INTRODUCTION

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 regulatory responsibilities is to assure safety of blood transfusion by monitoring transfusion-related adverse events (AEs) in the recipients, 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 is a distributed data network which applies the Observational Medical Outcomes Partnership (OMOP) common data model (CDM) of the Observational Health Data Sciences and Informatics (OHDSI) Consortium and utilizes administrative claims and electronic health record (EHR) data sources which capture health care exposures, diagnoses, procedures, and outcome data. The BEST Initiative is a collaboration with IQVIA, OHDSI Consortium, Columbia University, Stanford University, Regenstrief Institute, Georgia Institute of Technology, and University of California Los Angeles. The BEST Initiative is comprised of a large administrative claims data source and three EHR data sources including Columbia University, Stanford University, and Regenstrief Institute. The most comprehensive and granular blood component exposure data are captured by using the Information Standard for Blood and Transplant (ISBT) 128 coding system whereas billing coding systems do not provide the same level of granularity and comprehensiveness. The aim of this study was to build an infrastructure component of a national hemovigilance system using EHR data sources to monitor transfusion-related AEs by incorporating the ISBT 128 coding system into the OMOP CDM. As a test case, we ascertained the utilization of blood components within these three EHR data sources.

METHODS

Three BEST EHR data sources (labeled Site 1, 2, and 3), covering approximately 24 million patient records from January 1, 2012 through December 31, 2017 along with a library of 14,543 ISBT 128 codes were explored. We assessed transfusion of red blood cells (RBCs), platelets, and plasma within each data source. Each occurrence of a record of an ISBT 128 code was counted and aggregated within a blood component category (RBCs, platelets, and plasma) and stratified by year and separately by age into three categories: 0-17, 18-64, 65+.

SUMMARY

This study demonstrated that the BEST Initiative was able to successfully build an infrastructure component of a national hemovigilance system using EHR data sources and ISBT 128 coding system. Based on statistics from the American Red Cross, 36,000 units of red blood cells (68%), 7,000 units of platelets (13%), and 10,000 units of plasma (19%) are needed in the US daily. We tested the new system by assessing the utilization of blood components over time in data sources from three sites, and the results showed that blood components transfusions are well captured. Incorporation of ISBT 128 codes into the CBER blood surveillance system has expanded the capability to capture blood transfusions and will assist to enhance the system’s capability to conduct active monitoring of transfusion-related adverse events.

REFERENCES