

Quality Improvement Projects

Introduction and Guide

Quality Improvement projects are “systematic data-guided activities designed to bring about immediate positive changes in health delivery in particular settings” (1). The Federal Government defines research as “*systematic* investigations *designed* to develop or contribute to *generalizable* knowledge” (45 CFR 46.102(d)). Further, human subjects research is that research that involves “*obtaining information about living individuals*” (45 CFR 46 102(f)).

Because both quality improvement and research activities require systematic collection of data and may involve human subjects, it is easy to see how the two can overlap. In fact, one can even do research on quality improvement! From the definitions above, however, you can see one key difference between research and QI: research projects produce information that is generalizable to other patients or settings, whereas QI is focused on the processes in a particular setting.

The desire to publish is not a criterion used to differentiate QI from research. Researchers have an obligation to report their results; however, QI champions should also disseminate their findings as an example of how to tackle a quality issue.

When a project involves systematic collection of data on human subjects, it is prudent to have the IRB review the project to help make the determination if the project is considered research or not. At this time, per government guidance, this distinction should not be made by the investigator/quality champion, but by the IRB.

The table below summarizes some of the characteristics that differentiate quality improvement from research (2):

	Research	Quality Improvement
Purpose	Develop or contribute to generalizable knowledge	Implement knowledge, assess a process or program as judged by established/accepted standards
Starting Point	Knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis	Knowledge-seeking is integral to ongoing management of the system of delivering health care
Design	Follows a rigid protocol that remains fundamentally unchanged during the research	May have an adaptive, iterative design
Benefits	Might or might not benefit current subjects; intended to benefit future patients	Directly benefits a process, system or program; might or might not benefit patients
Risks	May put subjects at risk	Does not increase risks to patients, with exception of possible patients' privacy or confidentiality of data
Participant obligation	No obligation of individuals to participate	Responsibility to participate as component of care
Endpoint	Answer a research question	Improve a program, process or system
Analysis	Statistically prove or disprove hypotheses	Compare program, process or system to established standards
Publication/Presentation	Investigator obliged to share results	QI practitioners encouraged to share systematic reporting of insights

The Model for Improvement (MFI) is one tool for executing improvement (3). It has two parts:

- **Three fundamental questions:**
 1. What are we trying to accomplish?
 2. How will we know that a change is an improvement?
 3. What change can we make that will result in improvement? and
- **The Plan-Do-Study-Act (PDSA) cycle for testing changes.**



Applying the MFI requires the following steps: Set an aim, establish measures, identify changes, test changes, implement changes.

The research protocol outline that we use at Ascension St. John Hospital can be easily adopted to be a QI protocol. Instead of a research question, you will have a project aim or objective. The methods section will include how you are going to assess the performance issue, what you will do to address the performance issue and how you will measure if your intervention led to improvement. Instead of “predicted results”, you will have “next steps”.

1. Introduction and Background: Identify what process you are trying to improve, why it is important and how others may have tried to address this issue in the past. A brief review of the literature and the current status should be discussed here. (Plan)
2. Project Objective or Aim: What are you trying to accomplish? (Plan)
(QI projects do not have hypotheses)
3. Methods: (Do, Study)
 - How will you measure the current problem?
 - What is your intervention to address the problem?
 - How will you measure whether the intervention worked?

- Who will be the participants?
 - How many people will participate? If you need to review charts, how many charts will you review?
 - How will you analyze the data to show whether there was an improvement or not?
4. Next Steps: (Act)
- How will you maintain the improvement?
 - If you did not see improvement or enough improvement, what would be then next step?

To avoid confusion, steer clear of these words: research, study and hypothesis. Instead, think in terms of quality improvement, program, quality initiative, aim, objective, practice gap and performance measure.

References:

1. The Hastings Center. The ethics of using QI methods to improve health care and safety. Hastings Center Report; 2006 July-Aug: S1-40.
2. Children's Hospital of Philadelphia. Quality improvement versus research. <https://irb.research.chop.edu/quality-improvement-vs-research>
3. Institute for Healthcare Improvement. QI 102: how to improve with the model for improvement. IHI Open School course materials. <http://app.ihi.org/lmsspa/#/1431fa43-38e4-4e40-ab3b-7887d3254f72>