Beyond Auditing and Monitoring and Towards Quality Improvement

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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?

**Today's 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?????

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](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: 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: 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](https://research.iu.edu/about/data-reports/compliance/index.html)
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?