Medical Device Standard Terminology Overview, Comparison, and Analysis

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Background

Many medical device related controlled terminologies exist, such as FDA's Product Code, Unique Device Identifier (UDI), Korean UDI system EDI, Global Medical Device Nomenclature (GMDN), SNOMED CT, CPT codes, FHIR medical device resources, and others. A bottleneck to generating Real World Evidence (RWE) for medical device regulatory decision making is the lack of associated meta-data with the devices in these terminologies that limit the ability to evaluate common materials, manufacturing techniques or changes in component versioning across time, and other associated elements. Each different terminology system was developed with specific requirements that have resulted in strengths and limitations. In addition, it is challenging to crosswalk between terminologies, as the coverage of the interoperability between them is variable and heterogenous. There is a need to characterize the commonalities, differences, and interoperability of those terminologies to support guidance for incorporating medical device data for use in OHDSI (Observational Health Data Sciences and Informatics) federated medical device network analysis.

Methods

Since 2019 when the Medical Device Workgroup was established, members of the workgroup have conducted various comparisons, such as UDI vs. EDI vs. SNOMED CT, UDI vs. OMOP, UDI vs. FHIR resources, or SNOMED CT vs. GMDN. The workgroup members also explored the OHDSI Vocabulary's Medical Device component with a focus on RWE use. Here we intend to provide a summary of 5 years' exploration and suggest a pathway to move forward.

Results

1. While implementing UDI needs long-term support and resources, UDI is more granular than SNOMED CT and supports more granular medical device RWE study designs.
2. There are critical gaps in meta-data characteristics of medical devices needed for categories of use cases such as analysis of component composition, version changes over time, among others. This degrades the capacity to automatically execute studies by requiring manual data collection on an ad-hoc basis.
3. UDI and FHIR's medical device resources have similar meta-data to describe medical devices, however, these data are not included in the OMOP meta-data tables.
4. There remain limitations in transforming observational data for medical devices into the OMOP CDM. Third-party vendors managing organizational supply chain data have the capacity and interest to implement the UDI, however, the inventory systems will need to be connected to patient data from the EHR and available to support utilization.
5. There is a need for an informatics system where harmonized medical device terminologies or code systems can be searched via a common interface or an API. It is important that this system also serves as the one-source of truth of medical devices.
6. Resources and long-term leadership support is critical for any medical device related RWE project.