Documentation and Document Management Module
Part 1: Documentation in Clinical Research

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Agenda

- Clinical documentation
- Source documents in clinical research
- Clinical research specific documentation

Why Document

- Communication among the healthcare providers that provides a complete and accurate record of the patient's condition, treatment and response to treatment

One Medical Record Many Purposes

- A record for reimbursement
- A record for guiding quality improvement
- A record for evidence in legal proceedings
- A record for research

What is the Legal Medical Record?

- Electronic/Paper

What is it not?

- Shadow charts
- Paper CRFs

Who Regulates Medical Records

- Federal and state laws
- Accrediting organizations (eg., JCAHO)
- Licensing statutes
- Case law
- Facility policy/procedures

Documentation "Do's"

- Use legal medical record
- Document all patient encounters
- Use concise, factual, concrete terminology
- Describe reported symptoms accurately
  - Use the patient's words in describing symptoms whenever they might be helpful
- Use acceptable abbreviations
- Describe only what you observed and assessed
- Use correct spelling

Documentation "Don'ts"

- Document in advance
- Document until you've confirmed you are in the correct medical record
- Use slang
- Use medical terms unless their meaning is known
- Document for others

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

- Hospital record
- Clinical or office charts
- Pharmacy dispensing records
- Recorded data from automated instruments

Research Record

- Copy of signed informed consent document
- Subject diaries, QOL or other PRO documents
- PK worksheets
- Eligibility Checklists (MUST have documentation in the medical 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

Subject Specific Documentation: ALCOA

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate

Clinical Research Documentation

Documentation acceptable in clinical practice may need additional details when the patient enters a clinical trial.

Research source documentation is never by exception!

Two Basic Rules

- All participant encounters should be documented in the legal medical record
- Conflicting documentation/discrepancies in source documents require a clarification note

Initial Clinical Trial Discussion

- Discussion of protocol(s), associated schemas, adverse events, disease response follow-up, clinic visits, labs, compensation, etc.
- Copy of the appropriate consent form(s) given to patient to review
- Tests done or to be done
- Concerns patient and/or family and how addressed

Informed Consent (IC)

- Includes:
  - A discussion occurred
  - All questions were reviewed and answered to individual's satisfaction
  - A copy of the signed IC document was given to the subject
- Know your institutional policy

Eligibility and Baseline

- Eligibility criteria
- All appropriate baselines testing was completed
- All baseline symptoms including start date and severity
- Review of patient completed forms, if applicable
- All concomitant medications or measures

Concomitant Medications & Measures

- Drug name or type of therapy
- Dates taken – both when started and when stopped or dosage changed
  - Month and Year is acceptable before enrollment to study
  - Day, month, year once participant has started on the intervention
- Reason/indication
- Dosage/Amount including unit of measure
- Frequency

Study Visits

- All visits/procedures
- All adverse events including:
  - Start date
  - Stop date
  - Description of severity
  - How treated if applicable
  - Attribution to study intervention
- All concomitant medications including:
  - Ongoing, Dose changes, New
- Response
- Biospecimen collection
- Missed visits including reason and any follow-up
- All unscheduled visits, procedures, exams

Study Drug Administration

- All study drugs administered MUST be recorded in the medical record by the licensed practitioner who gave the drug(s)
- Documentation should include:
  - Date, time, amount, route
  - For IV medications, start and stop times
- Missed doses need to be documented including reason

Self-Administered Study Drug

- Instructions for proper use/administration and storage
- Amount taken and over what period of time
- Date and amount dispensed/returned to support s participant's compliance with regimen

Off-treatment

- Document date and why
- Date off treatment

Follow-up

- Document all protocol-specific activities in the follow-up period.
- 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

- Document date and why
- Lost to follow-up:
  - Every attempt should be made to locate patient/subject including:
    - Contact referring physician
    - Contact emergency contact patient identified on admission
    - Send certificated, return receipt letter
    - All attempts should be documented

Telephone & E-mail

- Phone Call
  - Document reason for call
  - Document outcome of call
- E-mail
  - Allowed via secure system?
  - Able to include in medical record or is summary needed?
  - Kept in research record?
  - Does subject need provide evidence that email communication is acceptable?

Summary

- Documentation in clinical research contains more details than in general practice
- Quality of the documentation directly affects the quality of the data