Navigating the Path to Clinical Research

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http://bit.ly/researchatDLC
http://bit.ly/Researchwithclinicaldata

Key Attributes of Quality When Considering the Re-Use of Clinical Data for Research

1. **Correctness**
    - Complete
    - Accurate
    - Legible
    - Avoidance of abbreviations, jargon
    - Current—are the data documented at the time the intervention occurs?
    - Use of free text allows for information that does not fit into structured fields to be accurately recorded.

2. **Credibility**
    - Patient centered
        i. Are the right assessments being used to measure a client's status?
        ii. Have instructions been provided in the patient's primary language?
        iii. Are accurate inferences possible?
    - Use of objective data
    - Do the data guide clinical decision-making?
    - Verifiable – is the information original, reliable, attributable?
    - Use of standardized validated protocols

3. **Consistency**
    - Internal—is there discrepancy of information on the same chart?
    - External—data consistent with other sources?
    - Consistent vocabulary, medical coding, international classifications of diseases
    - Standardized data entry , fields, structured data sets
    - Standardized protocols
    - Structured data preferable for analysis than free text (forced fields, coded data, quantitative measures)

4. **Accessibility**
    - Is the information easy to read and process?
    - Is the information easy to find?
    - Are data placed in a consistent place in the chart?
    - Specificity—is only data required for the intended purpose displayed? (absence of extraneous information)
    - Compact—is a large amount of information available "at a glance"? (Grids, charts, graphs may be more accessible than narrative.)
    - Relevance—are the data applicable to the purpose intended?

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Preparing for Research: 5 Steps to Front Line Staff Participation

1. **Be curious** – Observe patterns and trends. Ask 'why'. Keep track of clinical questions that need answers.
2. **Talk to Manager** – Discuss research idea, potential time commitment, costs, and potential implications for core responsibilities.
3. Desig**n Study** – Develop idea formally. Help is available here: http://umanitoba.ca/faculties/medicine/units/chi/7820.html
4. **Ethics Approval**
    a. Each research group much include at least one person who has completed the ethics course here: http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/
    b. Details on requirements for ethics submission (U of M Bannatyne campus) are here: http://umanitoba.ca/faculties/medicine/ethics/2688.html.
    c. Ethics review for most nursing and social work related research is conducted at the Fort Garry Campus. Details are here: http://umanitoba.ca/research/orec/ethics/human_ethics_REB_forms_guidelines.html.
5. **Site Approval**
    a. See Deer Lodge Centre website for details: http://www.deerlodge.mb.ca/research.html.

Highlights from the Literature on Clinical Documentation and Research

The main purpose of documentation should be to support patient care and improved outcomes… documentation for other purposes should be a byproduct of care delivery. (Cusack et al, 2011)

Electronic health records with well-designed, structured data sets balanced with clinical narrative could help accelerate research and facilitate better care . . . (Barr, M.S., 2013)

Electronic health records should be used as a tool to support clinical curiosity and critical thinking rather than simply to expedite clinically meaningless documentation. (Barr, M.S., 2013)

It is generally accepted that, as a result of differences in priorities between clinical and research settings, clinical data are not recorded with the same care as research data. (Weiskopf & Weng, 2013)

Coding of clinical data is the conduit to consistent and standardized retrieval of medical conditions/information.(Nair, G.J., 2013)

Sources:

Barr, M.S., The Clinical Record: A 200 year-old 21st Century Problem. *Annals of Internal Medicine*. 2010; 153:682-3

Cusack et al. The future state of clinical data capture and documentation: a report from AMIA's 2011 Policy Meeting. *Journal of the American Medical Informatics Association* 2013; 20:134-140.

Haux, Knaup, & Leiner. On educating about Medical Data management. *Methods Inf Med* 2007: 46:74-79

Kush et al. Electronic Health Records, Medical Research, and the Tower of Babel. *The New England Journal of Medicine*, 2008, 358(16) 1738-1740.

Nair, G. Ensuring quality in the coding process: A key differentiator for the accurate interpretation of safety data. *Perspectives in Clinical Research*, 2013; 4(3): 181-185

Ozmen-Ertekin, D. & Kann, O. Dynamic data maintenance for quality data, quality research. *International Journal of Information management*, 2012; 32; 282-293.

Ryan et al. You and the EMR: the research perspective. *Canadian Family Physician,* 2011; 57:1473-1474

Terry, C., et al. Using your electronic medical record for research: a primer for avoiding. *Family Practice* 2010; 27:121-126

Weiner & Embi. Toward reuse of clinical data for research and quality improvement: The end of the beginning? *Annals of Internal Medicine*, editorial, 2013, 151 (5):359-361.

Weiskopf & Weng, Methods and dimensions of electronic health record data quality. *Journal of the American Medical Association* 2012; doi:10.1136.

World Health Organization. Handbook for Good Clinical Research Practice: Guidance for Implementation. 2002.