Quality Assurance: When is it also research?

Background: Since the Belmont Report’s qualitative improvement in 1979, the report was revised in 1984 to add IRBs to the ethical review of research involving human subjects. In 1988, the US Department of Health and Human Services issued new regulations to implement these revisions. The purpose of these regulations was to ensure protection of human subjects by mandating the use of IRBs and other safeguards. However, there are still many challenges in determining what constitutes research and what constitutes QA/QI activities. Understanding the parallels between QA/QI activities and research is crucial for ensuring that the rights and welfare of human subjects are protected.

Federal Regulatory Definitions

- Research involves a systematic investigation, including testing and validating hypotheses, of the potential applications and effects (positive and negative) of interventions, procedures, and medical and public health strategies.
- QA/QI activities are designed to ensure the quality and effectiveness of healthcare services and programs, rather than to advance new knowledge. They are typically performed on existing data or procedures, rather than creating new data or procedures.

Hypothesis: Research involving retrospective chart reviews is considered research (45CFR46.102(e)) but QA/QI projects are considered quality assurance activities (not research) (45CFR46.102(d)). It is important to distinguish between research and QA/QI activities, as QA/QI activities are not subject to the same level of oversight as research.

Parallels:

- **QA/QI Project** vs. **Research Project**
  - QA/QI projects are designed to improve the quality and efficiency of healthcare services, while research projects are designed to advance new knowledge.
  - QA/QI projects are typically performed on existing data or procedures, rather than creating new data or procedures.
  - QA/QI projects are not subject to the same level of oversight as research projects.

Scenario A: Non-Research QA of IV Catheters

- The QA department is asked by the medical staff to do a QA review of IV catheter types 1 and 2 that are in common use in the hospital and hospital IV pharmacy. The QA nurse is responsible for collecting and reviewing data on the IV catheters to determine if any improvements can be made.

Scenario B: Research QA of IV Catheters

- The QA department is conducting a research project to investigate the effectiveness of IV catheter types 1 and 2 in the hospital and hospital IV pharmacy.

The key difference between the two scenarios is the purpose of the investigation. In Scenario A, the purpose is to improve the quality and efficiency of healthcare services, while in Scenario B, the purpose is to advance new knowledge.

Conclusion: QA/QI activities are essential to ensure the quality and efficiency of healthcare services, but they are not considered research. However, QA/QI activities that meet the federal definition of research may be subject to oversight by IRBs to ensure that the rights and welfare of human subjects are protected.

(45CFR46.102(e)) – The Six Exempt Research Categories

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as classroom teaching.
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(45CFR46.101(b)) – The Six Exempt Research Categories

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