A Strategy for Defining Common Data Elements to Support Clinical Care and Secondary Use in Clinical Research

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Abstract Submission**

A Strategy for Defining Common Data Elements to Support Clinical Care and Secondary Use in Clinical Research

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Abstract

The objective of the Diabe-DS (Diabetes Data Strategy) proof-of-concept project is to identify the minimum data set and define, based on clinical and business requirements, the Electronic Health Record standards required for the capture and representation of data related to Type 1 Diabetes assessment. The identified data elements can be meaningfully repurposed for clinical research and quality reporting. The Diabe-DS has successfully harmonized data requirements for multiple secondary uses with clinical capture data representations. The project scope includes harmonization of data definitions, which are required to thoughtfully apply these standards, re-use technical components, and re-purpose collected data. The artifacts, processes and methodologies of this project are generalizable, and can be applied to the development and harmonization of common data elements for other disease domains. This work provides a framework for the "collect once, repurpose many times" paradigm, which is vital to support the next generation of clinical and translational research.

Introduction & Background

The healthcare industry has a need to develop and harmonize clinical content data standards (e.g., data elements, definitions and value sets) which can support both patient care and secondary data uses, including those that could support a spectrum of clinical research activities. These clinical content data standards will likely be developed in disease- or therapeutic-specific contexts. Consequently, researchers and implementers - representing multiple scientific disciplines - are developing potentially overlapping clinical content data standards. This creates a need for a standards-based process and methodology to analyze the data requirements for both patient care and clinical research, and to tie these requirements and data standards to EHR functional specifications.

Methods

The Diabe-DS (Diabetes Data Strategy) project was formed in early 2009 and includes representatives from academic medical centers, professional societies and standards development organizations. Diabe-DS was designed to be a proof-of-concept focused on creating a narrow set of artifacts, processes, and methodologies applied to a similarly narrow use case: the collection of pediatric Type 1 Diabetes (T1D) assessment data in an outpatient clinic setting (patient care) that can support related clinical research and quality measurement (secondary data use).This project solicited and utilized requirements for T1D clinical data and secondary data uses. This included harmonizing data definitions from a selected set of T1D clinical trials, including the protocol eligibility process; (non-trial) clinical research; quality measurement; and direct patient care. The artifacts of the Diabe-DS include the harmonized data definitions in a HITSP format, mappings of these data elements (via a Domain Analysis Model) to HL7 Detailed Clinical Models (DCMs) and EHR system functions for both patient care (e.g., EHR-S FM, Child Health Functional Profile) and clinical research and quality measurement (via the EHR Clinical Research Functional Profile).

Results

The team has assembled a collection of over 150 data elements (question, value set, and narrative definition) from various sources including clinical note and EHR specifications, observational and interventional clinical research data forms, and standard (federally approved) quality measures. Collectively, these elements can be represented in a Domain Analysis Model that is suitable for review and discussion by broader T1D stakeholders, such as the American Diabetes Association. There are two outcomes of this project—the production of data content (i.e., a preliminary set of T1D data elements sufficient for clinical and secondary uses), and technical specifications that tie T1D domain-specific data capture needs to functional requirements.

Discussion

The Diabe-DS is a novel project that is harmonizing data requirements for multiple secondary uses, and in turn harmonizing those elements with clinical capture data representations. Much of the process and lessons learned is applicable to other disease areas. Further, this project harmonizes data *definitions*, which are required to thoughtfully apply these standards and to validly re-use technical components or re-purpose data. If successful as a proof of concept, these artifacts and methodologies can be applied to the development of common data elements for other disease domains, as well as to specific clinical research use-cases. Additionally, this work provides solution to the "collect once, repurpose many times" paradigm which can benefit clinical research.