Quick Reference Guide:
Quality Improvement or Research?

In the era of quality improvement, questions about the line between QI and research come up frequently. This guide is a supplement to HRP-421 WORKSHEET – Human 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(d))

General Characteristics of Quality Improvement vs. Research

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

Examples

<table>
<thead>
<tr>
<th>Quality Improvement</th>
<th>Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>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.</td>
<td>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.</td>
</tr>
</tbody>
</table>
FAQs about Quality Improvement Projects

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

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 a New Study to the IRB.

If you are unsure of whether you need IRB approval, submit a Request for Determination. 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.

See Also: FAQs about Quality Improvement Activities from the Office for Human Research Protections (OHRP): http://answers.hhs.gov/ohrp/categories/1569.
**ACT**
- What changes are to be made?
- Next cycle?

**PLAN**
- Objective
- Questions and Predictions (why)
- Plan to carry out the cycle (who, what, where, when)

**STUDY**
- Complete the analysis of the data
- Compare data to predictions
- Summarize what was learned

**DO**
- Carry out the plan
- Document problems and unexpected observations
- Begin analysis of the data
The Scientific Method as an Ongoing Process

1. **Make Observations**
   - What do I see in nature? This can be from one's own experiences, thoughts, or reading.

2. **Think of Interesting Questions**
   - Why does that pattern occur?

3. **Formulate Hypotheses**
   - What are the general causes of the phenomenon I am wondering about?

4. **Develop Testable Predictions**
   - If my hypothesis is correct, then I expect a, b, c,....

5. **Gather Data to Test Predictions**
   - Relevant data can come from the literature, new observations, or formal experiments. Thorough testing requires replication to verify results.

6. **Refine, Alter, Expand, or Reject Hypotheses**

7. **Develop General Theories**
   - General theories must be consistent with most or all available data and with other current theories.
**Defining Terms**

**Quality Improvement:** the process by which practitioners improve practice by applying currently accepted high level of evidence-based practice

**Research:** the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions

**Research Question:** directs and grounds your idea and should be clear and focused

**Hypothesis:** explanation for the occurrence of certain behaviors, phenomena, or events; a prediction of research findings

**Construct:** an abstraction that cannot be observed directly; it is a concept invented to explain behavior

**Quantitative Research:** the collection and analysis of numerical data to describe, explain, predict, or control phenomena of interest

**Qualitative Research:** the collection, analysis, and interpretation of comprehensive narrative and visual data to gain insights into a particular phenomenon of interest

**Independent Variable:** a behavior or characteristic under the control of the researcher and believed to influence some other behavior or characteristic (X)

**Dependent Variable:** the change or difference in a behavior or characteristic that occurs as a result of the independent variable (Y)

**Nominal Variable:** level of measurement where values represent qualitative differences (categorical)

**Ordinal Variable:** level of measurement where data are ordered or ranked

**Interval Variable:** level of measurement where the distance between score points is uniform, but the zero point on the scale is arbitrary (continuous)

**Ratio Variable:** level of measurement where scale has a true zero

**Descriptive Statistics:** a collection of statistical procedures used to summarize a sample of data, and includes measures of central tendency, dispersion, or variability, and shape

**Inferential Statistics:** used to make inferences about parameters, based on the statistics from a sample

**Power:** refers to the ability of a significance test to identify a true research finding

**Statistical Significance:** refers to the probability that the results would have occurred due to chance

**Effect Size:** a numerical expression of the strength or magnitude of a reported relation
Research Questions

• If participants are given __________, then their __________ will increase/decrease/stay the same.

• What is the relationship between _______ and ________?

• Is there a difference in ________ based on ________?

• Does the difference in ________ vary by ________ and/or ________?

• Is there a difference in ________ based on ________ while controlling for ________?

• How do ________ vary over time?

• How does ________ vary by ________ over time?

• To what extent are _______ and __________ predicted by ________?
Choosing Statistical Analyses Decision Tree

Level of measurement of the DV?
- Nominal or Ordinal
- Interval or Ratio

Are IVs/Predictors Categorical or Continuous?
- Categorical
  - Analysis of Frequencies (Nominal):
    - Chi-Square
    - Phi Coefficient
  - Analysis of Ranks (Ordinal):
    - Wilcoxon*
    - Mann-Whitney*
    - Kruskal-Wallis*
    - Friedman ANOVA*
- Continuous (or combination)
  - Correlation-Based Analyses:
    - Spearman Correlation
    - Logistic Regression*
  - Means Comparisons:
    - Independent t-test
    - Dependent t-test
    - ANOVAs

Are IVs/Predictors Categorical or Continuous?
- Categorical
- Continuous (or combination)
  - Correlation-Based Analyses:
    - Pearson Correlation
    - Bivariate Regression
    - Multiple Regression

Non-Parametric Analyses

Note. To choose among the various analyses listed in the bottom level (yellow boxes), you will need to determine (a) how many independent variables/predictors (and levels of each) are involved, and (b) whether each independent variable/predictor is a between subjects or within subjects variable.

* Analyses marked with an asterisk are included only as a reference. These analyses are typically not covered in our curriculum.
References


