Data Integrity Concerns Regarding EHR Data for Clinical Research

Using standardization and intelligent reasoning to mitigate problematic EHR documentation practices

Introduction

Health care experts are increasingly enthusiastic about big data's potential to effect major change in the way we care for patients, determine pricing, conduct clinical trials and use medical records for research. Many are focused on electronic health records (EHRs), which certainly contain a wealth of data. The issue with EHR data, whether it's being used for big data projects or research on narrowly defined populations, is integrity in the way it's captured.

In this white paper, we'll discuss the four EHR documentation practices that health information management (HIM) professionals consistently identify as problematic (default, design, duplication, and dictation—the four D's). Next, we'll look at the effect data quality and integrity can have on clinical research findings. Finally, we'll explore best practices such as intelligent reasoning and look at their role in conducting successful research that includes medical record (chart) abstraction when the medical records are maintained electronically.

The Current State

Over the past several years, a number of organizations and researchers have spoken out about the state of EHR data collection. In 2006, the eClinical Forum and the PhRMA EDC/eSource Taskforce noted that although government-encouraged use of EMR systems meant patient data was increasingly being entered and maintained electronically, the data in most EMRs could not be used directly for clinical research purposes because of the variability of the data and because "the systems and infrastructures are not governed by clinical research regulations."[1]

In 2010, researchers found that electronic notes promote information redundancy in EHRs. Transfer and progress notes were particularly redundant, with an average of 78 percent and 54 percent of information duplicated from previous documents, respectively. There was significant information duplication between document types as well (e.g., from an admission note to a progress note).[2]

In 2013, the Pennsylvania Patient Safety Authority spotlighted errors related to the use of default values. It said that although the use of default values is intended to improve efficiency and standardization, its reports showed patient harm can occur when a default value is used inappropriately.[3]

Also in 2013, an American Health Information Management Association (AHIMA) representative testified at a Clinical Documentation Hearing held by workgroups of the Office of the National Coordinator for Health IT that more focus is needed on data quality, information integrity and good documentation practices to achieve the policy goals of EHRs. "The concept of 'collect once and use many' will be compromised if the health information created is inaccurate or erroneous," said Michelle Dougherty, adding that "Meaningful Use EHR standards do not require systems to create, maintain, and preserve an official record of care."[4]

Most recently, the HHS Office of Inspector General (OIG) reported problems with data entry in EHRs, saying that two types of poor data entry linked to billing fraud could compromise data extracted from EHRs in a research environment. One problem is cloning: inaccurate information can enter the medical record if users are allowed to select information from one source and replicate it in another location and fail to update it or ensure accuracy. The second problem is over-documentation, in which fields are auto-populated when using built-in templates.

[1] "The Future Vision of Electronic Health Records as eSource for Clinical Research," eClinical Forum and PhRMA EDC/eSource Taskforce, September 14, 2006.

[2] "Quantifying clinical narrative redundancy in an electronic health record," Wrenn, et al., JAMIA, downloaded October 18, 2010.

[3] "Spotlight on Electronic Health Record Errors: Errors Related to the Use of Default Values," Erin Sparnon, Pennsylvania Patient Safety Advisory, September 2013.

[4] Testimony of Michelle Dougherty on behalf of AHIMA to the HIT Policy Committee Hearing on Clinical Documentation, February 13, 2013.

Elsevier Business Intelligence noted that OIG's findings bring into question how effective EHRs would be in research should the documentation issues not be addressed. Inaccurate information in EHRs could affect various aspects of how they should be used in research, from helping to select patients for clinical trials to aggregating data for outcomes studies.[5]

It's important to note that many individuals working in health care, including researchers, believe that EHRs that have been certified under the Meaningful Use program meet existing requirements and standards for medical records. But developers and users of EHRs do not understand record-keeping and evidentiary requirements related to medical records.

