QI and Human Research

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FRIENDS RESEARCH INSTITUTE, INC.

WHY QI?

- Helps demonstrate an Institutional Commitment to Human Research Protections for

Research Participants

The Community

Regulators

Sponsors

Your Employees

Quality Improvement forged out of "Quality Control" before, during & after WW II

- **Autos & Guns: need for high quality, high output, AND interchangeable parts**
- **Influence of Western Electric & Bell Labs, War Dept., Shewhart, Feigenbaum, Deming, Juran, Berwick**
- **The "Japanese Miracle" after WWII**

Quality Control / Improvement forged before, during and after WW II

- **Application to Health Care**
- **bit of a stretch…to**
- **Research, more of a stretch, but can be**
- **adapted**

- **A Good QI Definition: A method of identifying and remediating *Barriers to Quality* through staff reports (PQIs), QA data, Benchmarking, QI Studies & Committee discussion VIA the QIC**

KEY QUESTION THIS AFTERNOON

CAN QUALITY IMPROVEMENT METHODS ENHANCE YOUR HUMAN PROTECTIONS & LESSEN INSTITUTIONAL LIABILITY & EXPOSURE…

WITHOUT EFFECTING IRB AUTONOMY ?

Quality Improvement in Human Research

QUALITY IMPROVEMENT METHODS CAN BE APPLIED TO AN ENTIRE INSTITUTION, e.g.

- CLINICAL
- FINANCE
- MANAGEMENT
- PURCHASING
- IRB Administration
- HR…etc.

Why QI in Human Research?

1. The availability of public, private, and industry [“Big Pharma”] $$$

2. Pace of scientific advancements

3. Our troubled history - use (and abuse) of human subjects

4. AN ACTIVIST PLANTIFF’S BAR

Other Advantages of QI

- ✓ Independent of IRB – lessens COI
- ✓ Reports directly to IO
- ✓ Built-in risk management and prevention thru root cause analysis of defective process
- ✓ THE PROCESS IS BAD—NOT THE PERSON (usually)

How to Start QI in Human Research

- Hire or train someone in QI Methodology. CPHQ is credential. Janet Brown Course.

- RNs, PA-Cs excellent for QI personnel

How to Start QI in Human Research

- Sensitive liaison with the IRB
- Medical Director as co-chair with QI Director of the QI Committee (QIC)
- NOT THE QI POLICE

Practical Guide to QI in Human Research 101

- Leadership and "buy in" absolutely necessary from Board of Directors and CEO or IO
- Multidisciplinary QIC; must have MD/DO Co-Chair if doing medical research
- Feedback loop to Institutional Official and IRB Administrator
- Training and education of governing body, leadership, employees, PIs, etc.

Practical Guide to QI in Human Research-101

- Use internal and external QA audit data

- Trending by QI of QA data
- Review and trending by QI of SAE reports

- Implementation of "PQI" process: staff trained to submit confidential Potential Quality Issues to QI Director

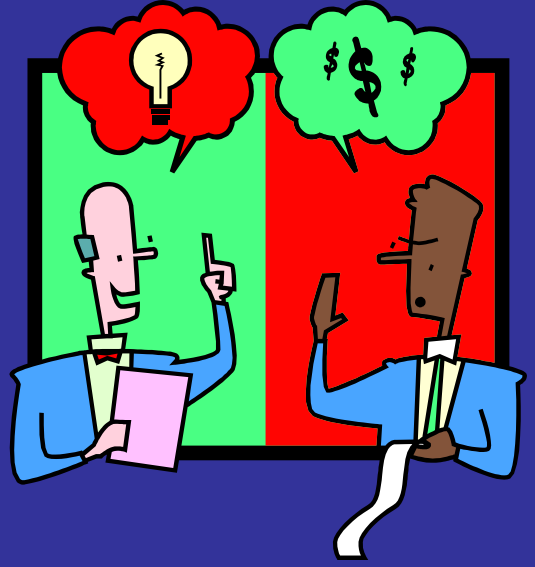
Practical Guide to QI in Human Research-101

- Establish a Quality Improvement Committee (QIC)- meet at least Quarterly
- Regular review of outcomes and identification of benchmarks and quality indicators
- Educational and other Interventions, i.e. Quality Initiatives / Studies; Investigator Education; Corrective Action Plan from PI, etc.
- N.B. !!

