Beyond Auditing and Monitoring and Towards Quality Improvement

HCCA Indianapolis Regional 2019
John Baumann, PhD.
Associate Vice President for Research Compliance
Office of Research Compliance
Vice President for Research
baumannj@iu.edu
www.researchcompliance.iu.edu

Introduction

- We begin with some assumptions
  - Every HRPP wants to improve its processes, its compliance, its efficiency.
  - Within every HRPP lies a mountain of 'data" either already collected or collectible
    - Data includes
      - Audit and monitor reports
      - Research team reports to HRPP: non-compliance, deviations, adverse events, etc.
      - Data collected by the HRPP
        - From its records
        - From specific purposeful outreach efforts

Introduction

- Why not, then, act like researchers and use this data to focus and direct quality improvement activities?

- **Todays objectives:** To discuss methods for collecting, assessing and using data for the selection of QI areas on which to focus, implementing QI activities; and assessing programmatic outcomes of QI efforts.

- Specifically:
  - Why do we do QI
  - What do we QI
  - How do we do QI
  - Consider the who (us) and the where to be given

What is QI

- Quality Improvement (QI)
  - "The systematic approach to reduction or elimination of waste, rework, and losses in production process."
  - "To identify opportunity for process improvement, address potential problems and promote best practice."
    - To correct workflow processes, improve efficiencies, reduce variations in outputs, and address areas of non-compliance.
    - A Performance enhancement in response to observed trends or findings

- QI can take many forms, but the philosophy remains: **The systematic and continuous actions that lead to measurable improved performance.**
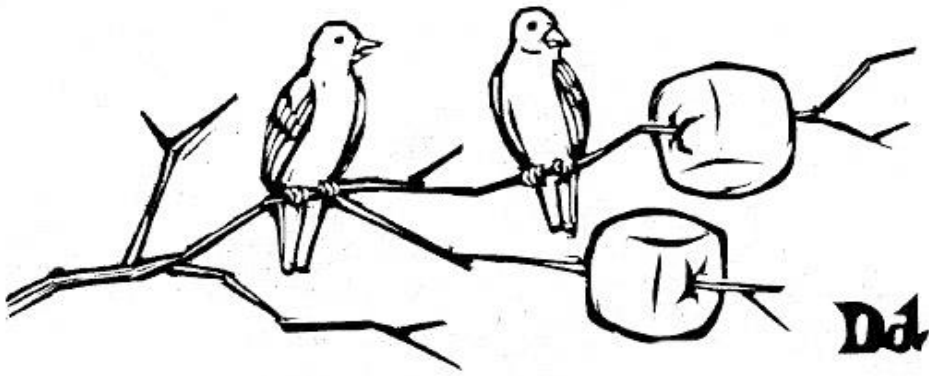
Why Do We Do QI

- ◆ Improve Integrity of the Processes
  - ◆ Challenge of meeting regulatory requirements
- ◆ Improve Efficiency
  - ◆ Minimize burden on researchers and ourselves
- ◆ Identify and Address Deficiencies
- ◆ Why else?????

Why? To Not Settle

"Personally, I think this country was in trouble when we decided to make sliced bread the high-water mark."

Why? To Minimize Surprises
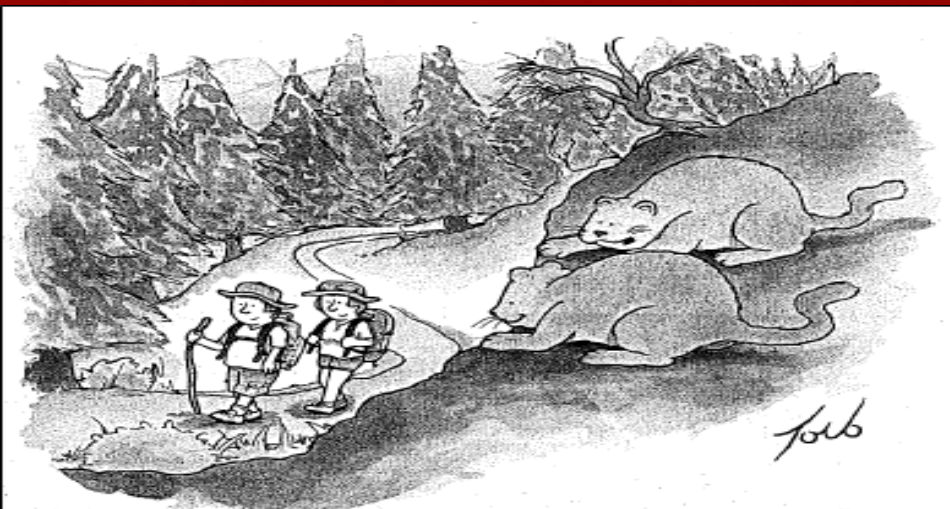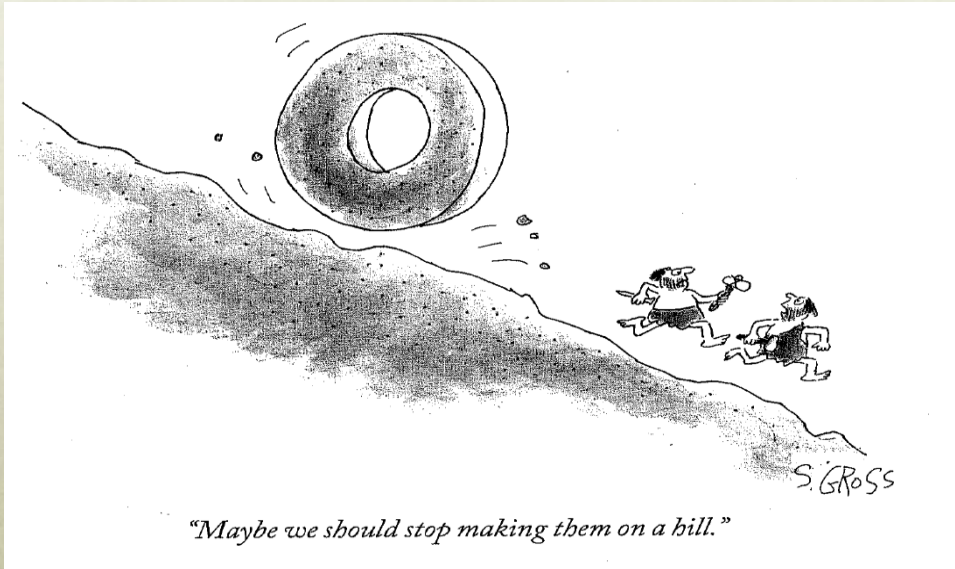

