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CONTINUING EDUCATION

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Integration of Clinical Research Documentation in Electronic Health Records

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Clinical trials of investigational drugs and devices are often conducted within healthcare facilities concurrently with clinical care. With implementation of electronic health records, new communication methods are required to notify nonresearch clinicians of research participation. This article reviews clinical research source documentation, the electronic health record and the medical record, areas in which the research record and electronic health record overlap, and implications for the research nurse coordinator in documentation of the care of the patient/subject. Incorporation of clinical research documentation in the electronic health record will lead to a more complete patient/subject medical record in compliance with both research and medical records regulations. A literature search provided little information about the inclusion of clinical research documentation within the electronic health record. Although regulations and guidelines define both source documentation and the medical record, integration of research documentation in the electronic health record is not clearly defined. At minimum, the signed informed consent(s), investigational drug or device usage, and research team contact information should be documented within the electronic health record. Institutional policies should define a standardized process for this integration in the absence federal guidance. Nurses coordinating clinical trials are in an ideal position to define this integration.

KEY WORDS

Clinical research • Clinical research nurse • Clinical trials • Electronic health records • Electronic medical record • Research nurse coordinator • Source documentation

Documentation is a key requirement when conducting a clinical trial in accordance with good clinical practice (GCP) and federal regulations. The International Conference on Harmonisation (ICH) defines GCP as an international standard for the ethical conduct of clinical trials involving human subjects.[1] The ICH/GCP guidelines include standards for recording and reporting of data and trial conduct. A research record contains this required documentation in the form of both clinical trial protocol-related data and individual subject data. The research record may include medical records to validate data points in the trial.

In the paper medical record, a patient's chart was often "flagged" using bright stickers to let other clinicians in the facility know the patient was participating in a clinical trial. If an investigational test article was utilized, this information would also be included in the patient chart. As paper medical records are replaced with electronic health records (EHRs), researchers must develop new methods to communicate clinical trial participation. Electronic health record is defined as a record containing patient data in a digitalized form encompassing all healthcare encounters.[2] As institutions move toward EHR, not only are former tools for "flagging" the chart of a research subject inadequate, but also the legal requirements of EHR make it necessary to improve the integration of clinical research documentation. Inclusion of clinical research documentation is often excluded from the planning stages of EHR rollout.[3] This article reviews clinical research source documentation, the regulatory documentation requirements of EHR, areas in which the research record and EHR overlap, and implications for the research nurse coordinator (RNC) in documentation of the care of the patient/subject. As the use of EHR increases, incorporation of clinical research documentation will lead to a more complete patient/subject

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medical record in order to fully comply with both research and medical records regulations.

BACKGROUND

The Food and Drug Administration (FDA) defines a clinical investigation or clinical research as "any experiment that involves a test article and 1 or more human subjects."[4] In an effort to enhance knowledge about health and disease, clinical trials involving investigational treatments take place in hospitals and healthcare facilities throughout the world and often are carried out concurrently with medical treatment.[5,6] Not all clinical trials are conducted alongside clinical care. For instance, phase I trials typically are conducted with normal healthy subjects in order to learn about an investigational drug's pharmacodynamics and adverse effects and are short in duration.[7] This article focuses on those clinical trials involving investigational test article use in targeted populations, typically phases II, III, and IV.

Federal regulations, state law, The Joint Commission, and institutional policy each define the medical record in some way.[8] As the digital form of the medical record, the EHR must also comply with these rules. The Health Information Technology for Economic and Clinical Health Act, in an effort to improve healthcare in the US, has established criteria for the "meaningful use" of EHR and the promotion of health information exchange.[9] In order for true health information exchange to occur throughout the US, the medical record must be complete, including relevant clinical research information. Clinical trials seeking approval for investigational drugs or devices meant to treat illness and disease take place alongside clinical care.[5] This information must be shared with other providers both within and outside a healthcare system.