Information in EHR systems must be managed throughout its lifecycle to meet the demands of all its uses, including patient care, quality measures reporting, billing, professional oversight, accreditation, certification, licensure, litigation, and clinical research. To do this, basic record-management functions must be incorporated in EHR systems. The gaps in EHR record management functionality are particularly evident when content is scrutinized for legitimacy, accuracy and completeness. Widespread use of EHR data for clinical research is of little value if the data is erroneous, incomplete, redundant and/or untrustworthy.

Health information management (HIM) professionals have identified four documentation practices that are problematic in EHRs, contributing to poor data quality and information integrity issues. These practices—the four D's—should raise red flags for policy-makers because they increase the likelihood of collecting inaccurate data that is used for communication with other care providers, care coordination, research, quality reporting and other secondary uses.

Default Values That Create Documentation

Default refers to a documentation design in some EHR systems that adds default values and creates documentation. It's sometimes called point-and-click documentation because a single click by a provider auto-populates all the fields within a template.

For example, in some EHRs, clicking the Review of Systems box signifies that all body systems were reviewed and were normal. Providers may mistakenly check the box without having reviewed all systems or neglect to go back through and edit the individual fields to accurately reflect the patient's status.

Defaults are viewed by many physicians as helping them efficiently comply with their organization's documentation requirements. The system generates the detailed documentation that helps them meet coding and billing requirements for a higher level visit, resulting in higher payment.

From a data quality perspective, defaults are highly problematic. Meaningful clinical research data is dependent on specific details relevant to a patient's unique circumstances, not canned documentation collected through the use of templates.

Imagine a scenario in which a physician wishes to assign a Type 2 diabetes diagnosis to a patient. Not realizing there is a Type 2 option, the provider chooses Type 1 diabetes from the EHR's checklist. Regardless of the correct diagnosis being assigned in the dictated clinical notes, the erroneous Type 1 diagnosis is propagated throughout the medical record.

[5] "OIG Raises Concerns About Accuracy of Data in E-Health Records," Gregory Twachtman, Elsevier Business Intelligence, January 17, 2014.

Poorly Designed Documentation Templates

Well-designed EHR documentation templates can improve data collection, ensuring that all relevant patient information is collected by prompting the provider during the documentation process. Templates also enable a structured format by creating discrete data elements that can be mined.

However, templates that were designed to meet reimbursement criteria sometimes miss relevant clinical information and may encourage over-documentation to meet reimbursement requirements. When researchers use ICD or CPT codes to select study populations, templated data can result in patients being included in the study who do not have the diagnosis or treatment under consideration.

Poorly designed templates can cause enormous problems for researchers trying to retrieve data. Because the focus is on making data entry as easy as possible, little or no thought is given to how the records are organized or how they will print. For example, instead of a summary of glucose values over a 40-day period in a page or two, researchers are faced with 40 pages of daily results. Similarly, instead of being able to access just one record type (e.g., labs), labs, progress, notes, and registration pages from multiple visits flow continuously from one page to the next.

Issues also arise when the template being used is not a good clinical fit. Not having the correct options on the template can result in services being improperly documented or not documented at all. When a limited number of templates are available, the provider must try to make the patient "fit" into the options in the template, resulting in data that all looks the same, rather than an accurate reflection of the patient's condition and treatment.

In general, templates aren't the best approach for patients that are atypical, have multiple conditions, or require extensive interventions. Because templates have a limited number of selections, they result in reduced specificity of patient conditions, especially in complex cases.

Duplicated Documentation

Duplication (also known as copy/paste, copy forward and cloning) speeds up documentation and improves the consistency of static health information, such as medical history.

However, when misused, duplication leads to redundant, misleading, inaccurate, documentation that jeopardizes quality of care and downgrades the quality of the data for secondary uses. Limitations on provider ability to copy and paste in an EHR system are vital for data accuracy.

