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

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)

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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

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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 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