

RESEARCH  
versus  
PRACTICE

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# Recent Controversy

## J Neurosurg 2004

- Human albumin commonly used to boost volume, CVP in critically ill patients
  - Costly
  - Possibly ↑ morbidity, mortality in critically ill pts
- May 1999: hospital changes policy, requiring saline instead of albumin
- Neurosurgeons examined results of policy for patients with subarachnoid hemorrhage (SAH) after aneurysm rupture, comparing before vs. after policy

# Recent Controversy

J Neurosurg 2004, cont.

- Neurosurgeons' post hoc chart review was IRB-approved, with informed consent to obtain Glasgow Outcome Scores
- Findings: for SAH patients, albumin is associated with better 3-month outcomes (difference faded by 6 and 12 months), fewer in-hospital neuro complications, lower cost via fewer radiologic interventions
- (Various reasons why this group of patients might do differently with albumin)

# Recent Controversy

J Neurosurg 2004, cont.

- Ethics challenge (Rie, Kofke, Fahy)
  - Cost containment policies like this constitute experimenting on patients without IRB review
  - Violates Nuremberg principles!
  - Violates Declaration of Helsinki!
  - No informed consent!

OOPS

# Research vs. QI

- The real problem: Hospital's policy was changed with no research whatever--and perhaps without doing adequate 'homework'
- Thus, the problem, if any, was not "doing research without IRB," but \*failing\* to do research (or homework) before implementing a significant policy change
- Neurosurgeons analyzing data did obtain IRB approval; much of their work was arguably QI

# **CASE: Ancheff v. Hartford Hospital, 799 A2d 1067 (Conn. 2002)**

- Patient had back surgery, developed enterococcal osteomyelitis (difficult to treat)
- Hospital protocol: high-dose Gentamicin with Unasyn, frequent monitoring, collection of results
- Automatic dose escalation if no untoward toxicity
  - 7 mg/kg instead of usual 3 mg/kg
  - 1 daily injection instead of 3, per protocol
- No IRB involvement
- No research informed consent
- Hospital physicians lectured to other physicians about the protocol

# **Ancheff v. Hartford Hospital, 799 A2d 1067 (Conn. 2002) (cont.)**

- Pt developed ototoxicity, balance problems
- Lawsuit alleged "research without IRB, research consent"
- Arguments from Plaintiff's witness:
  - Systematic application of a given regimen to many patients; not individualized Rx
  - Systematic collection of data
  - Collected data were not in the patients' charts, but in a research office
  - Purpose of the program was to be able to publish their results in medical literature and hospital newsletters

# Ancheff v. Hartford Hospital

## Hospital's responses

- Treatment protocol  $\neq$  research protocol
- Hospitals frequently establish standardized protocols to ensure quality
- Protocol was not to study safety of Gentamicin: hospital had studied Gentamicin issues for many years prior to this protocol, including extensive literature search
- Goal was only to implement best practices
- This protocol could not yield generalizable results: only one arm (no comparison-arm); no randomization, no blinding
- This protocol approved by P&T committee, infectious diseases dept, medical executive committee
- Goal: use scientific data to maximise efficacy, safety by permitting longer drug-free period (q.d. rather than t.i.d.)

*SO ...*

*WHAT DO WE MAKE  
OF THESE CASES?*

# QI versus Research

- Research
  - Requires IRB review of risks, benefits, ethics, etc
  - Requires informed consent
- QI (quality improvement)
  - Exempt from research regulations

# Research versus QI

- 45 CFR 46.102: "*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."
- 45 CFR 45.101(b)(4) (exempt from review):  
"Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."

# QI: Definition

- QI: "small-scale cycles of interventions that are linked to assessment and that have the goal of improving the process, outcome, and efficiency of complex systems of health care"
  - Casarett, Karlawish, Sugarman JAMA 2000
- Focus is usually on improving local systems for delivering care rather than changing the content of care
- 'Protocol,' if any, often changes in mid-stream to adjust as data comes in

# QI: Examples

- Helping to 'install' the standard of care
  - Pre-op: ensure prophylactic Abx are given within one hour prior to first incision, stopped within 24 hours after surgery
  - AMI patients: aspirin, beta blockers at arrival and discharge; smoking cessation advice
- Decreasing recognized overuse of vancomycin, other powerful antibiotics
  - Original order is only for 3 days
  - Require I.D. consult to continue vanc
- Review results to discern policies' success, safety, make changes p.r.n.

# QI: Shortening ER Wait-Times

- Bed availability on floor
  - Patients couldn't be discharged earlier: meds not ordered
  - Nurses not report empty room until end of shift
  - Housekeeping not get to that floor until later
- Transportation to radiology, lab
- Reporting back of lab, x-ray results
  - Fax at the back of the room: bell not audible
- Type and mix of ER staffing
- House staff's other patients, new admissions
- New computer software slows down documentation; complex discharge process
- Figuring out where, physically, a patient is (RFID)

# QI versus Clinical Research: What's the Difference?

- Not "intent to publish"
- Not "innovative" or not
- Not "carrying extra risk" or not
  
- So ... what's the difference?
  
- No consensus, but some general differences ...

# QI versus Clinical Research

- QI
  - Mandatory within any health care organization
  - Activities may be set virtually entirely within normal conduct of care
- Research
  - Essentially optional
  - Activities are at least partly outside parameters of usual care (e.g. special measurements)

# QI versus Clinical Research

- Research: scientifically generalizable
  - Fixed protocol  $\Rightarrow$  "systematic" investigation
  - Clear, established set of controls
  - Often focuses on basic physiology, Dx, Rx
  - Applicability not ordinarily dependent on locale
- QI: not scientifically 'generalizable'
  - Evolving 'protocol'  $\Rightarrow$  not "systematic" investigation
  - Absence of fixed controls
  - Often prompted by local needs, peculiarities
  - Usually focuses on processes for delivering care, more than content of care
  - Usefulness to others requires local adaptation

**CAVEAT:**

**"This Is Not Research"  
does \*not\* mean  
"No Need for Ethical Review"**