Research and Quality Improvement:
Data-Driven Methodologies and Practical Applications

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Today's Objectives

- Briefly compare and contrast quantitative research studies versus quality improvement projects.

- Apply qualitative and quantitative research methodologies using an SDoH case study example.

Research Versus Quality Improvement

Many things in common:

✓ Both seek to discover something new.

✓ Both require planning and organization.

✓ Both analyze/examine the data in some structured manner.

☞ *The differences lie in **how** these areas are interpreted and carried out.*

Key Terms and Concepts

Quantitative Research	Quality Improvement
Designs and categories	*PDCA methodology*
Sample group (representativeness and statistical power)	*Sample groups (representativeness and "just enough data")*
Primary and secondary outcomes	*Process and outcomes*
Type of data needed for inferential statistical comparisons	*Type of data needed for process analysis and outcome assessment*

Summary:
Research Designs & Categories

Meta Analysis

Interventional

- *Randomized control trial*
- *Quasi experiment*

Observational

- *Prospective cohort study*
- *Retrospective study (chart review)*
- *Cross-sectional study*

Quality Improvement
PDCA Methodology

- **Plan:** *What's the problem, and what might be causing it?*

- **Do:** *How can we solve the problem, and what should we do to implement our solution?*

- **Check:** *Is our solution working? How do we know?*

- **Act:** *How can we adopt and fully implement the solution for all stakeholders, as well as monitor its effectiveness over time (or make changes if things didn't work well)?*

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Research Sample Groups

- **Goal #1**: Get a representative "slice" of the bigger patient population.

  - ✓ Sample representativeness depends on *1) the selection process 2) the number of people*

- **Goal #2**: Make sure the representative population "slice" is large enough to ensure accurate statistical comparisons (*i.e., statistical power*).

  - ✓ To do this, you must first define the **effect size** (size of the difference between groups) you want to detect

  - ✓ This should come from *previous literature (best option),* your own *small pilot study (Plan B)*, or determination of the *smallest clinically meaningful difference (Plan C).*

Quality Improvement Sample Groups

- **Goal #1**: Choose a subset from the larger population (e.g., "cardiovascular surgery patients") that is representative and generalizable.

- **Goal #2**: Obtain *"just enough data"* to understand and track performance.

Quality Improvement Sample Group Types

- **Systemic**: Collect data at set times or intervals (*e.g., every hour, every fourth patient*)

- **Block**: Choose sampling units based on a prespecified size, or block (*e.g., the next 10 patients*).

- **Short survey**: Provide simple, prompt feedback about whether improvement efforts are "working".

Quick Comments about Surveys

- **Less is more**—include the smallest number of questions that will adequately address your content areas.

- **Pilot test for face and content validity** with a small group of participants.

  - ✓ *Face validity: Do the questions appear to measure what they're supposed to? Or will people be confused about what you're measuring, and why you're doing it a certain way?*

  - ✓ *Content validity: Do the questions cover all of the relevant topics for a specific construct (e.g., "emotional intelligence")?*

Quick Comments about Surveys

- **Expect some degree of selection bias** because survey response rates are notoriously poor (even when you include a large participant group).

  - ✓ *Consider offering incentives if feasible (although this can create its own biases).*

- **Online surveys** are most efficient—protect confidentiality by assigning a unique, random survey link/code to each participant; preventing IP addresses from being captured; and avoiding asking for names or email addresses.

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Research Outcomes

- **Primary**: The main outcome(s) for which the study sample size has been calculated based on a defined effect size.

- **Secondary**: Additional outcomes of interest that must be validated as primary outcomes through additional research.

Quality Improvement Process & Outcomes

- **Process**: What are the different sources of influence, and how does everything fit together?

  - ✓ *Flow charts, fishbone diagrams, run and statistical control charts, etc.*

- **Outcomes**: What are we trying to measure *(e.g., patient falls, complications, mortality rates),* and how does the process impact this *(both before and after our QI project implementation)*?

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Research Data Types

- **Continuous/ratio:** Passes the "ruler test" *(e.g., height, BMI, fasting glucose, length of stay)*

- **Ordinal:** Ranked values from lowest to highest *(e.g., patient pain from 0-10)*

- **Categorical:** Grouped values *(e.g., biologic gender, smoking status, 30-day mortality)*

  ☞ ***Key point: The type of data drives the choice of statistical analysis.***

Quality Improvement
Data Types

- Can be continuous/ratio, ordinal or categorical (similar to research data types).