The RNC is a specialized nurse who provides nursing care for the research participant and executes and manages clinical research protocols. The RNC coordinates the trial, recruits and enrolls subjects, and maintains data integrity through consistent protocol execution in compliance with regulatory authorities.[10] The legal medical record and the research record are both essential to the care of the clinical trial patient/subject and the collection of clinical trial data. Documentation is a key responsibility for both the RN and the research professional.[1,11] Not all research coordinators are RNs, or licensed professionals. Nonlicensed research professionals may not be aware of medical record requirements, so the RNC, under the delegation of the principal investigator, may need to provide education of the importance of research related documentation in the medical record. It is vital that those involved in the documentation of clinical research are well versed in not only GCP source requirements, but also medical record requirements.

LITERATURE REVIEW

A literature review was conducted in MEDLINE and CINAHL to determine the current thinking in regard to clinical research documentation within the medical record and EHR. MEDLINE was searched using PubMed with results refined to the English language, humans, and published within the last 5 years. The MeSH term, *clinical trials as a topic*, was searched separately, and the following MeSH terms were searched using Boolean phrase OR: *medical records*, *electronic health records* and *medical records systems*, *computerized*. These searches were then combined using the Boolean phrase AND. In addition, keyword searches were performed with the same or similar terminology. Search results were combined for a total of 561 articles. A similar search was completed using CINAHL with subject headings *computerized patient record* OR *medical records*. This search was then combined using AND with the search clinical research OR clinical trials, resulting in 323 articles. Articles that described clinical trial results were removed, resulting in 134 articles from MEDLINE and 36 articles from CINAHL. The search results are noted in Table 1.

The titles and abstracts of the remaining 170 articles were reviewed, and only four of the articles dealt with integration

Table 1

Search History on Clinical Research Documentation and the EHR

	MEDLINE (PubMed) Query	Items Found
1	Search "Clinical Trials as Topic"[MeSH]	50 064
2	Search "Medical Records"[MeSH] OR "Medical Records Systems, Computerized"[MeSH] OR "Electronic Health Records"[MeSH]	17 750
3	Search 1 AND 2	260
4	Search (("clinical trials") OR "clinical research")	66 542
5	Search 2 AND 4	429
6	Search "clinical trial documentation"	0
7	Search "source documentation"	8
8	Search 3 OR 5 OR 7	561
9	Remove articles discussing clinical trial results from search 8	134
	CINAHL Query	
S1	Search (MH "Computerized Patient Record") OR (MH "Medical Records+") OR ("electronic health record")	11 377
S2	Search (MH "Clinical Research+") OR (MH "Clinical Trials+")	23 964
S3	Search S1 AND S2	323
S4	Remove articles discussing clinical trial results from S4	36

Note: Searches completed using the following filters: published in last five years, Humans, full text available and English language

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of clinical research documentation within the EHR. The remaining articles fell into the following categories: extracting data for clinical trial use and eligibility screening (28%), clinical trial design (21%), harmonization of terminology used in EHR and clinical research (14%), and general information about EHR or clinical trial management systems (16%), with the remaining articles focusing on learning healthcare systems, patient-centered clinical research, remote monitoring, and privacy issues. There is little written in scholarly literature about documentation of clinical research within the EHR, or even the medical record. An expanded search of the nonindexed literature produced some additional resources for this article. Although there is limited literature to back this up, as the implementation of EHR continues, integration of clinical research documentation must take place to better communicate subject participation. This gap in indexed literature should be addressed as EHR systems are developed and healthcare reform mandates documentation revisions for clinical practice.

RESEARCH RECORD: SOURCE DOCUMENTATION

A clinical trial involving investigational treatments must be conducted following a protocol that has been approved by the appropriate authorities including an institutional review board and the FDA.[12] The ICH, in the Guidelines for Good Clinical Practice, defines source documentation as "original documents, data, and records"[1(p7)] that report trial activities, observations of study staff, and clinical results. These data are transcribed into a case report form and analyzed by the sponsor to obtain trial results. Source documentation may come in many forms: a handwritten note, x-rays, progress notes, diagnostic images, patient diaries, laboratory results, investigational drug dispensing records, or electronic data pulled from the EHR.[1,13] Source documentation of subject participation includes medical records validating eligibility criteria prior to participation, the informed consent process, investigational test article usage and all data collected throughout the study from the medical record or through interaction with the subject.[13] The source documentation must describe events in enough detail that someone not involved in the trial could replicate the conduct of the study.[14]

In the US, the legal requirements for source documentation are found in Code of Federal Regulations and require principal investigators and their delegated study team(s) to maintain case histories.[15,16] These records should include investigational drug dispensing logs/investigational device accountability, the informed consent process, the signed consent forms, and all observations and data pertinent to the trial, which often include progress notes or nursing notes from the EHR. The research record should also include a medical history, results of diagnostic testing, adverse event reports, and description of the subject condition from enrollment to end of study.

