Research and Quality Improvement: Methodologies, Data Analysis, and Applications

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Today's Objectives

- Compare key terms and concepts in quantitative research studies versus quality improvement projects.
- Review data analysis tools and techniques in quantitative research studies versus quality improvement projects
- Discuss how to conduct a quantitative research study versus quality improvement project using a clinical example.
- Contrast qualitative and quantitative research using an SDoH case study example.

What is the Difference Between "Research" and "Quality Improvement"?

- **Research: definition** *(Webster's dictionary):*
  - ✓ "Careful or diligent search"
  - ✓ "Studious inquiry or examination; *especially* investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws"
  - ✓ "The collecting of information about a particular subject"

What is the Difference Between "Research" and "Quality Improvement"?

- **Quantitative research and hypothesis testing**
  - ✓ Null hypothesis
  - ✓ Alternative hypothesis
  - ✓ Test criterion
  - ✓ Decision rule

What is the Difference Between "Research" and "Quality Improvement"?

- **Quality Improvement: definition**

  (National Association for Healthcare Quality, http://www.nahq.org)

  - ✓ "…find processes that will work in actual practice, so the activities and solutions are less formal and more focused on a specific setting and set of variables than traditional research"

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*

Key Terms and Concepts

Quantitative Research	Quality Improvement
Designs and categories	*PDCA methodology*

Research Design Types

- **Observational** = no intervention, just observing what naturally occurs

- **Interventional** = actively intervening to determining cause-and-effect relationships

Research Categories

Meta Analysis

Interventional

- *Randomized control trial*
- *Quasi experiment*

Observational

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

Research Designs and Categories

1. Meta analysis

- ✓ "Doing research about research"; often used to examine causal relationships.
- ✓ Combining different studies statistically to obtain a comprehensive estimate of the treatment effect.
- ✓ *Example: Determine long-term risk of oral contraceptive use on breast cancer in the absence of high-quality individual studies.*
- ✓ Limitations: "garbage in, garbage out"; publication bias; between-study heterogeneity

Research Designs and Categories

Interventional:

2. Randomized control trial (RCT)

- ✓ The “gold standard” for determining cause and effect in research (because people are randomly assigned to treatment and control groups).
- ✓ *Example: Pharmaceutical company-sponsored clinical trials*
- ✓ Limitations: expensive, time consuming, requires significant human resources

Research Designs and Categories

Interventional:

3. Quasi experiment

- ✓ The “silver standard” for research (i.e., convenience samples versus random assignment).
- ✓ *Example: Comparing BMIs in patients receiving four-week exercise program (SL-Allentown) versus no intervention (SL-Bethlehem).*
- ✓ Limitations: Can’t fully control for potential confounding variable effects (especially unmeasured ones) due to no random assignment; therefore, can’t definitively prove causation.

Research Designs and Categories

Observational:

4. Prospective (longitudinal) cohort study

- ✓ Tracking a cohort over time to observe outcomes.
- ✓ Cohort = any group that shares something in common (e.g., age, gender, exposure to risk factor).
- ✓ *Example: Framingham Heart Study*
- ✓ Limitations: Can't fully control for potential confounding variable effects; therefore, can't prove causation.

Research Designs and Categories

Observational:

5. Retrospective study (chart review)

- ✓ Retrospectively compare people with a disease/condition (*cases*) versus people without the disease/condition (*controls*).
- ✓ Retrospectively assess a group of patients sharing something in common, like a risk factor (*cohort*).
- ✓ *Example: Chart review of demographic differences and diagnostic outcomes in patients with gestational diabetes versus normal insulin profiles.*
- ✓ Limitations: Can't fully control for potential confounding variable effects; therefore, can't prove causation.

Research Designs and Categories

Observational:

6. Cross-sectional study

- ✓ Participant outcomes are measured at one point in time.
- ✓ *Example: Surveying patients to determine pain control and overall quality of life.*
- ✓ Limitations: Can't fully control for potential confounding variable effects; therefore, can't prove causation.

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)?*

Key Terms and Concepts

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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***

Research Sample Groups

- Which is most representative of “adult female hospital patients in Pennsylvania”?