  QI Studies *May Constitute Human Research*

QI IN RESEARCH: PROS AND CONS

PROS



- Added oversight & enhances Human Protections
- Discerns thru Potential Quality Issues, and Tracking / Trending analysis, potential disaster or “Tipping Point” (Gladwell 1996,2001)
- Flexible & Scaleable—you can develop a unique QI Program adapted to your institution

PROS

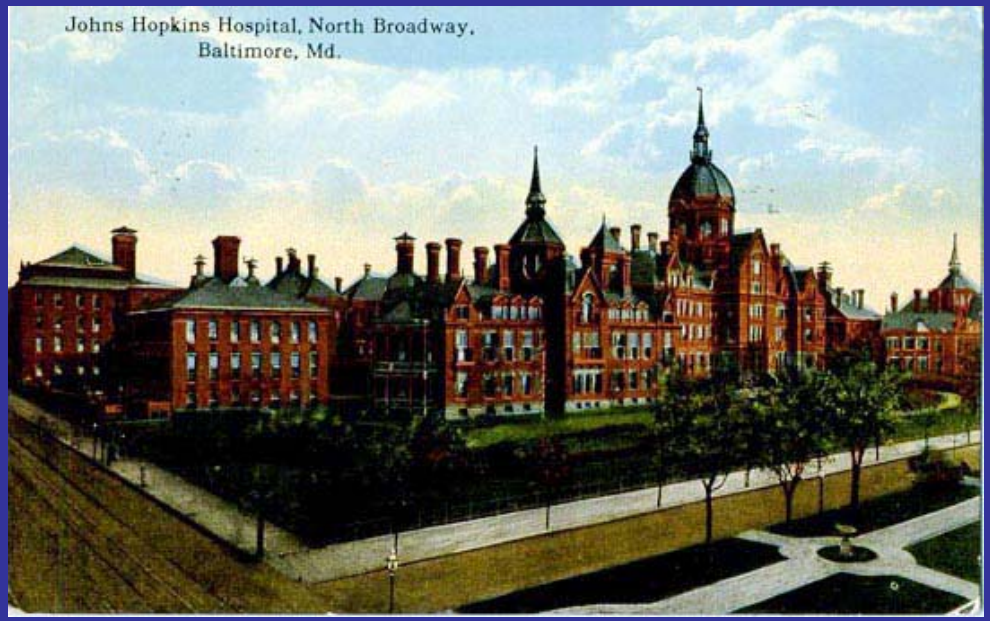
- QI and IRB: cross-fertilization of SAE handling and interpretation enhances protections
- Enhances Institutional Due Diligence and may lessen exposure and liability/risk

PROS

- Can launch internal exploration of issues before it becomes external issue --read: Lawsuit
- Can trigger internal corrective procedures before they are imposed by outside agencies--read: Loss of FWA / MPA

PROS

- Allows Key Institutional Leaders and staff to examine **<u>entire</u>** institutional system, not just research



cons

cons

- Must sell the QI Mantra : "Its the System not the Person"
- IRBs may feels autonomy threatened
- Fantasy of "QI Police" Ratting to the IO, IRB & Board of Directors

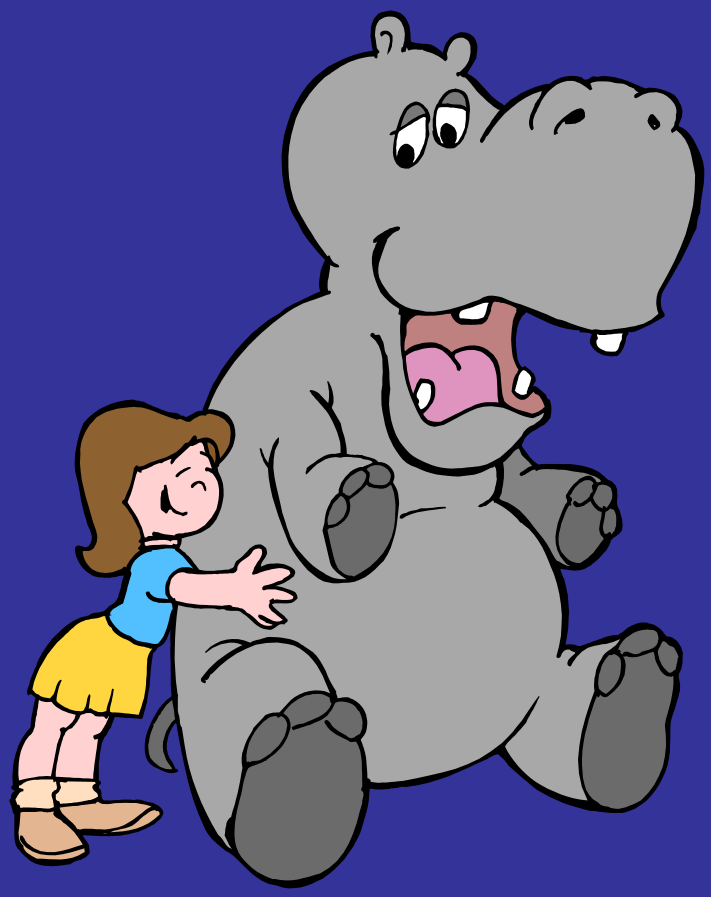
cons

- **It costs, but can ultimately Pay for itself**

- **QI and QIC data and work products do not have same protection from discovery as peer review**

QI and HIPPA

QI usually not a HIPAA burden…is "healthcare operations"



DOES QI WORK?

- **Effectiveness of QI–Well-accepted in industry; seems to work in CLINICAL MEDICINE. No data published yet on effectiveness in the research setting**
- **We may soon say "Eureka" as we discover QI's effectiveness. Or, we may not….**

"I heard von Schleflin yell 'Eureka,' and then kerblam!"

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