According to the FDA, case history source data must be ***a***ttributable, ***l***egible, ***c***ontemporaneous, ***o***riginal, and ***a***ccurate to meet ALCOA standards in order to provide quality data for clinical trials.[17,18] It must be clear who entered the data (attributable).[19] The data must be readable (legible), should be entered close to the time data were collected (contemporaneous), should be the earliest record of an event (original), and should be a valid reflection of the data collected (accurate). Changes to the source document must not obscure original entries. As stated in 21 CFR §11, regulations require electronic records and signatures also meet ALCOA criteria.[20] The electronic record requirements include the ability to provide a time-stamped audit trail of creation, modification, and deletion of entries into the record. Each user must have a unique sign-on that is linked to their entered records, which are then electronically signed. The computer system requirements are outlined in the regulation and guidelines provided by FDA.[17]

In a recent guidance document, the FDA addressed the increasing use of electronic source data, defined as "data initially recorded in electronic form."[21(p3)] With the growing use of medical devices (eg, electrocardiograph machine), instruments (eg, noninvasive blood pressure machine), and EHR, FDA felt guidance was necessary in order to ensure that data were being taken from the original source (data originator). The EHR is considered an example of a data originator, and data pulled may be considered source documentation, but must also be listed as an authorized data originator in study files.

The recent announcement of the enforcement of a Centers for Medicare & Medicaid Services (CMS) requirement for clinical research billing adds a new twist to source documentation.[22] Clinical trials that enroll Medicare patients often collect research data from procedures that are considered usual care and will be paid for by CMS. The new ruling requires special coding of the claim and inclusion of the national clinical trial number (NCT number) found on the clinicaltrials.gov Web site. In addition, the medical record must include the following: trial name, sponsor, and sponsor-assigned protocol number. If the EHR is the data originator for source documentation, and the item is a routine cost billable to CMS, the record must include the required information.

ELECTRONIC HEALTH RECORDS

Medical Record: Legal Definition

The medical record is discussed but not clearly defined in several federal regulations.[8] The CMS regulations state, "A medical record must be maintained for every individual evaluated or treated in the hospital"[23(p17)] and should

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include records supporting diagnosis, all orders, test results, evaluations, care plans, treatments, executed informed consent forms, interventions, care provided, and patients' response to medications and treatments. Evaluations and findings (including complications and adverse reactions to therapy) of those involved in the care of the patient must be included in the medical record. The medical record also consists of nursing notes, medication records, and "other information necessary to monitor the patient's condition."[23(p18)] The records must be legible and complete.

Regulations provided by HIPAA protect the privacy and security of a patient's health information including the health record, but the Act does not clearly define what is included in the health record.[24,25] State law and institutional policy further define the medical record at a local level.[8]

The Joint Commission provides detailed description of a complete medical record and states that the contents of the medical record remain the same, regardless of the media used, paper, electronic, or both.[26] The medical record should include any observations significant to care, treatment or services, patient's responses to treatments, progress notes, all orders, any medications prescribed, adverse drug reactions, diagnostic results, and any medications dispensed. According to The Joint Commission, the hospital should use standardized methods to document patient care and treatment to promote continuity of care among providers. The Joint Commission considers the record of care to serve as a means of communication between clinicians to facilitate clinical decision making.[8]

Electronic Health Records

Healthcare facilities are moving toward EHR to meet "meaningful use" objectives in order to receive incentives outlined by CMS. The goals of meaningful use of the EHR are to provide safer, more efficient care and improve care coordination and patient outcomes.[27] Electronic health record implementation allows for health information exchange while improving quality of care.[28] The secure sharing of a patient's medical record with other healthcare providers (not only clinicians within the same facility) is a significant measure of meaningful use success.[29] A number of measures focus on medications, such as the use of computerized order entry for medication orders and the ability to track medications and have drug-drug and drug-allergy interaction checks within the system.[30] Medication reconciliation should be performed as a patient moves to another provider or setting of care, and a summary of care should be provided at this transition and should include incorporation of laboratory and test results.