  - ✓ ***5,000 patients ages 20 - 70 from the St. Luke’s Allentown, Bethlehem, Miner’s and Quakertown campuses who volunteer to participate in your study so they can get free medical care as an incentive.***

  - ✓ ***500 patients ages 18 - 80 selected at random from hospitals in the cities and surrounding regions of Philadelphia, Harrisburg and Pittsburgh, with no incentives given for participation.***

Research Sample Groups

- **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).***

Research Sample Groups

- **Effect size example:** You want to compare serum fasting glucose levels in normal weight (BMI<25) versus overweight (BMI 25-29) adult patients.

  - ✓ *To detect a **5 mg/dL difference**, you'll need **394 patients per group**.*
  - ✓ *To detect a **15 mg/dL difference**, you'll need **64 patients per group**.*

Research Sample Group Types

- **Random sample:** Every person in the larger population has an equal chance of being selected *(e.g., all adult female hospitalized patients in Pennsylvania in the year 2022 agree to be in your study).*

- **Convenience sample:** You get whoever is available *(e.g., first 100 patients who come through the door).*

  - ✓ *Disadvantage: May be less representative (and therefore less generalizable).*

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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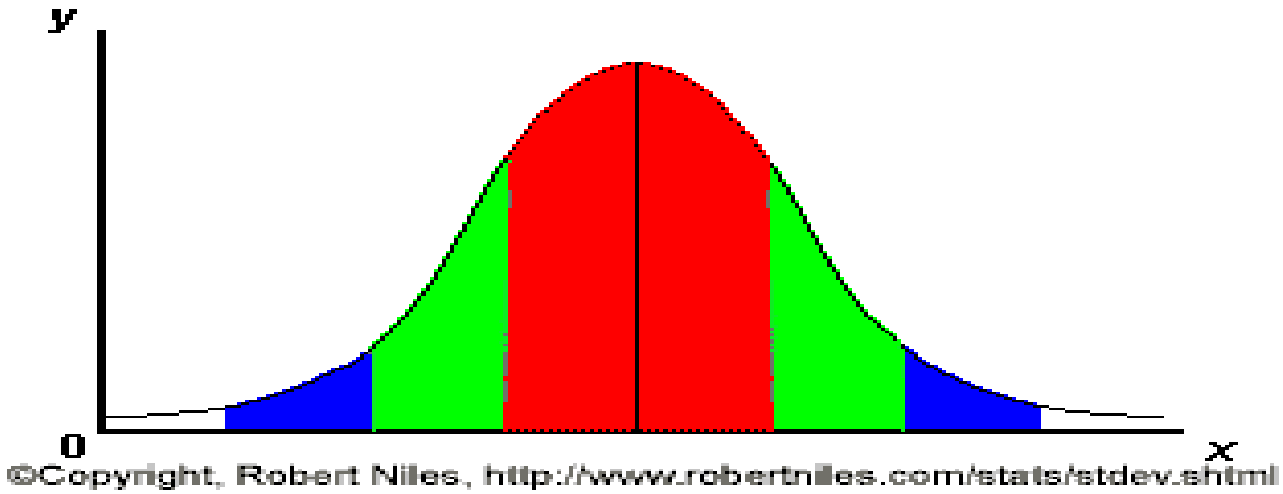
Research Data Types

- **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., gender, smoking status, 30-day mortality)*

