Comparing Strategies: Traditional Research vs. Performance Improvement

Ventilator Associated Events as an Exemplar

Lynn E. Bayne, PhD, ARNP, NNP-BC

A Special Thanks...

- Jerry Castellano, BS, PharmD, CIP
  Corporate Director
  Institutional Review Board
  Christiana Care Health System

Fifty Shades (or More) of Gray: Determining What is and isn't Human Subjects Research
Introduction

- Activities or projects considered as **Performance or Quality Improvement/Quality Assurance** may be difficult to distinguish from **Research** requiring IRB approval.
- The distinction, however, is critical to the investigator and to the institution.

What is the IRB?

- Institutional review board serves:
  - To protect safety, rights, and welfare of human subjects
  - To guide by ethical standards:
    - **Respect** for persons
      - Recognizing autonomy, dignity
    - **Beneficence**
      - Protecting from harm, optimizing benefits
    - **Justice**
      - Fair distribution of benefits, burdens of research
  - As a resource to researchers
    - Educational mentoring
    - Guidance

What do you see?

Do you see gray areas in between the squares?  Now where did they come from?
Confusing similarities: Traditional research vs. PI

- May use of *same sources of information*
- May use of *similar analytic methods*
- May have *comparable conclusions*

What is research?

THE COMMON RULE
Office of Human Research Protection (OHRP)

*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

[45 CFR 46.102(d)]

What is NOT research?

- "...nonsystematic investigation..."
- Ad hoc efforts are not included
- Single case studies are not included
- Innovative ideas or procedures – new suturing techniques are not included
- "Practices" designed solely to enhance the well-being of an individual patient are not included
- Some surveys may not be included
Human subjects research: Defined

If an *intervention* is performed or if an *interaction* occurs that is out of the ordinary, AND/OR

Non-public information, data or specimens are obtained, used or recorded outside of the standard of care

WITH THE INTENT TO

Test an idea or *hypothesis* or amass knowledge

Attempt to draw a conclusion which may contribute to *generalizable knowledge* about whether one way of doing something is better than another.

Activities defined as *Research* often:

- Promote new and generalizable knowledge
- Show no particular, direct benefit to the population under study
- Subject the participants to *some additional risks or burdens* beyond usual clinical practice
- Invite critical appraisal of its stated conclusions by peers through *publication and debate* in the relevant body of literature

Activities defined as *Research* often:

“...including research development, testing and evaluation to develop or contribute to ...”

“...include pilot testing and evaluations”
Human subjects research: Defined

- is designed to:
  - Test hypotheses/objectives/questions
  - Require formal protocol and plan
  - Be built on procedures designed to reach objectives
  - Draw conclusions
  - Provide generalizable knowledge

What is NOT generalizable knowledge?

- "... is not generalizable knowledge."
  - Information expressed in theories, principles, and statements of relationships;
  - Excludes non-generalizable results;
  - Excludes organized processes to diagnose individual patients' conditions.

What is "generalizable"?

Purpose, design, and generalizability usually distinguish PI from research
Is it something other than research?

- Quality improvement
- Quality assurance
- Process improvement
- Program evaluation
- Public health surveillance
- Emergency response

That other something may have many names....

- Process management
- Performance improvement
- Lean manufacturing
- (Lean) Six Sigma
- Business process improvement
- Business process reengineering
- Hoshin Kanri
- ISO 9000
- Just In Time manufacturing
- Theory of Constraints
- Total Quality Management
- Trillium Model
- Twelve leverage points
- Capability Maturity Model Integration/ Capability Maturity Model

...And does that other activity need IRB approval???

Possibly YES
Maybe NOT
Purpose of performance improvement in healthcare:
- To determine quality;
- To improve patient services;
- To improve provision of healthcare at unit, institution, or system level of care;
- To motivate change of practice in a certain location;
  - Generally a defined institutional setting;
  - Procedures do not involve greater than minimal risk to patients;
  - Allow ongoing modification of project;
- To create a benefit for the majority of patients included in the data analysis.