Although the regulations do not specifically address clinical research documentation, it seems clear that study participation, testing, and interventions in clinical research will often affect clinical care and should be communicated within the medical record or EHR in a consistent manner. This information is important not only during clinical trial participation but also after the study is complete.[31] Typically, EHR systems do not address clinical research.[3] As institutions move to EHR, the documentation expectations increase.[8] With the increased exchange of health information, those involved in clinical research must ensure that documentation is in compliance with not only GCP and federal research regulations, but also regulations defining the medical record.

OVERLAP OF RESEARCH AND MEDICAL RECORDS

Upon review of the research record and the medical and EHR requirements, there are areas in which the two records overlap. Table 2 outlines this author's suggestions for which documents belong in the research record or the medical record or should be included in both records. At a minimum, in order to comply with regulations, the fully executed informed consent and HIPAA authorization for research, investigational drug or device usage and research team contact information should be included within the EHR. In addition, responses to treatment, especially adverse reactions to investigational drugs or devices, should be documented within the EHR. Ideally, there should be a method of "flagging" the record to notify all clinicians that a patient is a research subject with basic clinical trial information available and the ability to send notifications to the research team in the event of an emergency. The inclusion of laboratory and diagnostic results collected for research purposes only should be considered especially if the results are abnormal and clinically relevant. As Mattern[32] suggests, ultimately decisions should be made based on whether inclusion of specific research information will benefit the subject.

Lack of communication about investigational treatments may lead to errors that place a subject at greater risk.[3] In emergent situations, study medication may be inadvertently discontinued prior to discussing with study staff. Contraindicated medications may be administered to the patient. If the study team is unaware of an unexpected hospitalization, required regulatory reporting of a potential serious adverse event may be delayed. Late reporting of serious adverse events to the institutional review board and the sponsor is not only a deviation from the protocol, but also it places all subjects within the trial at increased risk. Serious adverse events, especially if a causal relationship is present, may lead to the closing of a study, protocol changes, or changes to the informed consent to notify current subjects of any additional risk.[33] These delays could be avoided if clinical trial information was readily available for all care providers.

Poor communication is most frequently mentioned as a contributing factor to adverse events in healthcare, so

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Table 2

Clinical Research Documentation: What Belongs in the Research Record Versus the EHR

Research Record Only	Both Research Record and EHR	EHR Only
Regulatory documentation (non–subject-related information: ie, CVs, institutional review board submissions, normal laboratory values, delegation of authority logs, DSMB reports, off-site Medwatch reports)[1]	Informed consent—signed form and consent process[23,a]	Clinical trial summary (basic information as noted on clinical trials.gov)[32]
Protocol[1,b]	Signed PHI authorization[23,a]	Summary of investigational drug (ie, mechanism of action, contraindicated medications, common adverse effects)[32]
Investigational brochure[1,b]	Prescription (or order) for Investigational drug[23,a]	Summary of investigational device (basic safety information, contraindications pertinent to other clinicians)[32]
Drug and device accountability (shipping records, logs)[1]	Administration records of investigational drug[8,23,a]	Research team contact information[a]
Case report forms[1]	Investigational drug dispensing records[8,23,a]	NCT number on clinical research billing[22]
Completed subject questionnaires/surveys[1,32]	Investigational device usage[8,23,a]	Trial name, sponsor, and sponsor number on research records related to above billing[22]
	Case history[15,16]	
	Clinically significant test results[32]	
	Outside laboratory or diagnostic tests performed for research only	

[a]Minimal requirements for inclusion in EHR.
[b]Sponsor proprietary information.