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

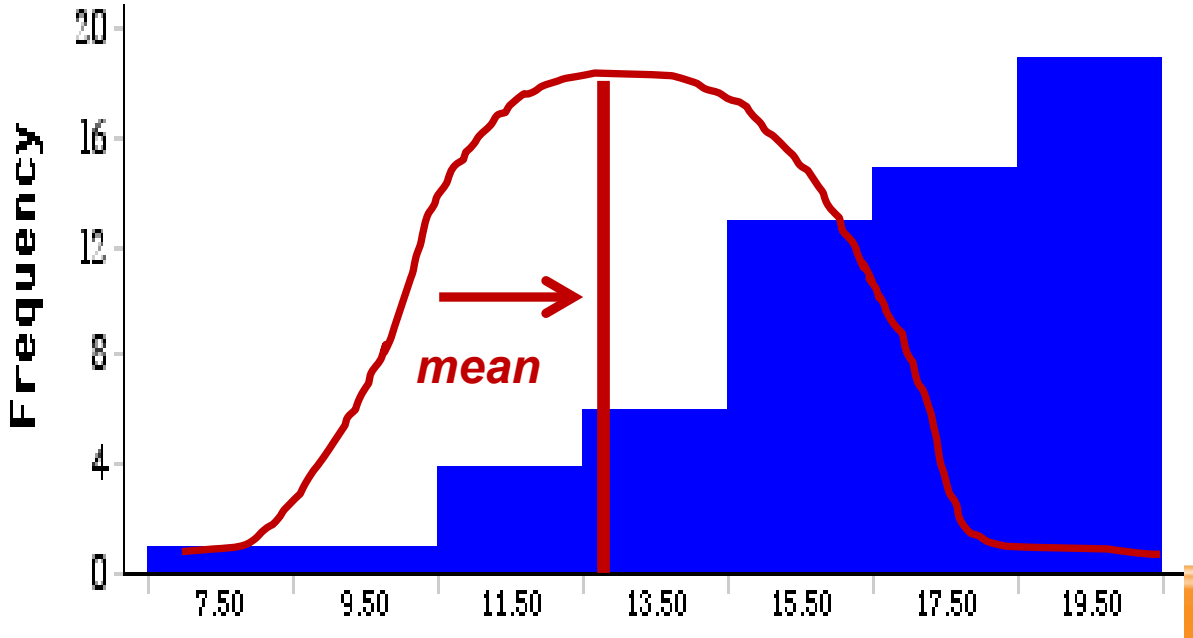
Research Data
Types and Statistical Tests

- **Continuous/ratio data *(e.g., hospital length of stay)***
  - ✓ Compare ***means*** with t-tests, analysis of variance, etc. (only if normally distributed/"bell curve" shape)



Research Data
Types and Statistical Tests

- **Ordinal data *(e.g., patient pain scores)***
  - ✓ Compare ***medians*** with Mann Whitney rank sums test, Kruskal Wallis test, etc.
    - ☞ This also applies to ***skewed continuous data*** (e.g., patient BMIs)



Research Data
Types and Statistical Tests

- **Categorical *(e.g., smoking status)***
  - ✓ Compare ***frequencies and percentages*** with chi square tests, Fisher's exact tests, etc.

Research Data
Types and Statistical Tests

- Determining **statistical significance** is a central goal of outcomes analysis in research.

  - ✓ *Example:* ***Is there a statistically significant difference between biological males' and females' BMIs after receiving a six-week diet and exercise intervention?***

