Clinical Documentation Hearing
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Comments by:
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Last week we held a launch meeting on the topic of Essential Standards to Enable Learning for a Learning Health System/Community. One consistent theme, during the opening remarks by experts from around the country, was that the quality of the information in the EHRs is critical for a number of reasons; poor quality data engenders a lack of trust in the technology by all stakeholder communities – users, providers, patients, everyone.

My own experience has borne this out – in looking at what was entered in my medical record after a simple annual physical, I was extremely disappointed to see that the information did not accurately or appropriately reflect what I thought were the salient parts of my encounter.

Clinical research processes, particularly those for regulated clinical research, are focused upon creating databases with minimal to no errors along with audit trails that capture any changes that have been made, why they were made, when and by whom. Electronic systems must be validated to ensure data integrity. These are requirements per 21 Code of Federal Regulations Part 11 (21CFR11) and related FDA Guidances for eSource, Computerized Systems Used in Clinical Investigations and Good Clinical Practices.

To enable the capture of high quality structured data in a standard format, CDISC has been working with its stakeholder community, FDA, HHS/ONC, IHE and others for over a decade to develop standards and integration profiles; the CDISC Healthcare Link Initiative emerged in 2003. A set of 'enablers' is now freely available. These enablers include:

- Retrieve Form for Data Capture (RFD) and a number of associated profiles to address protocol processes, security, privacy, and related clinical research activities such as
- CDISC CDASH – format standards for a minimum core dataset that pave the way for data aggregation across investigative sites and ultimate submission of tabulation and analysis datasets in the appropriate standard format for FDA
- Clinical Research Document (CRD), which maps CCDA content into CDASH, and other content profiles

In a project conducted at Harvard (ASTER), with Pfizer and CDISC, clinicians who never reported serious adverse drug events because it took 35 minutes - too long to fill out a form and fax it, began reporting these through a process involving RFD. Upon discontinuation of a drug, the AE reporting form popped up in the EHR window with part of the fields completed. To complete the remaining fields and send the form (with accurate high quality data in a standard format) took the clinician less than a minute.

The key features were:

a) Dramatic workflow improvement with the process integrated into clinical care
b) A remotely managed form with structured, standardized content (global research standards)
c) Partially relying on EHR information but not requiring that the EHR vendors hard code the information needed into their systems in a standard format. (Note: Research data will never be

completely covered within an EHR or we would not be doing research). The EHRA endorsed RFD for its ease of use.

d) Not requiring the EHR to be validated per 21CFR11, but rather the process (RFD- defined forms archiving)
e) An information model (BRIDG) that link healthcare and research (which includes AE domains and harmonizes the CDISC global research standards, linking with healthcare standards)

These enablers are available now and can be leveraged. Some are cited in the Structured Data Capture Initiative scope statement and charter. They are powerful and have the potential to integrate research into a clinician's patient care workflow, thus expanding the capacity for research in our country and providing information for a learning health system to benefit all of us.

_____(for written submission only)_____

The questions we would like your panel to address are questions below:

- Describe the disconnect between data needed for secondary use and data collected in an EHR (clinical documentation). What challenges do you face and what solutions have you identified to overcome them so that you can use data collected by providers in an EHR?

  Clinicians enter information that is important to them and to their patients for billing purposes and patient care; these data are not adequately structured or standardized across systems to support clinical research. And, they are frequently skewed towards reimbursement vs. answering research questions.

  We have developed a workflow enabler that can use the best parts of existing EHRs and marry them with research tools and standards that allow the EHRs and clinicians to do their primary jobs to care for the patients while adding very little burden to produce quality research data in a standard format to support clinical research studies. These standards and enablers include RFD, CDASH, CRD/CCDA and associated profiles to address privacy, security and related research needs.

- Privacy policies vary from state to state and for instance in public health, among communicable diseases. What impact does this have on capturing data for secondary use?

  Clinical research studies typically address patient privacy on a global basis through:

  a) informed consent forms approved by IRBs;
  b) leaving the patient identification information at the site and using a study patient ID (pseudonimization)
  c) privacy and security profiles
  d) Good Clinical Practices

- Discuss the role of inference in capturing data for secondary use of data (i.e. using data from clinical notes to infer a condition, etc.).

  In regulated clinical research, structured data on case report forms is the primary data source. There are text areas to explain complicated issues, but these are used as supportive vs. for direct inference.

- How has / can technology evolve to capture data for multiple purposes that does not always directly benefit the patient and the provider?

  If the patient or provider are not informed of the results of a study or if the study results are locked in filing cabinets or are in proprietary formats that are not shared and are not published or used for the good of others, then there is a disservice that has been done to take these data from patients who agree to participate in the research studies.

- How do you use data to address dynamic data needs? (i.e. influenza breakout, etc.)

  The RFD profile was used by CDC to collect H1N1 virus breakout information because it could be implemented quickly, was easy to implement within EHR systems and provided rapid and dynamic information in a structured standardized format without having the EHRs change their internal codings.

- What policies have your implemented to streamline the data coordination process?

  To support regulated research, we follow global Good Clinical Practices by ICH (International Conference on Harmonization), FDA regulations and guidance, European Medicines Agency (EMA) guidance. We use CDISC standards, IHE Integration profiles developed by CDISC through IHE, MedDRA (international AE coding system) and harmonize standards in the BRIDG model.