

Documentation in Clinical Research

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Objectives

Documentation in clinical practice is essential for communication among healthcare providers. It is from this documentation that protocol-specific data are abstracted from and transferred to case report forms (CRFs). This module will outline appropriate clinical research practice documentation.

At the conclusion of this module, the learner will be able to

- Describe 5 time points in the course of a study where documentation is required in the medical record.
- List 4 methods of patient/subject contact that are necessary before taking a patient who is lost to follow-up off study.
- Discuss how to handle discrepancies among source documents.

Why Document.....

- Provides a complete and accurate record of the patient's condition and treatment
 - Includes diagnosis, assessment, treatment/services, clinical course/response
- Communication among the healthcare providers
- Provides organization and continuity of care

....Why Document

- Provides for evaluation of health care operations and use of resources by providing data and determining reimbursement
- Affords risk management and malpractice protection
 - Pursue or defend from medical malpractice claims
- Complies with legal, regulatory and institutional requirements (e.g., state practice acts)

What is the Legal Medical Record?

- Electronic/Paper

What is it not?

- Shadow charts
- Paper CRFs
- Shared files on computer

Note to Staff

Data Managers working in the CCR are not allowed to document in the medical record. This includes copying and pasting emails onto a progress note.

Basic Chart Documentation Principles

- Entries are to be complete and legible
- Each patient encounter should be documented
- Follow SOP for medical record documentation including late entries, corrections, and acceptable abbreviations
- Do not erase or use correction fluid

Documentation “Do’s”

- Write the patient's name and medical record number on each sheet of the medical record (bottom left at NIH) or use labels
- Read other healthcare professionals' notes prior to caring for patient
- Make entries in order of consecutive shifts/dates
- Write the complete date and time of each entry
- Use concise, factual, concrete terminology
- Describe reported symptoms accurately

....Documentation “Do’s”

- Use the patient's words in describing symptoms whenever they might be helpful
- Use acceptable hospital abbreviations ([see NIH policy](#) for current list)
- Describe only what you observed and assessed
- Chart only in ink
- Each entry should be signed with name and title
- Stay current in terminology and pathophysiology, new diseases, and new assessment tools

Documentation “Don’ts”

- Leave any space between the last entry and your signature
- Chart in advance
- Chart until the patient's name is checked to confirm correct medical record
- Backdate, tamper with, erase, or add to notes previously written
- Skip lines between entries

....Documentation “Don’ts”

- Write relative statements
- Use slang
- Use medical terms unless their meaning is known
- Chart for anyone else
- Use correction fluid
- Spell words incorrectly

REMEMBER.....

If it was not documented in the patient's medical record, it was not done or never happened!

What is a Source Document?



Medical
Record

+

Research
Record

Key Purposes of Source Documents

- Provide original documents, “raw” data and records
- Document existence of the subject
- Substantiate compliance with the protocol and integrity of the study data
- Serve as audit trail = recreate the progression of clinical trial

Medical Record vs. Research Record

There are some documents that serve as source documents that are not allowed to be placed in a medical record. However, they need to be maintained as source documents. Creating a research record (aka: shadow chart) allows you to save these types of source documents.

Hospital records/medical charts/ Clinical and office charts include:

- Physical exam findings
- Consent process
- Diagnostic reports
- Operative reports
- Laboratory reports
- Data recorded from automated instruments

Research records/shadow charts include:

- Copy of signed informed consent document
- Subject diaries
- QOL or other surveys
- PK worksheets
- Eligibility Checklists

Clinical Research Documentation

Documentation that is acceptable in clinical practice may need additional details when the patient, now research subject, enters a clinical trial.

Research source documentation is never by exception.

Informed Consent and Eligibility Process

- Informed consent process
 - Note stating that the process occurred and that the subject received a signed copy.
 - See Informed Consent Module 8 for more details
- Verification of eligibility:
 - Note stating that subject meets all inclusion criteria and has no exclusionary criteria
 - All results for labs, pathology and any other procedures that are required to confirm eligibility should be in the appropriate section of the medical record (paper or electronic)
- Past medical hx/prior therapies
 - Summary from initial H & P, or more recent one
 - Outside records that confirm prior cancer therapies, pathology, etc. are to be placed in the medical record

Concomitant Medications

- All con meds that the patient has been taking including:
 - Dates taken – both when started and when stopped or dosage changed
 - Month and Year is acceptable for con meds taken before enrollment to study
 - Day, month, year is to be noted once patient has begun treatment on study
 - Reason/indication
 - Some meds are given for indications not approved by the FDA, so you can't assume that the patient is taking them for the condition indicated in the package insert. This is referred to as off label use.
 - Dosage/Amount in unit of measure (i.e.: mg, tab)
 - Frequency

Scheduled Study Visits

- All protocol related visits, procedures, exams, etc. need to be noted in the medical record that they occurred:
 - Document occurrence, results, who conducted and any follow-up. Some of the information may be on the final report.
 - Protocol-specific info (i.e.: PKs drawn, biopsy obtained)
- If a scheduled visit is missed, this also needs to be noted including the reason and then any follow-up that needs to occur (i.e.: Day 8 labs missed by patient and arrangements made to be drawn on Day 10 instead).