significant information must be shared with other care providers to ensure that a patient receives safe care.[3] Clinicians armed with pertinent information about a patient/subject's participation in a clinical trial may avoid contraindicated therapies increasing patient safety while decreasing the chance for deviating from the study protocol.[34]

Electronic health record documentation also provides a method to improve the principal investigator's oversight of the clinical trial and participants.[35] Communication about adverse events, clinically significant laboratory values, and study visits is facilitated through EHR documentation. With remote access, investigators may review collected data and follow-up through secure messaging within the EHR. This ability to look at study data alongside clinical data may improve investigators' ability to oversee the trial execution and electronically sign off after evaluating collected information. At the same time, other care providers will have a more accurate accounting of the patient's/subject's treatment plan.

Weisskopf et al[31] describe Swiss University Hospital's approach to inclusion of research documentation in the EHR. Trials are entered within their EHR, and subjects then linked with trials upon enrollment. Basic trial and contact information is available for all care providers, and an alert is sent to the study team if patient/subject is unexpectedly hospitalized. In order to provide standardization, templates housed in the EHR were developed to facilitate the capture of specific information for a research event, such as a follow-up visit.[31] When a subject is registered to a clinical trial, study information is automatically pulled into templates allowing for standardized documentation of medical history, physical examination, concomitant medications, and study drug compliance. By pulling previous adverse event information from the earlier visits, documentation of ongoing adverse events and clinical outcomes is facilitated. An enrollment template ensures that the informed consent process is documented in accordance with federal regulation. Although the use of these tools has not been mandated, the number of patients registered to trials has steadily increased.

Electronic Records and Signatures: 21 CFR §11 Compliance

The Code of Federal Regulations outlines requirements for the use of electronic records and signatures in place of paper records for investigations of FDA-regulated products in 21 CFR §11.[36] There has been concern among industry and investigators that with the increasing use of EHR, the FDA and sponsors may require that an EHR system be validated as 21 CFR §11 compliant.[19,21] The FDA states that regulation of EHR systems is not under their jurisdiction, and there are no plans to assess EHR compliance with 21 CFR §11. In fact, the FDA is encouraging industry to look for methods of extracting source data directly from the EHR in order to increase data quality.

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The increased use of EHR can also decrease duplication for the research team. As the EHR is an acceptable data originator,[21] certain data that are also relevant to clinical care can be entered directly into the EHR and serve as both source documentation and the medical record, thus improving communication between care providers and improving data quality through reduction of duplication. By entering observations directly into the EHR at the time data are collected, relevant information is passed onto other clinicians and complies with FDA's definition of source data.[21,37]

Additional Considerations for Inclusion of Clinical Research Within the Electronic Health Record

Integration of clinical research documents within the EHR requires careful planning and consideration. Informed consent documents and HIPAA authorizations for research may need to be revised if research information will be included within the EHR for all care providers to view.[32] Researchers should consult with the institutional review board and HIPAA compliance officers about suggested revisions. Some studies may require special consideration because of the sensitive information that participation may reveal about a subject. Integration of sensitive research-related information may infringe upon the patient's privacy and thus should not be included in the EHR. Studies involving certain conditions, such as Alzheimer's disease, human immunodeficiency virus, substance abuse, mental illness, and genetic testing, require special consideration.[8,32] As data from a research study of a stigmatizing nature become part of the medical record, subjects may risk insurance denials or workplace discrimination.[38] The sponsor's proprietary information must be considered in weighing which materials should be included. The protocol or investigator's brochure is often considered confidential and therefore should be viewed only by the research team.[8]

Level of access to the EHR will need to be determined based on need.[31,39] Those members of the research team who do not interact with subjects may need a view-only access to EHR. The RNC will require access allowing for data entry in the EHR, especially important if the RNC functions as a clinician as well. Nonlicensed research professionals interacting with subjects may be given ability to enter data, but with restrictions on activities that require licensure. Defining roles and level of access to the EHR for the research team is imperative to comply with HIPAA regulations.[39] Conversely, restrictions on clinicians' access to sponsor proprietary information may be required as well.

