(A30) Overview of Global Real World Data Sources for Pediatric Pharmacoepidemiologic Research

Friday, August 25, 2023

8:00 AM – 6:00 PM ADT

Spotlight Poster Session A – Pediatrics

Gerold T. Wharton[1], Claudia Becker[2], Dimitri Bennett[3,4], Mehmet Burcu[5], Greta Bushnell[6,7], Carmen Ferrajolo[8,9], Sigal Kaplan[10], **Ann W. McMahon[1]**, Naimisha Movva[11], Sudha R. Raman[12], Oliver Scholle[13], Mina Suh[11], Jenny W. Sun[14], Daniel B. Horton[6,7,15]

[1]US Food and Drug Administration, Silver Spring, MD; [2]University Basel, Basel, Switzerland; [3]Takeda Development Center Americas, Inc., Cambridge, MA; [4]University of Pennsylvania, Philadelphia, PA; [5]Merck & Co., Inc., Rahway, NJ; [6]Rutgers School of Public Health, Piscataway, NJ; [7]Institute for Health, Health Care Policy and Aging Research, New Brunswick, NJ; [8]Campania Regional Centre for Pharmacovigilance and Pharmacoepidemiology, Naples, Italy; [9]University of Campania "Luigi Vanvitelli", Naples, Italy; [10]Teva Pharmaceutical Industries Ltd, Netanya, Israel; [11]EpidStrategies, A Division of ToxStrategies LLC, Rockville, MD; [12]Duke University School of Medicine, Durham, NC; [13]Leibniz Institute for Prevention Research and Epidemiology – BIPS, Bremen, Germany; [14]Pfizer, Inc., New York, NY; [15]Rutgers Robert Wood Johnson Medical School, New Brunswick, NJ

Background: Pediatric pharmacoepidemiologic research is often performed using a wide range of real- world data (RWD) sources. However, limited information is available specifically on global RWD sources for pediatric populations.

Objectives: To provide an overview of globally available RWD sources for pediatric pharmacoepidemiologic research, including attributes and capabilities.

Methods: An online questionnaire about RWD sources capturing pediatric data was sent to the ISPE Real-World Evidence Task Force RWD subgroup, four ISPE special interest groups, and representatives of nominated databases. Attributes collected included data source type, geographic coverage, number of pediatric patients captured, data accessibility, available data linkages, patient age groups, diagnoses and comorbidities, medications, vaccines, and other patient data. Questionnaire responses completed by ISPE members were verified by database representatives.

Results: Of 94 databases identified, 55 unique pediatric RWD sources were verified for pediatric pharmacoepidemiologic research. These included data from Europe (47%), North America (38%), multiple world regions (7%), Asia-Pacific (5%), and South America (2%). Most databases had nationwide coverage (80%) and contained either electronic medical/health records data (49%) or claims data (44%) (some with both).

Six databases (11%) reported having >20 million pediatric observations. Most (89%) included children of all ages (birth until age 18). Most (69%) had limited access (e.g., by approval only or through collaboration with local investigators), whereas only 9 (16%) databases were publicly available. Most (64%) could be linked with other databases for research purposes.Almost all databases (93%) contained data on pediatric outpatient medications, and about half (47%) contained pediatric inpatient medication data. Two-thirds of databases captured vaccine information for children (67%), and about one-third had regularly updated data on height (31%) and weight (33%) for children. Other pediatric data attributes captured include diagnoses and comorbidities - 48 databases (87%), lab results - 31 (56%), vital signs - 29 (53%), imaging - 22 (40%), device data - 21 (38%), narrative patient histories - 17 (31%), and genetic/biomarker data - 13 (24%).

Conclusions: Our study provides a comprehensive overview with key details about a diverse array of databases suitable for pediatric pharmacoepidemiologic research. Our study allows researchers to identify fit-for-purpose RWD sources useful for pediatric pharmacoepidemiologic studies. Future efforts should maintain up-to-date information about these databases and profile additional RWD sources useful for pediatric pharmacoepidemiologic research.