If a provider's EHR doesn't limit cloning, policies and procedures should be put in place to mitigate potential issues. For example, providers should be prohibited from using features like "make me the author" to assume the content of another person's entry and "demo recall" to copy forward vital signs.

Although many health care organizations have stated policies, noncompliance remains an issue in places where they are not enforced. Cloned documentation is common in the following medical record components:

- History and physical reports (particularly social, medical, and family history)
- Visit/clinic notes
- Inpatient progress notes
- Consults
- Vital signs
- Review of systems/physical exam

Researchers have found and documented the following:

- A clinic visit note cloned repeatedly for all patients seen by a physician for a two-week period, including a procedure and tests
- Inpatient progress notes that state the patient is "doing well" day after day, but on the last day, the patient expires
- Vital signs that never change
- Information from a patient's chart appearing on a different patient's chart

Cloning can cause serious research issues when trying to assess the effect of treatment over time. For example, a provider who is monitoring a diabetes patient's HbA1c levels might record a value of 9.2 during the patient's initial visit. If the provider clones the value during the next visit rather than changing it to reflect the most current lab value, it appears as though the patient's drug regimen is not effectively controlling the disease.

Dictation Without Validation

Many health care organizations are using voice - recognition tools to improve efficiency, reduce costs, and provide better patient care. Although the tools help providers with workflow, they can create significant data quality problems, especially if the validation step is skipped.

When a provider dictates into a traditional system, the medical transcriptionist edits and validates the content (back-end dictation). When a provider dictates directly into the EHR (front-end dictation), he or she is responsible for editing and validating the content. Providers are eager to move to front-end dictation, eliminating the time and cost associated with traditional dictation and transcription. But unless physicians take the time to review their reports, the potential for introducing errors into the record is substantial.

A 2010 report from the Association for Healthcare Documentation Integrity and the Medical Transcription Industry Association[6] found that traditional dictation/transcription technology resulted in an average of 0.33 errors per report, while front-end speech recognition technology resulted in more than four times as many errors per report, 1.48. Although speech recognition technology is improving, experts maintain it's unlikely to ever be error-free.[7] Issues arise when providers have accents, mumble or speak too fast, and/or dictate measurements such as centimeter (often replaced with millimeter). The omission of key words such as "yes" or "no" that can alter the meaning of a sentence also caused significant problems.

Even sophisticated voice recognition software designed for provider use requires significant time spent adding medical vocabulary. A study of these systems published in JAMIA found that lack of medication vocabulary caused the system to transcribe "put him on heparin and nitro paste" into "put him on Hackman and mitral paste" and "Lasix" into "lay 6."[8]

The researchers found that adding vocabulary raised recognition levels, but this took several weeks of persistent use and supplementation of the vocabulary as described. The system was unable to understand some short phrases, such as "bid," "tid," and "qid," even after repeated training with the utterances "bee eye dee," "tee eye dee," and "queue eye dee." The researchers had to substitute "once a day," "twice a day," and "four times a day" to get accurate recognition.

[6] "Healthcare Documentation Quality and Management Best Practices," The Association for Healthcare Documentation Integrity, July 1010.

[7] "Speech Recognition, a Work in Progress," Selena Chavis, For the Record, April 2013.

[8] "Continuous Speech Recognition for Clinicians," Zafar, et al., JAMIA, May/June 1999.

Standards and Intelligent Reasoning

In 2013, AHIMA published a practice brief calling for the development of standard clinical documentation practices, content standards that would be built into decision making screens, templates and drop-down lists in EHRs.[9] AHIMA noted the need to establish consistent data models, including standardized data definitions and structure for clinical content, and quality "checkpoints" to ensure quality data is captured.

In its brief, AHIMA stressed that ease of use and design can facilitate adherence to documentation guidelines and standards. Strong facility controls are also needed to address issues such as abbreviations (e.g., DOA may mean date of admission at one facility and dead on arrival at another). Such standards and controls are necessary for several reasons, including continuity of patient care, data sharing and reporting, and secondary purposes such as research.

