

Beyond Auditing and Monitoring and Towards Quality Improvement

HCCA CI 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?????

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: 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>

And If We Don't



Discussion and Questions?

 INDIANA UNIVERSITY