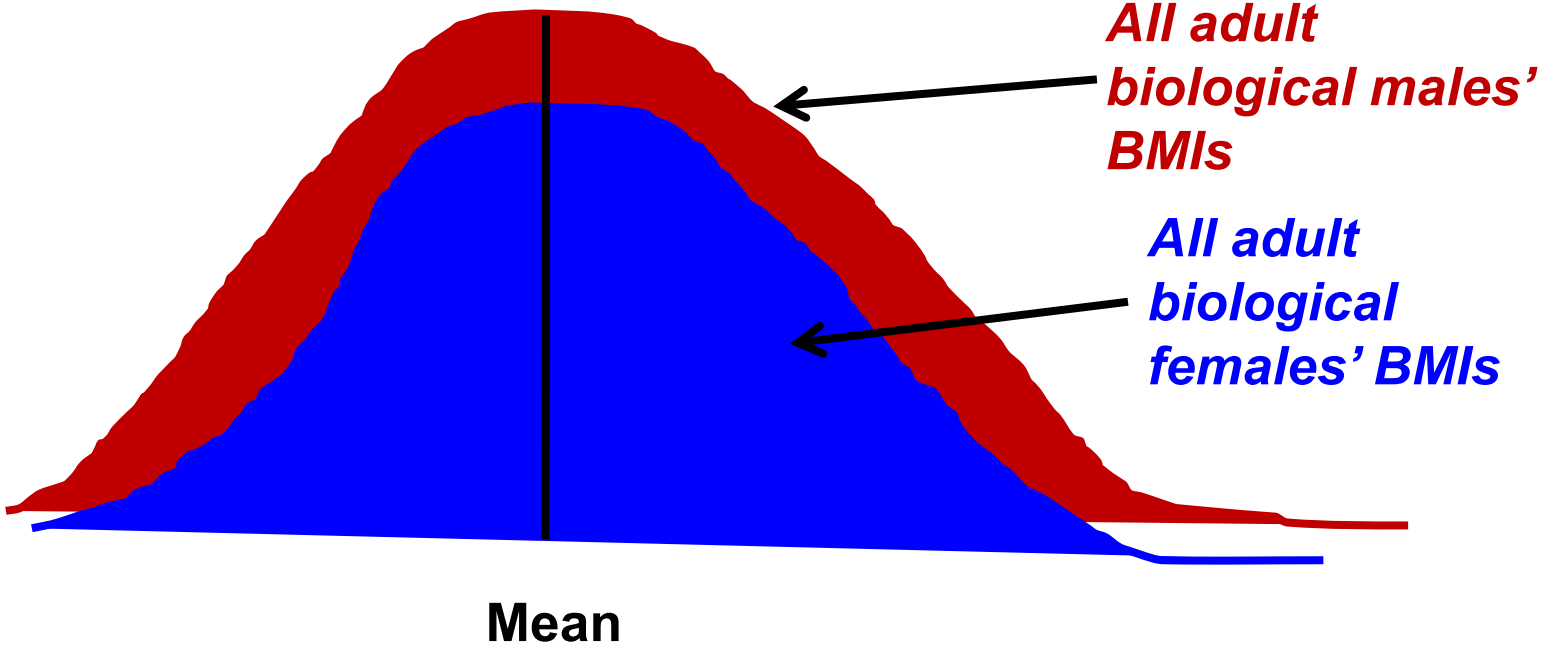
Research Data
Types and Statistical Tests

- The standard/common way to measure statistical significance is by:
  - ✓ *Choosing a **level of significance** (**Type I error rate**)—usually **.05/5%.***
  - ✓ *Comparing the statistical test's **p-value** to this level of significance.*
    - ♦ ***p-value** = **probability** that what you observe in your sample outcomes is **due to chance or is real/reflective of the larger patient population.***

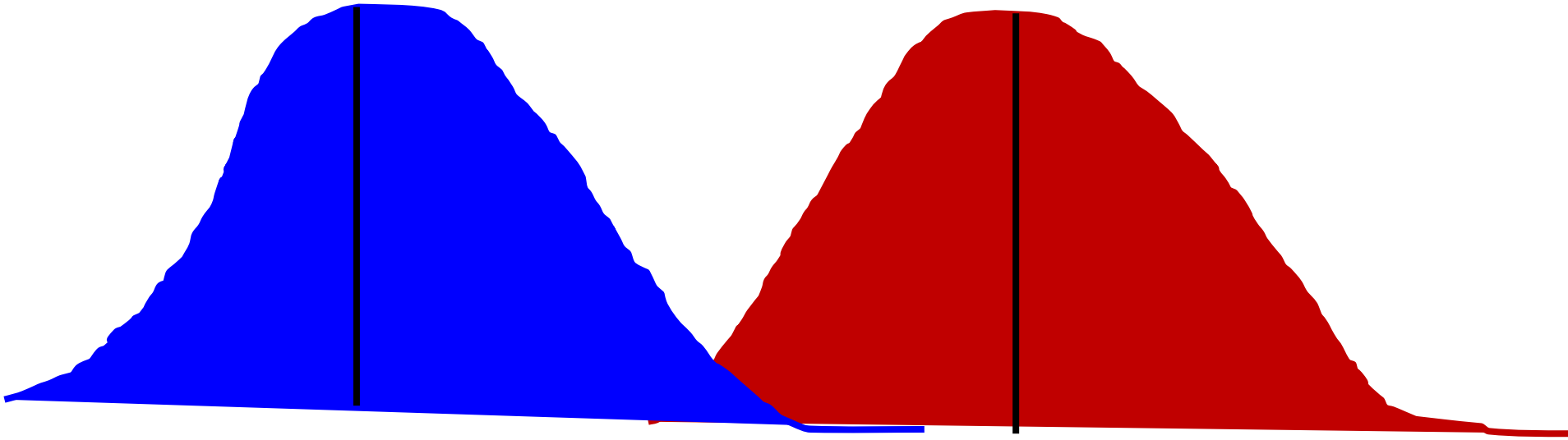
Research Data
Types and Statistical Tests

