Opportunities for Ontologies in Medical Device Total Product Life Cycle (TPLC) Evaluation

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Abstract

The mission of the Center for Devices and Radiological Health (CDRH) is to protect and promote public health by assuring that patients and providers have timely and continued access to safe, effective and high-quality medical devices, and safe radiation-emitting products. In 2012, CDRH launched a plan to establish a national system for the evaluation of medical devices; and in 2016, the Medical Devices Innovation Consortium (MDIC) was selected to establish the National Evaluation System for health Technology Coordinating Center (NESTcc). NESTcc is working with stakeholders within the medical device ecosystem to advance the timely and cost-effective development of real-world evidence (RWE) to support its use in regulatory and clinical decision-making. In addition, the Medical Device Epidemiology Network (MDEpiNet), a global public-private partnership launched in 2010, is one of the NESTcc data partners that brings together multiple stakeholders to conduct medical device studies (and/or surveillance) to better understand how devices perform in the real-world. Efforts of NESTcc and MDEpiNet focusing on linking different types of data sources and distributed data analysis could be enhanced by the science of ontology in several areas including: (1) mapping medical device specific outcomes to the International Statistical Classification of Diseases and Related Health Problems (ICD) and the Current Procedural Terminology (CPT) and Systematized Nomenclature of Medicine Clinical Terminology (SNOMED CT) codes; (2) defining device specific outcomes/adverse events; (3) building clinically meaningful medical device categories; and (4) mapping or harmonizing different common data models. The ontologies can potentially provide a common infrastructure for linking data from diverse sources, such as registries, electronic health records (EHRs), claims data and patient reported outcomes. We will describe our current efforts in RWE, building of NEST and the global MDEpiNet, challenges faced, and how the science of ontology relates to these efforts.

Keywords:

Medical devices, ontologies, Real World Evidence

Reference

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