Performance Improvement: Defined

Centers for Medicare and Medicaid Services definition...
- “...an assessment, conducted by or for a QI organization, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up”.
- A set of related activities designed to achieve measurable improvement in processes/outcomes.

Process Improvement (PI)

Process improvement is a series of actions taken to identify, analyze and improve existing processes within an organization to meet new goals and objectives. These actions often follow a specific methodology or strategy to create successful results.
Is it Research or QI?

Determining the difference between research and quality improvement.

**INTENT**

- Discovery of Knowledge
- Application of Knowledge

What determines gray area?

**MOTIVE**

- Discovery of Knowledge
- Needs of Patients or End Users

The timing of data collection—prospective or retrospective—often drives determination.

If you think you may want to publish, get IRB approval before gathering/looking at data!
**BENEFIT TO SUBJECTS**

Many argue that this area isn't so gray. Research needn't benefit anyone; QI should not only benefit those to whom performance improvement applied, but outcomes should translate much more quickly into improved practice.

**RISK OR BURDEN TO SUBJECTS**

This line isn't so gray, either. The more risk or burden to subjects, the more likely the activity is research and should be ethically reviewed. Some argue that QI should be reviewed when there is even minimal risk or burden.

**INFORMED CONSENT**

Other issues include deception (research) and voluntariness (QI is often required by job).
**VOLUNTARINESS**

- Required or waived only via regulatory and legal criteria.
- Sometimes participation in QI is required by one’s job.
- Some view research as optional activity; QI may be linked to survival of organization.

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**REWARD/RECOGNITION**

- Directly to people who conduct research.
- Indirectly by success of institution; QI may be conducted by external performers.

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**SOURCE OF DATA**

- Multiple organizations.
- Single organization.
OUTCOME MEASURES

- Study specific/or additional data beyond normal
- Routinely collected data

DEVIATION FROM PRACTICE

- Significant
- Minimal

EVALUATIVE CRITERIA

- Scientific rigor
- Process validity
Characteristics of Research vs. QI/QA/PI

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Research</th>
<th>QI/QA/PI</th>
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</thead>
<tbody>
<tr>
<td>To test a hypothesis or to establish clinical practice standards where none are already accepted</td>
<td>To assess or improve a process, program, or system OR to improve performance as judged by established/accepted standards</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Starting Point</th>
<th>To answer a question or test a hypothesis</th>
<th>To improve performance</th>
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<thead>
<tr>
<th>Benefits</th>
<th>Research</th>
<th>QI/QA/PI</th>
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<tbody>
<tr>
<td>May put subjects at risk</td>
<td>Knowledge sought directly benefits a process, program/system, and may or may not directly benefit patients</td>
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<table>
<thead>
<tr>
<th>Risks/Burdens</th>
<th>Research</th>
<th>QI/QA/PI</th>
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</thead>
<tbody>
<tr>
<td>May put subjects at risk</td>
<td>Does not increase risk to patients, with exception of possible privacy/confidentiality concern</td>
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</table>

<table>
<thead>
<tr>
<th>Data Collection</th>
<th>Research</th>
<th>QI/QA/PI</th>
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</thead>
<tbody>
<tr>
<td>Systematic data collection</td>
<td>Systematic data collection</td>
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<thead>
<tr>
<th>End Point</th>
<th>Research</th>
<th>QI/QA/PI</th>
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<tbody>
<tr>
<td>Answer a research question</td>
<td>Improve a process/system at CCHS</td>
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<table>
<thead>
<tr>
<th>Testing/Analysis</th>
<th>Research</th>
<th>QI/QA/PI</th>
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<tbody>
<tr>
<td>Statistically prove or disprove hypothesis</td>
<td>Compare a process/system at CCHS to an established set of standards</td>
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A Checklist

