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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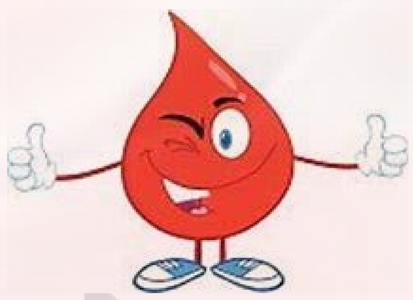
INTRODUCTION

The U.S. FDA Center for Biologics Evaluation and Research (CBER) regulates collection of whole blood and blood components utilized in transfusion[1].

CBER's Role in Blood Safety

To protect recipients of blood and blood components and to monitor transfusion-related adverse events (AEs)



BEST Initiative

Biologics Effectiveness and Safety (BEST) Initiative is a component of the CBER Sentinel Program. The BEST Initiative is made up of a distributed network of data providers that use claims and electronic health record (EHR) data sources transformed into a common data model (CDM).

Infrastructure for Hemovigilance

The most detailed blood and blood components data are included in the Information Standard for Blood and Transplant (ISBT)-128 coding system[2]. In laying the infrastructure for a hemovigilance system, we incorporated the ISBT-128 coding system into the CDM used by the BEST Initiative.

OBJECTIVE

The aim of this study was to build a component of 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[3].

METHODS

The CBER BEST Initiative is a collaboration with IQVIA, OHDSI Consortium, Columbia University, Stanford University, Indiana University, Regenstrief Institute, Georgia Institute of Technology, and University of California Los Angeles. Within the BEST Initiative, we used three EHR databases that cover approximately 24 million patient records from geographically diverse areas of the U.S. We added a library of 14,543 ISBT-128 codes to the OMOP CDM. Each EHR data source requested access to its corresponding blood bank data and transformed its data into the OMOP CDM containing the newly added ISBT-128 codes. By querying the databases, we determined the type and frequency of ISBT-128 codes used in patient records from 2010-2017 within the blood banks of EHR data providers participating in the BEST Initiative.

RESULTS

Table 1. Counts of ISBT-128 Codes Captured from 2010-2017 for Transfusions in Each Database

Database	# of ISBT-128 Codes Recorded	Time Period Covered
A	313,006	January 1, 2012- December 31, 2017
B	667,312	January 1, 2010- December 31, 2017
C	457,178	January 1, 2010- December 31, 2017

Each of the three EHR data providers was able to successfully access, load, and assess the frequency of ISBT-128 codes. Table 1 displays the counts of all ISBT codes present in the databases from 2010-2017.

Table 2. Number of ISBT-128 Codes Captured Categorized by Blood Component

Blood Components	Database A	Database B	Database C
Red Blood Cells	25	63	54
Platelets	5	19	20
Plasma	4	14	22
Whole Blood	1	4	0

We observed a difference with respect to the number of codes frequently used by each database provider which may represent different coding practices, and slightly different use of collection, processing, and storage methods. For example, within Database B, the transfusion centers used 63 ISBT-128 codes for red blood cells (RBC); whereas Database A only used 25 codes for RBC. For the coding of plasma, Database C used 22 codes compared to Database A which only used 4 codes to document transfusion of plasma. Table 2 displays the number of codes used for each type of blood component in the three different data bases.

SUMMARY

Incorporation of ISBT-128 codes into the OMOP CDM expands CBER's capability to monitor the frequency and type of transfusions and ultimately transfusion-related AEs. We have demonstrated that ISBT-128 codes can be captured and queried within the BEST EHR databases. We also observed that there are differences in the utilization of the ISBT-128 codes within each of the EHR systems. We continue our efforts in building this national hemovigilance system by further exploring these EHR databases to determine the limitations and strengths of using this type of data. In conclusion, the addition of ISBT-128 codes is a critical part of the hemovigilance infrastructure of the BEST Initiative, and this new capability will expand FDA's ability to conduct active monitoring of transfusion-related AEs.

References

1. Administration, U.S.FDA *Blood & Blood Products*. March 10, 2014; Available from: https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/default.htm
2. Information Standard for Blood and Transplant, https://www.iccbba.org, last accessed May 24, 2018.
3. The Observational Medical Outcomes Partnership (OMOP) Common Data Model, https://www.ohdsi.org/data-standardization, last accessed May 24, 2018.