

Planning Your Research Series From Question to Analysis

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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

Quality Improvement

- 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

Research

- 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

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.

Research

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

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.

Research

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

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?

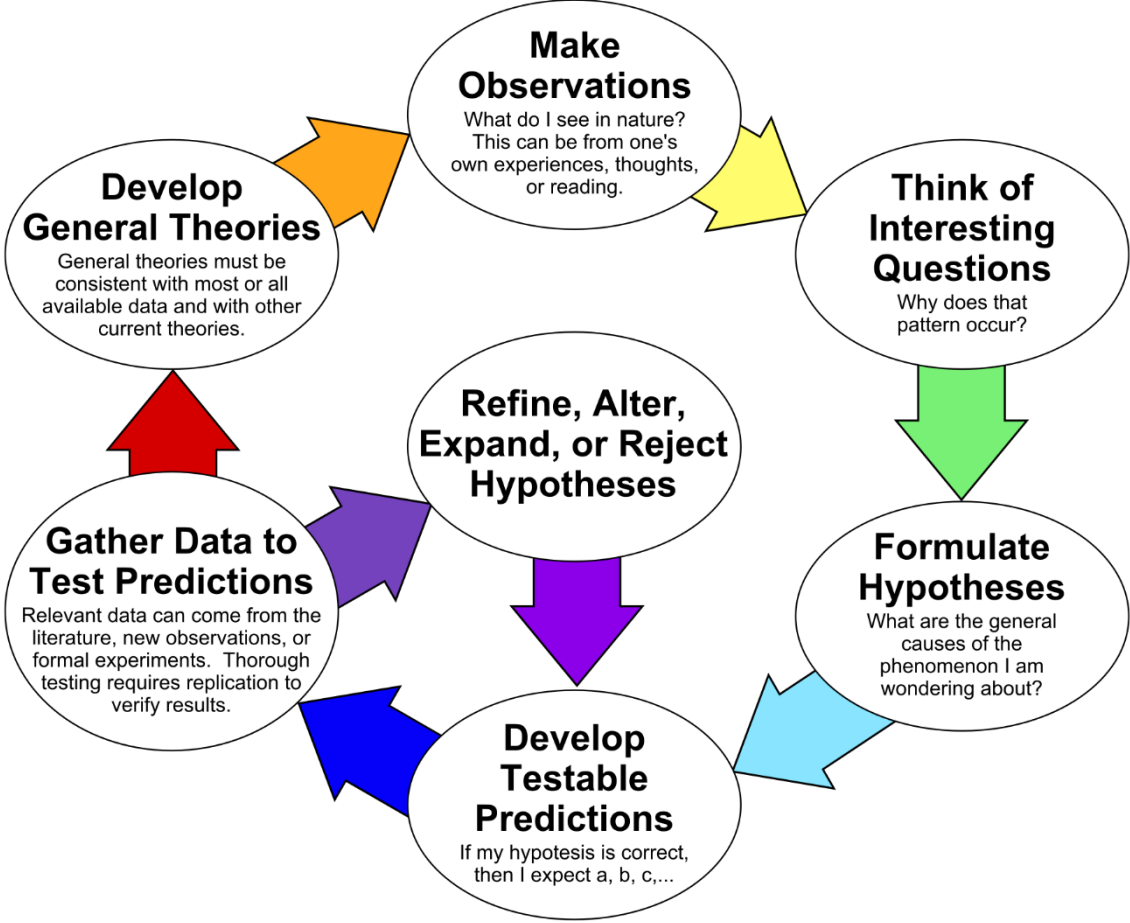
Stop working on the project and evaluate whether your goal has changed from a local improvement project to a generalizable systematic evaluation (in other words – it's now research). If so, you need IRB approval before continuing with the project and need to submit a New Study to the IRB.

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>.



The Scientific Method as an Ongoing Process



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

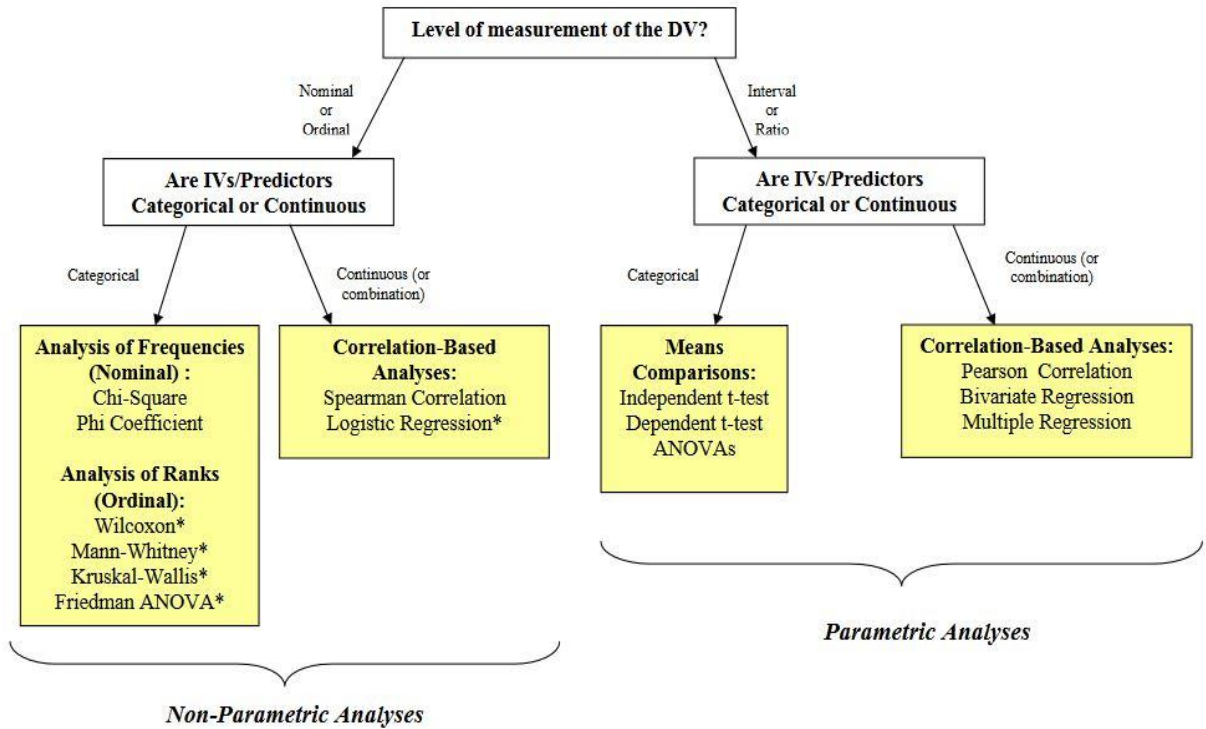
Statistical Significance: refers to the probability that the results would have occurred due to chance

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 does _____ vary over time?
- How does _____ vary by _____ over time?
- To what extent are _____ and _____ predicted by _____?

Choosing Statistical Analyses Decision Tree



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.

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