"I've got a bad feeling about this."

Why? To Minimize Not Knowing what's Around the Corner

"Wait until one of them says, 'It's so peaceful out here.'"

Why? To Change Practice

"Maybe we should stop making them on a hill."

What Do We QI

- Community Satisfaction/Dissatisfaction
- Regulatory Compliance
- Data Quality
- Efficiency
- Each Involves Assessments of
  - Policies
  - Procedures/work processes
  - Operations

How Do We Do QI: Satisfaction/Dissatisfaction

- Service Survey
  - Like many institutions, had annual survey
    - But what were we measuring?
      - Recent Experience?
      - Memories from 6 years ago?
  - Move to service survey
    - Focus on specific service experience; transactional
  - Survey sent out on Monday to all who received an approval during previous week
  - Standard questions (allow comparison over time) and selected misc. topics based need at the time
  - https://research.iu.edu/about/data-reports/service-survey.html

How Do We Do QI: Compliance

- 3W Committee: What Went Wrong
  - Sometimes referred informally to the WTF, WTH, or Oh @#$@! Committee
  - Very simple: Pull together and analyze as 'data' all non-compliance, protocol violations/deviations, adverse events, unanticipated problems etc.
  - Resulted in
    - Policy changes
    - Procedural changes
    - Educational outreach
    - Raising alarm with Dean, Assoc. Dean Research, Chair, etc.

How Do We Do QI: Compliance

◆ QI Reports
  ◆ Category of approval/determinations: properly determined and documented
    ◆ HSR: exempt, expedited, risk categories, vulnerable populations, waivers, etc.
  ◆ Minutes review
    ◆ Documentation audit for quorum, vote counts, expertise, determinations
  ◆ Flexibility review
    ◆ HSR: Federally funded not flexed
  ◆ Regulatory Review
    ◆ Random selection of studies for full audit based risk matrix
      ◆ Do not consider For Cause Audits to be QI per se

How Do We Do QI: Compliance

◆ EXERCISE
  ◆ How do you QI compliance?

How Do We Do QI: Data Quality

- Missing data
  - Ensure all data points captured in electronic system/files

- Expiring studies
  - Review of studies expiring in next few weeks
  - Ensure renewal in progress or confirm closure

- Electronic system review
  - Not yet submitted: created but never submitted for review
  - Pending submissions: electronic submission does not have corresponding entry in workload tracking system

- Determinations
  - All approved determinations in electronic record

How Do We Do QI: Data Quality

- EXERCISE
  - How do you QI data quality?

How Do We Do QI: Efficiency

- Maintaining metrics

- If we thought of it, we collect it (or are trying to think of a way to do so);
  - Turn around Time
  - Throughput
  - Touch times
  - Staff productivity
  - Staff responsiveness
  - Communications
  - What did we not think of?

How Do We Do QI: Efficiency

- What do we do with this?
  - Reviewing outliers
  - Noticing trends
  - Ad hoc reviews based on the above
    - What Happened?
    - Staff-researcher communications
      - Too many back and forth emails
      - Incomplete response to request for revisions

- https://research.iu.edu/about/data-reports/compliance/index.html

How Do We Do QI: Efficiency

◆ EXERCISE
  ◆ How do you QI efficiency?

And If We Don't

"With the money we'll save by shutting down quality control, we can issue some truly spectacular apologies."

Discussion and Questions?

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