusetts Hemovigilance Program(3) data showed that number of reported TAD cases and rates in Massachusetts varied by year: 2017 (N=21; 5.8 per 100,000); 2018 (N=13; 3.2 per 100,000), and 2019 (N=30; 8.2 per 100,000);**
- **Given the total of about 16.0 and 16.5 million units transfused in 2017 and 2019 (4,5), the estimated total number of TAD cases in the U.S. was 928 and 1,350, respectively, based on the annual Massachusetts TAD rates;**
- **Literature (2,3,6-9) has shown that TAD has occurred with RBCs, platelets, and plasma transfusions, and has also been reported as an adverse event following COVID-19 Convalescent Plasma.**

Background Cont.



- **The literature (2,3,6-9) suggests that TAD may be a serious transfusion-related pulmonary complication and thus needs:**
 - Population-based national monitoring of TAD occurrence trends over time and by different recipient and transfusion characteristics (e.g., demographics, blood components);
 - Investigation of potential risk factors in the elderly and other high transfusion risk populations (e.g., immunocompromised);
 - Further characterization to better understand pathophysiology of reported cases.
- **Currently, there are no national population-based studies of TAD occurrence in the U.S. given the absence of the specific ICD-10-CM diagnosis code that can be used for nationwide monitoring.**

Transfusion-Associated Dyspnea (TAD) Coding Proposal



- The objective of the FDA/CBER's proposal is to generate a specific code for TAD that distinguishes this transfusion-related adverse event from TACO and TRALI based on the established definition by CDC's NHSN Hemovigilance Module (1);
- Currently, there is no specific coding for TAD. We therefore propose to introduce a new condition-specific code titled: 'Transfusion-associated dyspnea (TAD)';
- The code for TAD should only be applied in the absence of TACO (E87.71), TRALI (J95.84), and transfusion related allergic reactions (e.g., T80.51);
- Therefore, the exclusion note should be added to reflect TAD definition by CDC's NHSN HM Module (1).

Transfusion-Associated Dyspnea (TAD) Coding Proposal cont.



➤ If introduced, a specific code for TAD will:

- Improve detection of TAD using real-world large administrative databases, by allowing providers to record specific TAD code in the absence of TRALI, TACO, and allergic reactions;
- Allow a more accurate surveillance using real-world evidence to assess transfusion-related pulmonary complications (e.g., TAD, TRALI, TACO), including geographic distribution, severity of cases, and underlying risk factors;
- Assist in the development of TAD prevention strategies and better understanding of its pathophysiology;

➤ Overall, having a specific code for TAD will improve coding precision for transfusion-related pulmonary complications and thus lead to better diagnosis, treatment and prevention strategies, and will further assure public safety.

References



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