IMPLICATIONS FOR THE RESEARCH NURSE COORDINATOR

Acting as a delegate for the principal investigator, the documentation tasks for both clinical care and clinical research source documentation primarily rest upon the RNC. In the US, professional nursing standards clearly define that communication is necessary to provide quality nursing care. Standard 11 of the Nursing: Scope and Standards of Practice outlines communication competencies.[11] The nurse is charged with informing other care providers of pertinent information in order to minimize patient risks. The nurse should use appropriate formats to accurately relay information to others involved in the patient's care. As a nurse, the RNC should communicate assessments, interventions, and responses to treatment through documentation.[40] Electronic health records may prove to be the most effective method of informing other providers of clinical trial participation.

As a member of the research team, the RNC should be knowledgeable of federal and state regulations and principles of good documentation as well as specific protocol-related procedures and institutional policies.[13,41] Lack of good documentation may affect data integrity for the entire clinical trial.[13] The RNC should educate members of the interdisciplinary team on protocol procedures, collaborate with multidisciplinary providers (both within and outside of the research team) to allow for safe execution of a clinical trial, and communicate the impact of study procedures on participants. This includes monitoring for and documentation of adverse events and response to treatment.[42]

The RNC as the expert in both nursing care and clinical trial coordination should lead efforts to improve clinical trial communication through documentation in the EHR.[28,42] Nonlicensed research staff may require education regarding medical record requirements. The RNC is charged with collaborating within their institution to provide an environment in which appropriate protections are developed and utilized to not only provide good quality data but also minimize risks to subjects.[42] The RNC should be involved in the development of researcher education that includes guidelines for the inclusion of research documentation in the EHR.

RECOMMENDATIONS

It is clear that health information exchange through implementation of EHR is changing the documentation process within healthcare. Although clinical research documentation is not specifically mentioned in guidelines and regulations governing the medical record, there are areas in which documentation should be included in both records. The specification of which records belong within the EHR will need to be addressed at the institutional level through policies and procedures.[8,32] New enforcement of Medicare research billing requirements makes this issue a priority for healthcare systems, because payment for routine costs for patients in clinical trials is dependent on inclusion of key information on claims and within the medical record. Undoubtedly, not all clinical trial information should be integrated into the EHR, but trials involving investigational

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treatments, drugs, devices, or other therapies are significant to medical care and should be included in the EHR.[8]

Implementation of EHR is challenging, and those individuals primarily involved have little knowledge of clinical research. Involvement of the research team and other stakeholders is imperative. It is important for individuals with knowledge of not only patient care standards, but also clinical research standards to be actively involved in the process. Lanter and Niemeyer[39] suggest that the EHR implementation team include privacy officers, institutional review board members, research coordinators, and the information technology and clinical implementation team. A knowledge of research workflow is necessary to develop procedures that allow for the inclusion of research information within the EHR. Appropriate training is critical to successful implementation. The research team requires specific training, as the research workflow changes.[39] In addition, researchers may require training on clinical documentation and research billing requirements. Once appropriate training is complete, a process for obtaining the appropriate level of EHR access based on professional licensure and role is imperative.[31] Policies should be developed and involve the appropriate stakeholders. Inclusion of research documentation within the EHR should not be an option; this should be the expectation. The patient/subject, the clinical trial, and the healthcare facility benefit from appropriate documentation of clinical research within the EHR.

SUMMARY

There is a lack of literature and research regarding the emerging world of EHR and how clinical research should be documented moving forward. Sponsors are primarily concerned with good-quality data and focus more on ensuring source documentation availability. Hospitals and institutions are focused on meeting criteria necessary for various incentives available through healthcare reform. Clinical research documentation is an afterthought. As the use of EHR increases, incorporation of clinical research documentation will lead to a more complete medical record in compliance with both research and medical records regulations. This is an issue that must be addressed through institutional policies and procedures. The RNC must be actively engaged in this process. Risks for the subject, the clinical trial, and the healthcare system can be reduced through communication of pertinent clinical trial information within the EHR. Although there are no clear guidelines for inclusion of research documentation, true health information exchange cannot take place without this integration.

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