Good Clinical Practice & Medical Record Documentation

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Objectives:

• Understand the history behind and define some key components of “Good Clinical Practice”

• Identify barriers to data extraction and reporting

• Explore some possible approaches for making data abstraction more efficient and accurate
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The history

Rigshospitalet, Copenhagen, Denmark
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Pure Food and Drug Act of 1906

- The agricultural society and traditional medicine.
- The Industrial Revolution.
- The “Poison Squad” and the novel “The Jungle”.
1937

The Elixir Sulfanilamide Incident.

• Sulfanilamide to treat Streptococcal infections
• Diethylene glycol = antifreeze = deadly poison (but pleasant taste)
• 107 people died

1941

U.S. vs. Dotterweich.

- Buffalo Pharmacal Company charged with shipping adulterated and misbranded products e.g. digitalis tablets

- Responsible individuals can be held personally accountable for the quality of the products manufactured by their company.
1960

The Thalidomide Incident

- Used, in Europe, to treat sleep disorder and morning sickness in pregnant women.
- In Germany alone 5000 babies were born with birth defects.
- 1962 Drug Amendment: safety requirements for testing on human subjects, information on experimental drugs, adverse effects during clinical trials, listing side effects as well as benefits.
1947
The Nuremberg Code

- Voluntary consent of the subject
- Results should be fruitful and not procurable by other methods
- Trial design should be based on the results of animal experimentation
- Avoid unnecessary suffering and injury
- If the researcher believes that death or disabling injury may occur during the trial, the research is not legitimate and should not be done
- The degree of risk may not exceed the benefits of the experiment
- Every possible action must be taken to protect the subject from injury, disability or death
- The experiment should be conducted by scientifically-qualified personnel
- The subject may terminate the trial at any stage
- The investigator must be prepared to terminate the trial at any stage
1964 Helsinki Declaration

• The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

• The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.
1961-1974
Milgram Experiment

- Social psychology experiments measured willingness to obey and authority figure who instructed them to perform acts that conflicted with their personal conscience.

- 65% (26 of 40) participants administered the experiment’s final 450- volt shock.
1996
International Conference on Harmonisation (ICH)

- Different guidelines in the U.S., Europe and Japan for clinical research => expensive drugs and long testing time.

- 1996: International guidelines for clinical trials incorporated into legislations (ICH-GCP)
Definitions from ICH e.g.

• **1.52 Source Documents**
  
  Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial).
Definitions from ICH e.g.

• **1.28 Informed Consent**
• A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.
The lessons from history

- Systematical gathering of data is necessary to gain new knowledge.

- To respect the individuals' rights and decisions when participating in clinical research.
Good Clinical Practice & Medical Record Documentation

Children’s Memorial Hospital
Terri Halverson
RN, BSN, CPON
Good Clinical Practice

• International ethical & scientific quality standard developed by the ICH

• Objectives:
  – economical use of resources
  – eliminate unnecessary delays
  – maintain quality, safety & efficacy safeguards
  – protect public health.
Good Clinical Practice

Provides assurance that

• The data and reported results are credible and accurate

• The rights, integrity and confidentiality of trial subjects are protected
Good Clinical Practice

Provides assurance that

• The data and reported results are credible and accurate
  = Quality data

• The rights, integrity and confidentiality of trial subjects are protected
  = Ethics

Quality data + ethics = Good Clinical Practice
Purpose of the Medical Record

- Serve as a basis for planning patient care and for continuity of care
- Document patient's evaluation & treatment
- Document communication between health care professionals
- Assist in protecting the legal interest of the patient, hospital & practitioner
- Provide data for support decision analyses.
Medical record uses

- Clinical care
- Legal document
- Financial record
- Data
  - clinical research
  - decision analysis
“Legal” medical record

- Record released upon request for accrediting, regulatory, and reimbursement purposes
- Released to others if authorized.
- Includes microfilm, scanned images, and the electronic record.
- Does not include aggregate or derived data, and administrative or business records.
Medical Record Documentation

- Multi-disciplinary tool

- Held to various Standards, Regulations & requirements

- Format
  - Paper
  - Electronic
  - Hybrid

- Documentation not always complete
Medical Record Data Quality

• Valid
• Accurate
• Complete
• Consistent
• Timely
• Accessible

• Confirm by audit
Problems extracting data from medical record

• Method:
  – Manually
  – Report

• Medical Record vs. Research

• Clinical Definitions vs. Form definitions

• Lack of communication
What has worked at Rigshospitalet & Children’s Memorial Hospital

- Source documentation from referring physician
- “Orient” new physicians
- Keep physicians abreast of regulatory changes & updates
- Audits & Record reviews
- Error correction process
- Build specific information needs into documentation system (forms, drop-down menus, etc.)
- Electronic Medical Record validation
- Communication
Business case for data quality

• Improve patient care

• Public reporting / transparency

• Opportunities for improvement

• Research: studies & papers
Resources

• Guidance for Industry, *Good Clinical Practice*:  

• ICH Website:  

• Web Lecture Archive Project, University of Michigan: http://www.wlap.org/
Thank you!

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