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Is the project primarily designed to test a specific hypothesis or answer a specific quantitative or qualitative question?</td>
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<tr>
<td>Does the project involve a comparison of multiple sites and/or control groups?</td>
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<td>Is the project designed to support generalizations that go beyond the particular population in the sample being drawn from?</td>
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<tr>
<td>Are patients or providers randomized into different intervention groups in order to enhance confidence in differences that might be obscured by nonrandom selection?</td>
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<tr>
<td>Does the project impose any additional risks or burdens on participants beyond what would be normally expected or normally experienced during the course of care, program participation, or role expectation?</td>
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<tr>
<td>Is the primary purpose of the project to produce the kind of results that could be published in a research journal?</td>
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<tr>
<td>Is there funding from an external organization based on support of a &quot;research paradigm&quot; to carry out the proposed activity?</td>
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<tr>
<td>Does the project seek to test interventions, care practices, or treatments that are not standard (Neither consensus-based, nor evidence-based)?</td>
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<tr>
<td>Will the project participants also likely be among those who might potentially benefit from the result of the project as it proceeds?</td>
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<tr>
<td>Is the project intended to develop a better practice within CCHS or your setting?</td>
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<tr>
<td>Would this project still be done at your site even if the results might not be applicable elsewhere?</td>
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<tr>
<td>Does the language used in the project description refer explicitly to features or a particular program, organization, or locale, rather than more general terminology such as rural vs. urban populations?</td>
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<tr>
<td>Is the current project part of a continuous process of gathering or monitoring data within an organization?</td>
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Research/QI Requiring IRB Approval

- Projects in which the primary objective is to generate generalizable knowledge for public dissemination, presentation and/or publication.
  - IF YOU PLAN TO PRESENT QI AT A CONFERENCE OR PUBLISH—GET IRB APPROVAL!
- All projects under the auspices of the FDA.
  - Experimental uses of approved or non-approved drugs, devices, biologics, in vitro diagnostics
- Program evaluations to test a not yet established program or intervention so that, if effective, it may be used in the future.

Research Requiring IRB Approval

- The research is conducted by or under the direction of any employee or agent of the institution, in connection with his/her institutional responsibilities.
- The research is conducted by or under the direction of any employee or agent of the institution using property, facility or personnel of the institution.
- The research involves the use of institutional, non-public information to identify or contact human subjects or prospective subjects.
Research Requiring IRB Approval

- The research involves the use of the institution’s internal registries, data repositories and electronic medical records.
- New, active patient interventions or prospective patient randomization study design (as opposed to only data collection and analysis).
- Data to be pooled outside of institutional boundaries.
- Medical record review by individual not involved in providing direct care.

Research NOT Requiring IRB Approval

- Data collection, analysis or release of data required by the institution to comply with external quality standards and clinical quality assurance requirements (ex: payers, government agencies, Joint Commission).
- Data collection, analysis or reporting of data for internal system initiated management or clinical initiatives to enhance or improve institutional performance.

Research NOT Requiring IRB Approval

- Surveillance projects involving regular, ongoing data collection and analysis of health related data to monitor disease occurrence, frequency and distribution in a particular population.
- Satisfaction surveys related to services rendered by the organization for Performance Improvement.
- Single clinical case report of provider’s own patient.
Considerations

- Any Research activity must receive appropriate IRB review and approval, in compliance with both Federal Regulations and institutional policies.

- A project may start out as Performance Improvement and, at any time, become a Research activity. It is the responsibility of the investigator to notify the IRB as soon as this is apparent.

Comparing Traditional Research to PI: Ventilator Associated Event

- Research
- PI

Conclusion

- Often difficult to distinguish Research from Performance Improvement
- Must consider intent of project
- Impact of HIPAA?
- The IRB reserves the right to review all research
  - Even that qualified for exemption from IRB review
  - To provide an additional measure for human subjects.
Performance Improvement vs. Research