Quick Reference Guide:
Quality Work or Research?

Definition of Research

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102(l))

General Characteristics of Quality Improvement vs. Research

Quality Assurance or Improvement	Research
• Identify issue and implement change according to mandates of hospital's Clinical QI program • Improve process or delivery of care with established/accepted methods • Implement systematic monitoring to ensure existing quality standards are met • All participants receive standard of care • Improve performance in a specific program	• May be funded by an external research agency • Answer a research question/tests a hypothesis • Uses research design: Group comparisons, randomization, control groups, prospective comparison, cross-sectional, case-control, etc. • Develops new paradigms or untested methods, establishes a new clinical practice standard • Follows a protocol that overrides clinical decision-making • Develop or contribute to generalizable knowledge

Examples

Quality Improvement	Research
Developing an outreach process to facilitate scheduling follow-up appointments for patients with blood pressure readings above goal, and measuring the percentage of follow-up visits scheduled before and after the intervention.	Randomizing patients who have blood pressure readings above goal at a primary care visit to receive either an email reminder or a phone call reminder in order to determine which method results in a higher percentage of patients scheduling a follow-up appointment.
Quality Improvement	**Research**
Hospital implements a procedure known to reduce pharmacy prescription error rates and collects prescription information from medical records to assess adherence to the procedure and determine if error rates have decreased as expected.	Investigators conduct focus groups and individual interviews with pharmacists at various hospitals in order to analyze likely causes of prescription errors in different types of hospital settings.

FAQs about Quality Improvement Projects

What is Quality Improvement and Quality Assurance?

Quality Assurance (QA) and Quality Improvement (QI) are complementary endeavors for attaining continual improvement in health care quality. They should present no risk to patients and involve the collection and analysis of data to which the investigators have legitimate access through their institutional roles.

QA can be defined as an effort to find and overcome problems with quality; directing the performance and behaviors of practitioners and institutions toward more appropriate and acceptable health outcomes, expenditures, or both. The central QA question is reactive, "Are we doing a task/procedure the way it is supposed to be done?"

QI activities are intended improve services or clinical care based on a known issue through a "plan, do, check, act" cycle. With this cycle, processes can be continuously revised and improved on the basis of the data derived from them. The central QI question is proactive, "How can we improve the way we do things?".

QA may entail comparing an internal program, process, or system to established standards outside of the organization. QI is the process of bringing Carilion up to that standard.

QA/QI work is not intended to be generalizable outside of the institutional setting.

How does it differ from research?

The difference between QA/QI and research is that **research is intended to be generalizable**, in that it is intended to have benefit to society outside of the institution. This is done through asking a new question or revising a question to try to advance knowledge. This may include assessing efficacy (prospectively or retrospectively) of a drug or determining whether the PCA pump light being always turned on leads to patients pressing the pump button more frequently.

If we want to publish our QI project, is that research?

Sometimes.

Usually, when you systematically collect information with intent to generalize the results to those outside your local environment, the project is research. The intent to publish can be an indicator that you intend to develop or contribute to generalizable knowledge. **However, it is possible to conduct a QI project that is specific to a local or very limited context and publish the results as an example for others to learn from without the project meeting the definition of research**. The data published under QI would be along the lines of a case study. "Here was the identified problem within our institution, and here is how we attempted to correct it".

It is also possible that a project is research even if there is no intent to publish.

Do quality improvement activities fall under the HHS regulations for the protection of human subjects in research (45 CFR part 46) if their purposes are limited to: (a) delivering healthcare, and (b) measuring and reporting provider performance data for clinical, practical, or administrative uses?

No, such quality improvement activities do not satisfy the definition of "research" under 45 CFR 46.102(d), which is "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge…" Therefore the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

The clinical, practical, or administrative uses for such performance measurements and reporting could include, for example, helping the public make more informed choices regarding health care providers by communicating data regarding physician-specific surgical recovery data or infection rates. Other practical or administrative uses of such data might be to enable insurance companies or health maintenance organizations to make higher performing sites preferred providers, or to allow other third parties to create incentives rewarding better **performance.**

What if I started a QI project, then the results were really interesting, and now I think the knowledge we are gaining might be generalizable, so I want to publish? I didn't have IRB approval when I started. What should I do?

Stop working on the project and evaluate whether your goal has changed from a local improvement project to a generalizable systematic evaluation (in other words – it's now research). If so, you need IRB approval before continuing with the project and need to submit an application to the IRB.

If you are unsure of whether you need IRB approval, submit a Determination Application. The IRB will determine whether your project qualifies as human subjects research, and if so what level of review/oversight is required. Once this is completed, you can proceed with the project.

Another Example involving central line infection rates:

QA (a made-up example): Central line infection rates at Carilion are 3x higher than the national average. Do physicians and nurses know best practices to reduce infections? Are most infections happening in one unit or across all units?

QI: How can we reduce central line infections? Let's add some interventions such as placing insertion checklists in each patient's room. The checklist will including reminders for best practices known to reduce infections, and we will also add in provider education. We will then reassess infection rates every 2 weeks. If infection rates don't drop, education for providers surrounding ultrasound-guided placement will be implemented, and then we again will reassess rates.

Research: Which skin antisepsis prior to insertion of a central line is superior for reducing infections?

- Patients will be randomized to one of three methods of skin disinfection and we will then collect the data to see if one group has less infection when all preparations for central line insertions are otherwise the same.
  OR
- A retrospective chart review will be conducted. Since certain providers have a preference for specific antisepsis, we will compare the rates of infection between the different methods of antisepsis.

See Also: FAQs about Quality Improvement Activities from the Office for Human Research Protections (OHRP): https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html

If there are any questions, please contact the IRB at IRB@carilionclinic.org.