

Abstract Title: BIOLOGICS EFFECTIVENESS AND SAFETY (BEST) INITIATIVE: INCORPORATING ISBT-128 CODES INTO OHDSI'S OMOP COMMON DATA MODEL TO BUILD A NATIONAL HEMOVIGILANCE SYSTEM TO MONITOR TRANSFUSION-RELATED ADVERSE EVENTS

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Category: 6.6 Hemovigilance and transfusion safety

Background: The U.S. FDA Center for Biologics Evaluation and Research (CBER) regulates whole blood and blood components used for transfusion among other biologics. One of CBER's goals is to protect blood recipients by monitoring transfusion-related adverse events (AEs), leading to the need to build a national hemovigilance system. CBER recently established the Biologics Effectiveness and Safety (BEST) Initiative, a component of the CBER Sentinel Program. The BEST Initiative, a distributed network of data providers, applies a common data model (CDM) and utilizes claims and electronic health record (EHR) data sources which capture health care exposures, treatment, and outcome data. The most detailed blood product data is included in the Information Standard for Blood and Transplant (ISBT)-128 coding system. ISBT-128 codes add specificity and granularity to the surveillance of blood products which other coding systems lack.

Aims: The aim of this study is to build the infrastructure for a national hemovigilance system using EHR data sources to monitor transfusion-related AEs by incorporating the ISBT-128 coding system into the Observational Medical Outcomes Partnership (OMOP) common data model (CDM) of the Observational Health Data Sciences and Informatics (OHDSI) consortium.

Methods: We explored three BEST EHR databases that cover approximately 24 million patient records from geographically diverse areas of the US. We added a library of 14,543 ISBT-128 codes to the OMOP CDM. We determined the type and frequency of ISBT-128 codes used in patient records from 2015-2017 within the blood banks of participating independent EHR data providers participating in the BEST Initiative. To identify additional blood and blood components, we also explored mapping standard terms used in blood banks prior to 2015 to ISBT-128 codes.

Results: Of the three EHR data providers, two have completed review their database (site A and B). Of the 14,543 codes, the two sites consistently used approximately 100 ISBT-128 codes. Among the 5.5 million (database A) and 2.3 million (database B) patient records, the frequency of all utilized codes was 536,097 and 426,826 (respectively). The most commonly used codes were E0357 (AS-3 Red Blood Cells Leukocytes Reduced Irradiated) and E0401 (AS-5 Red Blood Cells Leukocyte Reduced). Within EHR database A, E0357 accounted for 33% of all ISBT-128 codes compared to less than 0.03% within EHR database B. The most frequent code used within EHR database B was E0401 which accounted for 26.7% of all the ISBT-128 codes compared to 0.66% within EHR database A. Red blood cells (63.4%, 62.0%) accounted for most blood components used in database A and B (respectively), followed by plasma (15.5%, 22.2%), and then platelets (17.2%, 13.7%).

Summary/conclusions: Incorporation of ISBT-128 codes into the OMOP CDM has furthered CBER's capability to monitor the frequency of transfusion and transfusion-related AEs. We have demonstrated that

ISBT-128 codes are captured within the BEST EHR databases. The addition of ISBT-128 codes is a critical part of the hemovigilance infrastructure that will afford FDA the ability to conduct active monitoring of transfusion-related AEs.

Word count: 484/500