- **What does a *p*-value < .05 tell you?**
  - ✓ Assume you set your Type I error rate (level of significance) at .05/5%.
  - ✓ Assume there is really no intervention-based gender difference in the larger population's BMIs.
  - ✓ If you repeated your BMI study 100 times with the same type of patients and conditions, ***less than 5 of those studies would show a difference in BMIs as larger or larger than what you observed the first time***.

If THIS is actually true in the larger population…..



….then you don't want to see THIS in future research studies!



Mean BMI - Biological Females

Mean BMI – Biological Males

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

Quality Improvement
Data Types and Assessment Measures

- **Defining and analyzing the process-outcome relationship:**
  - ✓ *Flow chart*
  - ✓ *Fishbone diagram*
  - ✓ *Scatterplot*
  - ✓ *Run chart*
  - ✓ *Statistical control chart*
  - ✓ *Pareto chart*
  - ✓ *Histogram*

SUMMARY OF KEY DIFFERENCES

Quantitative Research	Quality Improvement
Observational and interventional designs and categories	***PDCA methodology*** (***more fluid and process oriented***, rather than design/category oriented)

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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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Primary outcomes = main focus Secondary outcomes must be validated in future studies	Focus on ***relationship between process and outcomes***

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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 QI objectives
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***

Practical Application

- **Area of interest:** *Turnaround time from arrival to discharge at a local emergency department.*
- **Key question:** *Which patient, provider and/or institutional factors affect ED turnaround time?*

Practical Application: Quantitative Research Approach

- **Refined key question =** What are the predictors of ED turnaround time?
  - ✓ **Design =** *observational*
  - ✓ **Category =** *retrospective chart review*

Practical Application: Quantitative Research Approach

- **Refined key question =** What are the predictors of ED turnaround time?
  - ✓ **Outcome** = turnaround time (continuous variable)
  - ✓ **Potential predictors** (from past research and/or clinical observation)
    - ***patient demographics*** (*e.g., age, gender, race/ethnicity, insurance status, presenting complaint)*
    - ***ED characteristics*** (*e.g., physicians' relative value units [RVUs]/hour, number of non-physician providers)*
    - ***external factors*** (*e.g., community disease outbreaks, time of day, season of year*)

Practical Application: Quantitative Research Approach

- **Institutional Review Board (IRB) approval**
  - ✓ *Before the study begins, all research (both prospective and retrospective) must go through the IRB to ensure patient safety and protection of confidentiality.*
  - ✓ ***Quality improvement projects can generally skip this step UNLESS certain "research-type" features are present*** *(for detailed information, see https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html).*
  - ✓ *Why is IRB approval necessary?*

Medical Research's Unsavory Past

- **Willowbrook Hepatitis Studies (1950s):** In order to see which factors might lead to hepatitis transmission, children living in a New York long-term care facility were fed a concoction containing feces from children with active hepatitis.