As the industry works to increase standardization, organizations in need of accurate records-based clinical research continue to rely on medical abstraction teams using proven best practices, including intelligent reasoning.

Professional medical abstractors using best practices can mitigate all of the issues associated with the variance in EHR data, including the four Ds. For example, because they're trained to recognize patterns within medical charts, they consistently identify records with duplicated data. When looking at a series of weight entries for a patient, if a patient weighed the same amount for multiple days with a weight drop of 20 pounds on a particular day, the abstractor would exclude the record or alert the research leader to a possible inaccuracy.

In a study involving thousands of patients, an outlier like the one just described remaining in the data set would likely not affect the outcome. In a study of only 50 or 100 patients, however, such an outlier could skew the results. In addition, simple data fields such as weight are often used in records-based research, and this example shows how even a simple data field can contain inaccurate data.

There are numerous other examples of how intelligent reasoning is critical to medical record data abstraction:

1. **Protocol interpretation.**
   Abstractors can view each submitted record with an eye toward the overall study goal to determine whether or not it should be included in the study sample.

2. **Scattered data.**
   Often, the same data is recorded in multiple places within a chart. For example, a lab result is recorded in the appropriate area and mentioned again in the dictated notes. An experienced abstractor can recognize this and prevent the result from being counted twice or select the best source.

3. **Unstructured text interpretation.**
   Experienced abstractors can read the complete text of a record, including free text and hand-written notes, to determine its relevancy to the study and include or exclude it accordingly.

4. **Date range issues.**
   When EHR records are extracted using data mining tools, there is no opportunity to validate the source. Professional abstractors who review records to determine their eligibility for a study can flag a record that is outside the date range but might still have relevance for the study.

5. **Coding issues.**
   As researchers know, the accuracy rate for coding diagnoses and procedures can vary within and across facilities and providers, affecting the accuracy of study samples. Expert

[9] "Assessing and Improving EHR Data Quality," AHIMA, March 2013.

abstractors are trained to spot records under review that may have been incorrectly included in a study sample due to coding errors. They know to alert researchers when documentation may mean a patient's record needs special handling. For example, a patient with fibrocystic breast disease should not be included in a research study on cystic fibrosis (CF) when the CF code is clearly in error.

5 Language issues.

The terms used by providers and labs can vary widely. For example, a microbe that researchers expect to be referred to as non-mucoid may be noted in some lab's reports as smooth or rough. Rather than skip over relevant documentation because it doesn't match an expected format, abstractors can apply intelligent reasoning to recognize when documentation outside the norm should be abstracted.

Finally, abstractors are capable of supporting studies that involve data drawn from multiple geographic areas and multiple sources (e.g., hospitals, ambulatory clinics, physician practices, labs). Their in-depth record review compensates for variances in the way clinical notes were dictated and how data was recorded, freeing researchers from having to design studies around structured data from similar sources.

Conclusion

Clearly, the challenges of EHR data cannot be easily overcome, but recognizing the problems is an important first step. Dr. Charles Bailey, a pediatric oncologist at the Children's Hospital of Philadelphia helped raise awareness when he discussed the limitations of EHRs in a presentation early this year.[10] "While some data is discrete and unambiguous (such as dates, vital signs, some demographics and some lab values), other data is discrete but not standardized (such as diagnoses or problem lists), other data may be well defined but not discrete, and the location may vary from place to place in the EHR," he said, adding that there are also issues with harmonizing technologies to use agreed-upon ways to name things.

Nevertheless, with intelligent reasoning and stronger data content standards, researchers can be optimistic about the role that the valuable data residing in EHRs can play in improving the way we diagnose and care for patients, determine pricing, and conduct clinical research in the future. ●

[10] "CHOP Researchers: Learning Health System Requires New Social Contract with Clinicians," Healthcare Informatics, January 27, 2014.

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