- However, ***the specific type of data is less important than defining and analyzing process-outcome relationships (e.g., flowcharts, fishbone diagrams, statistical control charts).***

- Determining statistical significance with p-values may be inaccurate because of limited sample size (Type II error).
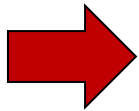
SUMMARY OF KEY DIFFERENCES

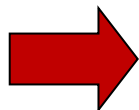| Quantitative Research	Quality Improvement
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Sample groups should be representative and large enough to ensure *adequate statistical power for detecting an effect size*	*Sample groups* should be representative using *"just enough data" to meet objectives*

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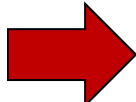| Quantitative Research	Quality Improvement
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Primary outcomes = main focus Secondary outcomes must be validated in future studies	Focus on relationship between process and outcomes
Type of data determines *which inferential statistical methods to use for significance testing (i.e., Type I error rate, p-value)*	Type of data is *less important than defining and analyzing process-outcome relationships*
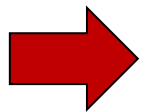
GENERAL SUMMARY

- **Quantitative research** = more rigidly defined, with specific rules and standards for hypothesis testing *(e.g., effect size, adequate statistical power, appropriate sample size, correct statistical test for the data, determining statistical significance)*

- **Quality improvement** = more fluid/flexible and focused on process-outcome relationships *(e.g., use of PDCA methodology with "just enough" data)*

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Quantitative versus Qualitative Research

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Source: https://www.simplypsychology.org/qualitative-quantitative.html

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Required minimum sample size to ensure adequate statistical power/lower Type II error	*No required minimum sample size*

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Required minimum sample size to ensure adequate statistical power/lower Type II error	No required minimum sample size
Statistical analysis of data to determine cause and effect or correlation	***Non-statistical grouping of data into common themes/categories***

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Keep in Mind

- Both quantitative and qualitative research can be incorporated into multiple settings, including educational and healthcare environments.

- **These two types of research don't have to be mutually exclusive**—they each add important sources of information to a project (i.e., mixed-methods study).

  - ✓ *Example #1: Use the descriptive, thematic-based results of qualitative research to help generate testable hypotheses for quantitative research.*

  - ✓ *Example #2: Following the quantitative research study, obtain qualitative descriptors/themes to provide greater richness and depth to the outcomes analysis.*

Social Determinants of Health (SDoH) Example: Qualitative Research

- **Objective:** *Determine barriers to adopting healthy lifestyle habits amongst lower-income adults.*

- **Suggested methodologies:**

    1. *Work with a team to **develop a limited set of questions** (around 5-10) **that will meaningfully address the objective** (i.e., identifying barriers to adopting healthy lifestyle habits).*

    2. *Invite a **small group of patients to participate** (maybe 10-20) based on pre-defined inclusion criteria.*

    3. *Conduct both **individual interviews and focus groups**, carefully **transcribe the responses**, then **categorize responses into common themes**.*

Social Determinants of Health (SDoH) Example: Quantitative Research

- Based on qualitative study results, two identified themes = 1) uncertainty about what to do, and 2) feeling overwhelmed by all the different options.

- **Quantitative study objective:** *Evaluate the effectiveness of an assigned health coach (intervention) on lower-income adults' adoption of healthier eating habits (part 1) and exercise behaviors (part 2).*

  - Might be more feasible to divide study into two parts, given financial, human resource, and/or time constraints.

Social Determinants of Health (SDoH) Example: Quantitative Research

- **Suggested methodologies:**

  1. ***Hire and train health coach(es)*** *using a standardized template for delivery of the intervention.*

  2. *Work with team to **develop a set of knowledge and attitude questions** (10-20) **that objectively measure the outcome** (i.e., effectiveness of health coach).*

     - ✓ ***Make sure the questions have adequate face and content validity**—do the questions reflect what they're supposed to, and at a lower reading grade level?*

  3. *Define **other outcome measures to capture "effectiveness"** (e.g., BMI, lab values).*

  4. *Determine **how often to obtain outcome measurements**.*

Social Determinants of Health (SDoH) Example: Quantitative Research

5. *Enroll participants based on **pre-defined inclusion criteria** (and **previous sample size calculation** to ensure adequate statistical power from data analysis).*

6. *Try to include a **comparison group that only gets standard of care office visits** (no health coach).*

   ✓ *Although random assignment to groups is best, this may not be feasible—if not, could consider a quasi-experimental design with Clinic A (intervention) and Clinic B (standard of care).*

7. *Collect **pre-intervention data from both groups** (including demographic information, knowledge questions, and physical data).*

Social Determinants of Health (SDoH) Example: Quantitative Research

8. *Create **Excel spreadsheet** with one row per participant and one column for every point of measurement (demographics and outcomes).*

9. *Upon study completion, statistically analyze the data.*

   ✓ *Consider **controlling for variables other than the intervention** (e.g., age, gender identity, race/ethnicity) to tease out contributing and/or confounding effects.*

   ✓ *This is **especially important for non-randomized participant groups.***

10. *Try to **collect follow-up data over time** (e.g., one year after study completion) to assess sustainability.*

Questions or Comments?