Practical Application: Quantitative Research Approach

- **Selection of statistical tests**
  - ✓ ***Perform diagnostics on the outcome and predictor variables before data analysis:***
    - *ED turnaround time is (roughly) normally distributed.*
    - *There are no extreme outlier values.*
    - *Predictor variables aren't too highly correlated.*

Practical Application: Quantitative Research Approach

- **Selection of statistical tests**
  - ✓ ***Multivariable linear regression*** *with dependent variable (ED turnaround time) and independent variables (previously identified predictors).*
  - ✓ ***Sample size is based on the number of predictors****— for linear regression, between 5-15 subjects for every predictor (so at least 50 patients if we include 10 predictors of ED turnaround time).*

Practical Application: Quantitative Research Approach

- **Selection of significance level (Type I error rate)**
  - ✓ *Presumably .05/5%; compare p-value to this level*
  - ✓ *How do I interpret?*
    - ☞ *Any predictor variable with p ≤ .05 means* ***that predictor independently contributes to ED turnaround time after controlling for the influence of every other predictor in the model.***

Practical Application: Quantitative Research Approach

Which factors predict ED turnaround time?

Predictor Variable	Regression Coefficient (ß)	*p*-value
Patient age	.80	.25
Patients' presenting complaint	***2.30***	***.001***
Physician RVUs/hour	1.10	.10
Time of day	***3.50***	***< .0001***
Influenza community epidemic	***4.35***	***< .0001***

Practical Application: Quality Improvement Approach

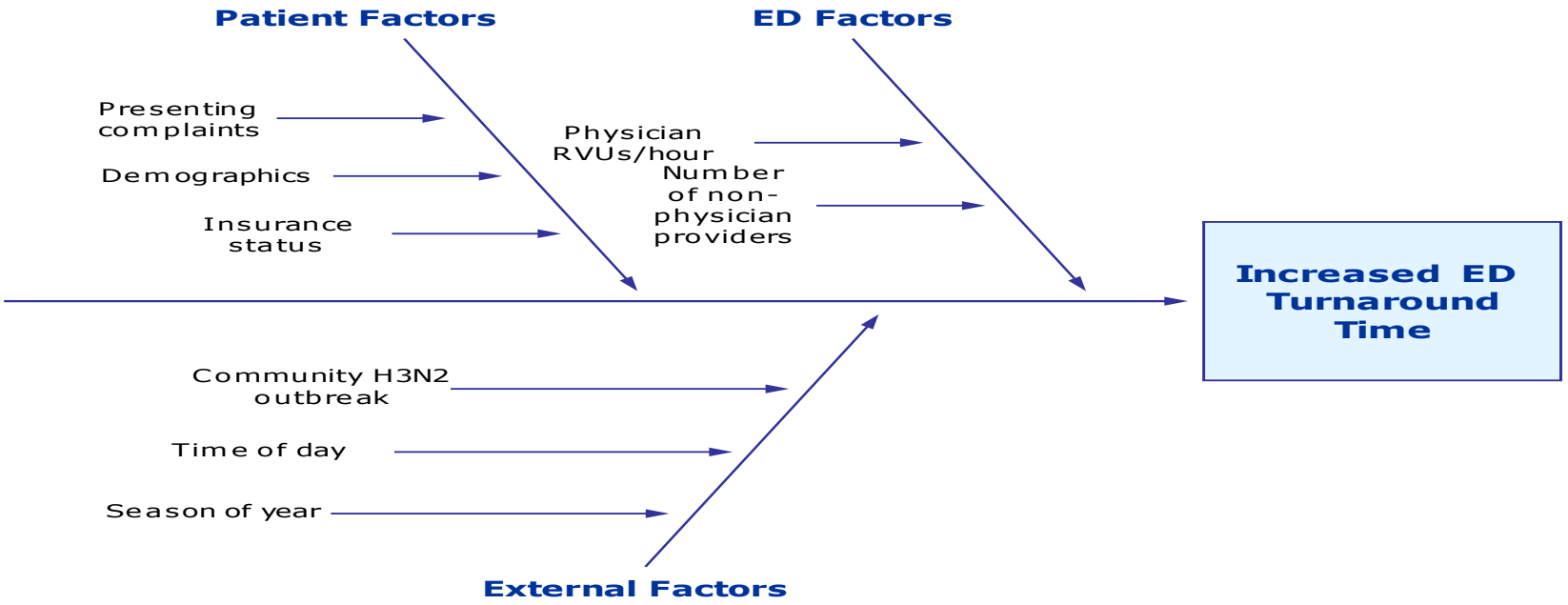
- **Refined key question =** How much do we want to reduce ED turnaround time, and what is the current process affecting this outcome?
  - ✓ ***Recall*: Research key question = What are the predictors of ED turnaround time?**

