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Connecting Healthcare, Research and Surveillance

Healthcare, research and surveillance entities currently operate advantage of modern information technology, a common understanding has to be developed. This can independently, with costly and time-consuming redundant data collection. Considering the rising cost of healthcare, the complexities of research, and the threat of widespread disease, it is critical to identify common needs and bridge the gap between systems. One way to address the gap is to develop a methodology to exchange, consolidate and reuse data across entities. A system that streamlines the sharing and re-use of data will produce efficiencies that will ultimately impact the timeline to translate research knowledge into patient care.

Illustration of a Problem

Collecting the same data multiple times for different purposes is the current practice in many countries. For example, when a healthcare provider receives a patient's test results and determines a diagnosis, they may enter the information into a phone or web system for the patient to retrieve. If a reportable disease is suspected, the information will be recorded on additional forms and entered into a surveillance system. Concurrently, the test results and diagnosis are written in the patient's paper medical record or entered into an electronic medical record. This same information is also recorded by another individual to code for billing and reimbursement. It is also often recorded on other forms to report to regulatory or monitoring agencies. If the patient is participating in a clinical research study, the study coordinator may retrieve the information from the medical record and enter it on a case report form or in an electronic data capture database. In this scenario, these data are recorded multiple times but could be entered electronically once and shared with the various users.

Solution

Using healthcare information technology will create effective and efficient interoperability between healthcare, research and surveillance organisations. Interoperability is defined as the ability of two or more systems to exchange information and to use the information that has been exchanged without customisation1 . To take advantage of modern information technology, a common understanding has to be developed. This can under-standing has to be developed. This can be achieved by developing standardisation in terminology and data transfer methods that is supported and used by all communities involved. Using data standards at the point of initial data collection reduces ambiguity and misinterpretation when data are exchanged among the industry and aggregated for research.

Obstacles

Standardisation of terminology is essential to interoperability. A clinical term may have different meanings to various groups or individuals. For instance, consider the term "site". In healthcare it can mean a point or location on a body; in research the definition of "site" may refer to a clinic or hospital that is participating in a clinical research study. Depending on the context, it may be challenging to determine which definition to apply - but dialogue between individuals clarifies the meaning and context. Computers have no ability to interpret meaning, therefore structured rules.

Current Initiatives

There are various organisations that have developed data standards or have come to a consensus on terminologies for use across communities. Two of these groups have been created to participate in the data standards arena to develop therapeutic area standards for cardiology and tuberculosis. The Clinical Trials Network Best Practices (CTNBP) and the Tuberculosis Trials Network (TBTN) are two of twelve Roadmap contracts awarded by the National Institute of Health (NIH) in the United States improve interoperability among clinical research networks, with a focus on using informatics to promote and translate research knowledge into practice. The two groups are working within other standardisation development organisations for data interchange and terminology - Health Level 7 (HL7) and Clinical Data Interchange Standards Consortium (CDISC) are facilitating the work. While HL7 has been recognised world-wide for its use in hospitals, clinics and country medical record systems, CDISC has been working internationally with the pharmaceutical industry and the Food and Drug Administration (FDA) in the US to develop clinical research standards for regulatory submission.

Cardiovascular Standards

A specific aim of the CTNBP is to develop and pilot the infrastructure supporting cardiovascular data standards development. This initiative has successfully engaged stakeholders from over 30 organisations, including professional societies, pharmaceutical companies, government agencies and standards development organisations (www.ctnbestpractices.org).

The first step to achieving this aim was to create semantic interoperability and then functional interoperability by:

1. Gathering cardiovascular data elements from various professional societies, pharmaceutical companies and other agencies to create a master set of data elements;

2. Meeting with key stakeholders to identify a manageable amount of data elements related to ischemic heart disease and create definitions based on use-case criteria;

3. Involving the stakeholders in coming to a consensus on standard terminology that will be used by the professional societies, regulatory agencies and pharmaceutical companies; and

4. Storing the data in the National Cancer Institute's Enterprise Vocabulary Server and Cancer Data Standards Repository open and free to all users.

The second step is to develop a method for exchanging data for reporting by developing a HL7 Version 3 message or Clinical Document Architecture (CDA), to be carried out in two phases:

1. A Cardiology Special Interest Group (SIG) has been established in HL7 in conjunction with CDISC to develop a standard method of representing cardiology data in the HL7 and CDISC models; and

2. Conduct a pilot to test using data collected electronically from healthcare facilities for multiple purposes, such as a clinical trial, quality improvement registry, and clinical performance measures.

Tuberculosis Standards

The primary objective of the TBTN project is to expand and enhance the capabilities of the public health system to engage in clinical research. The majority of patients with tuberculosis (TB) are treated in the public health system. IT systems supporting the public health system are therefore a key resource for identifying potential research participants.

The initial use-case of the project is to create a system whereby researchers can identify potential patients from hospital medical records and surveillance databases, thereby reducing the time to identify patients from weeks or months to hours. TBTN is collaborating with CTNBP in developing the same methodology to develop data standards for TB.

Thousands of data elements have been collected from various forms and databases, such as the World Health Organisation (WHO), Directly Observed Treatment (DOTS), the National Electronic Disease Surveillance System (NEDSS) and other TB research projects. From this master set of data elements, a subset of critical data elements based on set criteria for identifying and diagnosing TB will be defined first (www.tbtrialsnetwork.org).

The following group of International TB professionals meets regularly to decide on common terminology for TB:

+ National Institute of Health–(Current funder of the TB Data Standards Project);

+ National Heart, Lung & Blood Institute;

+ National Cancer Institute;

+ US Food & Drug Administration;

+ Global Alliance for TB Drug Development;

+ Center for Disease Control and Prevention (CDC);

+ National TB Controller Association;

+ Royal Dutch Chemical Association / Koninklijke Nederlandse Chemische Vereniging (KNCV);

+ Clinical Data Interchange Standards Consortium (CDISC);

+ Health Level 7 (HL7);

+ Duke University Medical Center;

+ TB Professional Societies; and

+ TB Industry and Researchers.

The TB group is also working with HL7 as a project in the Public Health and Emergency Response Special Interest Group to facilitate the development of TB-specific standards to accomplish the Study Participant Notification use-case.

Creating terminology standards using controlled terminology and data transfer standards specifically for TB will also enable industry and researchers to have the ability to combine data from various databases as they search for treatment of Multi-Drug Resistance TB (MDR-TB), with less cost and less ambiguity in understanding terminology across datasets.

Moving forward, both projects will continue to work with other groups that have existing standards and will develop new standards when one does not already exist. The hope is that this will continue to facilitate the use of standards across organisations. Regulatory groups are starting to endorse the use of standard terminologies in research grants requests and data submissions.

If you have knowledge of standards in the cardiovascular or tuberculosis therapeutic areas or want to participate in current efforts, please contact one of the authors.

For a list of references contained in this article, please contact k.r@hitm.eu.

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