Investigator Education: Training for Accountability in Human Research Protection Programs

Lynn Willis

Medical Research Summit

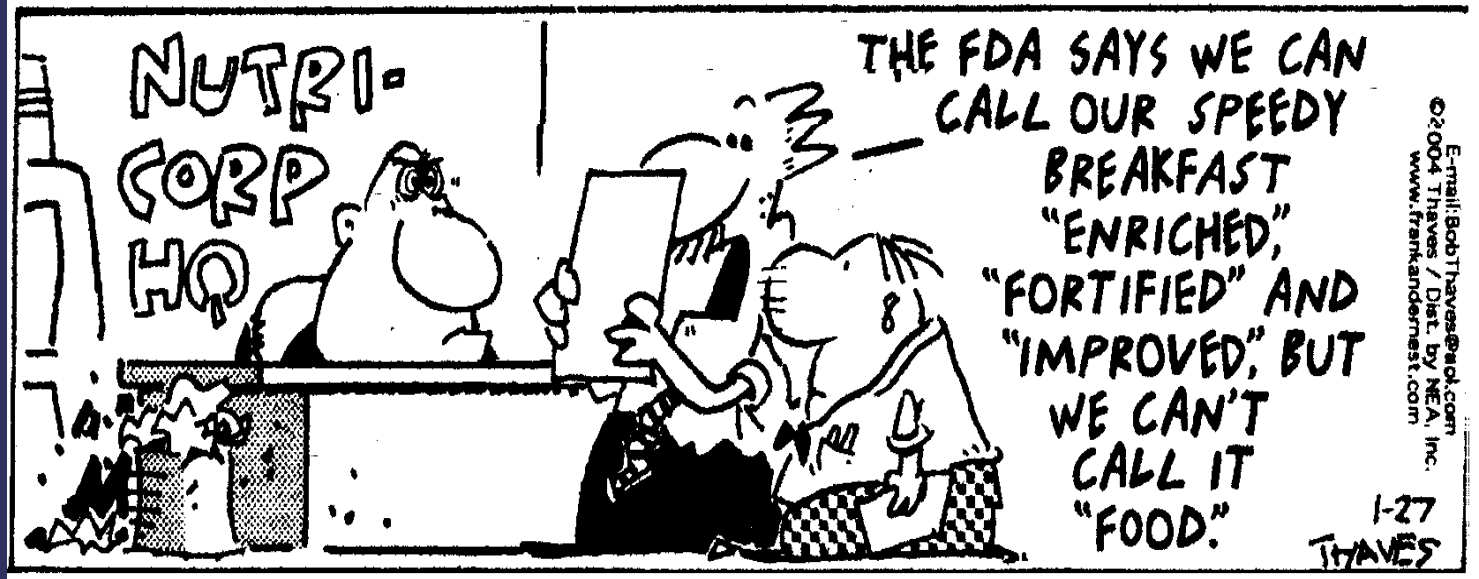
April 22, 2004

Session 3.03

Disclaimer:

- The views expressed in this presentation do not represent the official views of the Veterans Health Affairs (VHA) Office of Research Oversight (ORO), VHA or the US Government

FRANK & ERNEST By BOB THAVES



Related Publications

- Beecher, Henry *Ethics and Clinical Research* New Engl J Med (274) 1966: 1354-60
- Wyngaarden, JB *The clinical investigator as an endangered species* N Engl J Med (301) 1979: 1254-9
- Lehotay, DC et.al. *A program for training physician investigators.* J Med Educ 57(8) 1982: 602-8
- *NIH Director's Panel on Clinical Research Report 12/97* http://www.nih.gov/news/crp/97report/execsum.htm
- IOM *Integrity in Scientific Research, Creating an Environment That Promotes Responsible Conduct* 2002

Common Themes

- Shortage of well-trained physician-scientists dedicated to careers in clinical research
- Majority of US Investigators learn their role through informal or "on-the-job" training
  - reliance on sponsor instruction and feedback (what to do and how well it was done)
  - approach IRB approval as a challenge to be overcome
- “The most unpredictable and influential variable is the individual scientist”-IOM

Learning Organizations and Accountability

- Personal Mastery
- Mental Model
- Shared Vision
- Team Learning
- Systems Thinking

Senge, Peter *The Fifth Discipline, The Art of the Learning Organization* 1990 Doubleday Publishing

- Accountability-based design system
  - Roles are clearly defined
  - Expectations for the role are specified in detail so that performance can be measured
  - No difference between paper process and what is actually done
- Facilitated by supporting organizational structure
  - Institutional expectations should be unambiguous and the consequences of actions should be clear

Our system

- Culture of continuous learning
- Accountability based team approach
- Medical care model for KSA decisions
- Decision making at the point of care
- Focus on outcomes
- Business decision based on cost:benefit ratio

Findings

- Dialogue and decision making lead to new awareness and culture of compliance
- Success of clinical research depends on well coordinated, skilled, knowledgeable team
- Depends on everyone knowing and understanding role and having skills to achieve expectations (KSA)
- Not every clinical trial should be done