Study Drug Administration...

- All study drugs administered **MUST** be recorded in the medical record by the licensed practitioner who gave the drug(s)
- Includes all pre- or post-treatment medications that are listed as study drugs
- Documentation should include:
 - Date, time, amount, route
 - For IV medications, start and stop times

...Study Drug Administration

- Missed doses need to be documented including reason
- Subject self-administration of study meds:
 - Instructions for proper use/administration and storage
 - Date and amount dispensed/returned
 - Subject's compliance with regimen

Adverse Events

See Adverse Events module for details on medical record documentation of adverse events.

Unscheduled Visits

- All unscheduled study visits, procedures, exams, etc. need to be noted in the medical record including:
 - Reason for visit/procedure
 - Follow-up

Off-treatment

- When subject is taken off active treatment, a note needs to be written including why and the date.
- Date is the date when the MD/ Investigator decides that no further therapy will be given
 - This may be the same as the date of a scan or the last dose of drug, but not always.

Off-study

- When subject is taken off-study, a note needs to be written including why and the date
- For patients who are lost to follow-up, before they can come off study, every attempt should be made to locate patient/subject including:
 - Contact referring physician
 - Contact emergency contact patient identified on admission
 - Check [SSDI](#) (Social Security Death Index)
 - Send certificated, return receipt letter
 - All attempts should be noted in the medical record

Telephone Calls

- Document reason for call (adverse event, general question, test result, etc.)
- Document outcome of call (how adverse event to be treated, etc.)

Writing good progress notes.....



General Rules

- All patient encounters are to be documented in the medical record either using a progress note or CRIS. This ensures good practices AND allows for source documentation to be available at the time of a data abstraction, monitoring visit or audit.
- If at anytime there is conflicting documentation/ discrepancies in source documents a clarification note is required. Examples:
 - fellow note, dictated note, and/or nursing note have differing adverse event start dates
 - Tumor measurements/response per radiology report differ from medical record measurement progress note

Initial Visit/Screening Visit

- Document discussion of protocol(s), associated schemas, adverse events, disease response follow-up, clinic visits, labs, etc.
- Document that copy of the appropriate consent form(s) given to patient to review
- Document the consenting process, that patient signed consent and signed informed consent form copy given to patient
- Document tests done or to be done
- Document any concerns patient and/or family has and how addressed

On-study Visit/Eligibility Confirmation

- Document that eligibility is met
- Document that all appropriate baselines testing was completed and ensure that the results are in the medical record (not just hearsay, hard copy needed)
- Document all baseline symptoms including start date and severity
- Document all con meds including: dose, frequency, route, indication and start date
- Review of diary/surveys, how to complete, when to return, etc., if applicable

On-treatment/On-study Visits

- Review and document all adverse events including: date started, date stopped, description of severity (using CTC), how treated if applicable, and attribution to study/drug
- Review and document all concomitant medications including: which drugs are still ongoing, any dose changes with ongoing meds, addition of new meds including dose, frequency, route, indication and start date.
- Review compliance with protocol (i.e.: patient self-administration of study meds, tests/procedures conducted, tests/procedure missed and why)
- Ensure that there is documentation of disease/response assessment including results of scans/labs and decision to stay on/off treatment/study
- Ensure that the research bloods (pks, etc) drawn and pre-meds given are appropriately documented in the medical record

Telephone Calls

- Document reason for call (adverse event, general question, test result, etc.)
- Document outcome of call (how adverse event to be treated, etc.)

Off-treatment/Follow-up/ Off Study

- **Off-treatment note:**
 - Document reason off-treatment, including date
 - Document any follow-up that needs to occur
 - Document return of drugs, if applicable
 - Note any ongoing AEs and continue to follow if related to study
- **Follow-up note:**
 - Review and document all protocol-specific activities that occur in the follow-up period. This may include survival alone or in combination with: adverse events (new and/or unresolved), concomitant meds, tests/procedures conducted, disease/response and/or research labs
- **Off-study note:**
 - Document reason off-study, including date

Evaluation

Please complete the [evaluation form](#) and fax to Elizabeth Ness at 301-496-9020.



For questions, please contact Elizabeth Ness
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