

Research versus Quality Improvement in Healthcare

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We are pleased to publish the second issue of the *Global Journal on Quality and Safety in Healthcare* (JQSH). In this issue, we would like to discuss the similarities and differences between research and quality improvement (QI) projects in health care. Imagine you are working in a hospital or a department within a hospital and you want to improve an aspect of health-care quality and safety by focusing on the issue of medication errors. Given that situation, you decide to implement a “zero harm” rule because of medication errors. The question is will this be a QI or a research project? In another example, you are a resident working in an oncology department and you noticed that most patients receiving certain chemotherapeutic agents had neuropathy complications, so you decided to collaborate with the physical therapist on a project to compare patients who received chemotherapy drugs and exercise with those who did not exercise. Again, the question is will this be a research project or a QI project? Regardless of the answer, it is important to implement the project systematically. If your project is focused on QI, then you should consult the QI specialists in your hospital who can help you to use the appropriate QI methodology, which includes Plan, Do, Study, Act (PDSA) cycles. If your project qualifies as research, then you should consult a research methodologist and biostatistician regarding study design, sample size, and others and work with the institutional review board (IRB) to provide guidance and templates.

Many health professionals do not know how a research project differs from a QI project and when they complement each other.^[1-3] Our traditional thinking is that quality and safety improvement in health care as well as the effectiveness of an intervention can only be studied in the form of a traditional scientific research project, as it has its own well-established rigorous approach. We may be ignorant or unaware of how to use the QI scientific approach to study the performance of a health-care system.^[4,5] The problem lies within our frame of thinking

because we are prioritizing the proof of effectiveness over bringing about and sustaining improvement. We use the results of pre-assessment and post-assessment research as the gold standard for evidence-based policy and practice, whereas in reality, sustaining the improvement is continuous and more dynamic.^[1,6]

Research projects are question-driven and focus on providing proof of effectiveness. The main purpose of research is to generate new generalizable knowledge about a particular subject to a study population, where the study results often end up published in academic journals. In this case, researchers must follow a strict study protocol approved by the IRB, including obtaining the consent from study participants before starting the project and report any deviation from the protocol to the IRB, if needed.^[7-9] However, QI projects are data-driven and focus on showing sustained improvement to a specific process and system or outcomes within a health-care organization using, if possible, the research evidence generated as the basis for developing the improvement interventions.^[10] A QI project does not aim to generate new knowledge as a research project does, rather, it generates several learning lessons as to what actually works and does not work and why. A QI project produces empirical evidence to benefit other organizations within a similar context and setting, which are interested in replicating the change to improve a process or system using the rapid PDSA cycle approach.^[11] Through cycles of testing, we learn what is going to improve and why, without the need to generalize the results to another context, as research projects usually aim to do. Also in QI projects, the measurement framework is not about pre and post. It is about continually measuring the metric of interest that you want to improve and coming up with not

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Table 1: Comparison of quality improvement and research projects in health care

Aspect of the project	Quality improvement project	Research project
Aim	Improvement of patient-care or health-care process	Generate new knowledge
Study design		
Hypothesis	Flexible hypothesis, changes as learning takes place	Fixed hypothesis
Test observability	Test is observable	Test is blinded or controlled
Bias	Accept consistent bias	Design to eliminate bias
Sample size	“Just enough” data; small sequential samples	“Just in case” data
Testing strategy	Sequential tests (Plan, Do, Study, Act cycles)	Single test
Data analysis	Run charts/Shewhart control charts to measure quality improvement metrics	Statistical tests (<i>t</i> -test, <i>F</i> -test, chi-square test) for significant differences (<i>P</i> -values)
Data confidentiality	Data used only by those involved with quality improvement	Research subjects’ identities are protected

just one intervention but multiple interventions based on learning from prior PDSA cycles. At the end, you reach the point of realizing sustained improvement through a series of interventions that were informed by testing in the actual system that you want to improve. The PDSA cycle is repeated, and new changes are made to continue to improve a process and, ultimately, the outcome. The essential measurements included in a QI project are process measures, outcomes measures, and balancing measures, which are used to show that the improvement occurs over time. Data from QI activities are usually aggregated and presented in run/control charts, histograms, and line graphs, whereas data from research are analyzed using statistical tests such as *t*-test, chi-square test, and regression analysis, and then aggregated and presented in appropriate tables and/or graphs.

Typically, QI results are shared within the organization and might be implemented in other departments. The lessons learned from QI activities can be published; however, it must be clear to the readers that the project was for QI, not traditional research. Although a QI project does not require IRB approval, some organizations have QI committees that approve and coordinate QI project activities, and some organizations require articles to be approved before submitting for publication.

In summary, the sustained improvement realized in a QI project can be complemented and validated with a thorough research-based assessment of effectiveness.^[12] We should not consider the proof of effectiveness the same as the proof of sustained improvement, but they both are very important. I would like to emphasize that both research and QI projects use scientific and systematic approaches, albeit different, but both methods are scientific and rigorous in their own ways. The aims, methods, and outcomes in research and QI projects are quite different. Hence, understanding the differences and similarities between research and QI projects will help to determine the right approach when designing and implementing the right project for the right purpose using the right method. Table 1 is a snapshot comparison between QI and research with more focus on the project’s aim and method aspects.

In research projects, we can be guided by asking the following:

- Do we have a clear question to be investigated and answered?
- What do we hope to accomplish by answering the question?
- What is currently known about the topic?
- What are the risks and benefits for patients involved with the study of this topic?
- What type of study design will be used (observational vs. experimental)?
- How will the data be analyzed and presented (statistical tests, *P*-values, etc.)?

In QI projects, we can ask the following:

- What is the magnitude of the quality problem based on available data?
- What types of quality tools have been used to measure and assess the problem?
- What is the measurement plan to be used during implementation of the project?
- What types of changes/interventions will be tested during the PDSA cycles?
- Has the proposed change/intervention been used in other health-care settings or reported in the literature?
- Will the results of this project directly improve patient-care outcomes or processes?
- Is the organization’s management supportive of the project and willing to dedicate employee’s time and supplies to do the project?
- What is the sustainability plan for the results?

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