Practical Application: Quality Improvement Approach

- **PDCA methodology** guides the entire process, from start to finish.
  - ✓ ***Recall:*** *Research methodology is guided by the type of design (i.e., observational or interventional) and category (e.g., retrospective chart review).*
- **Outcome** = Reduce ED turnaround time by 30% in 6 months.
  - ✓ ***Recall:*** *Research outcome = ED turnaround time at some point in the past.*

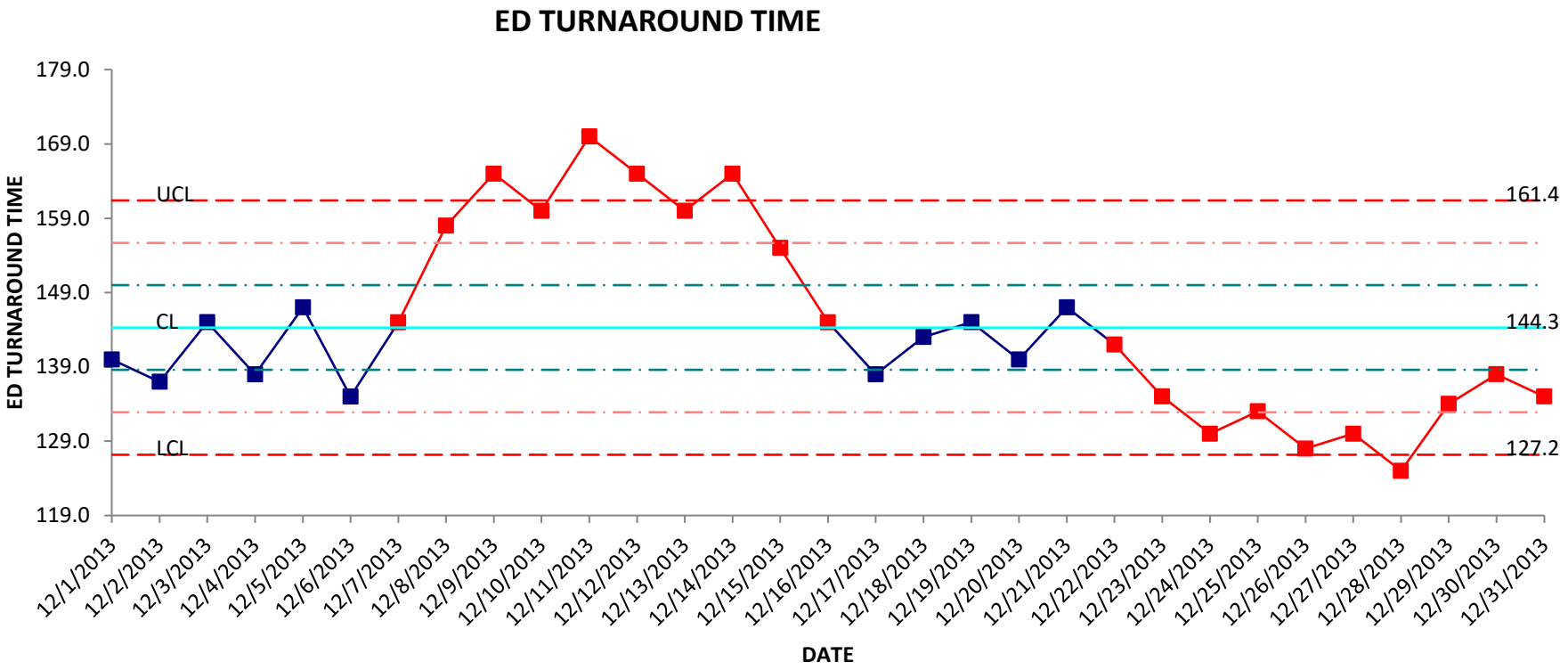
Practical Application: Quality Improvement Approach

Plan: Define the problem by identifying root causes



Practical Application: Quality Improvement Approach

Plan/Do: Further analyze the problem

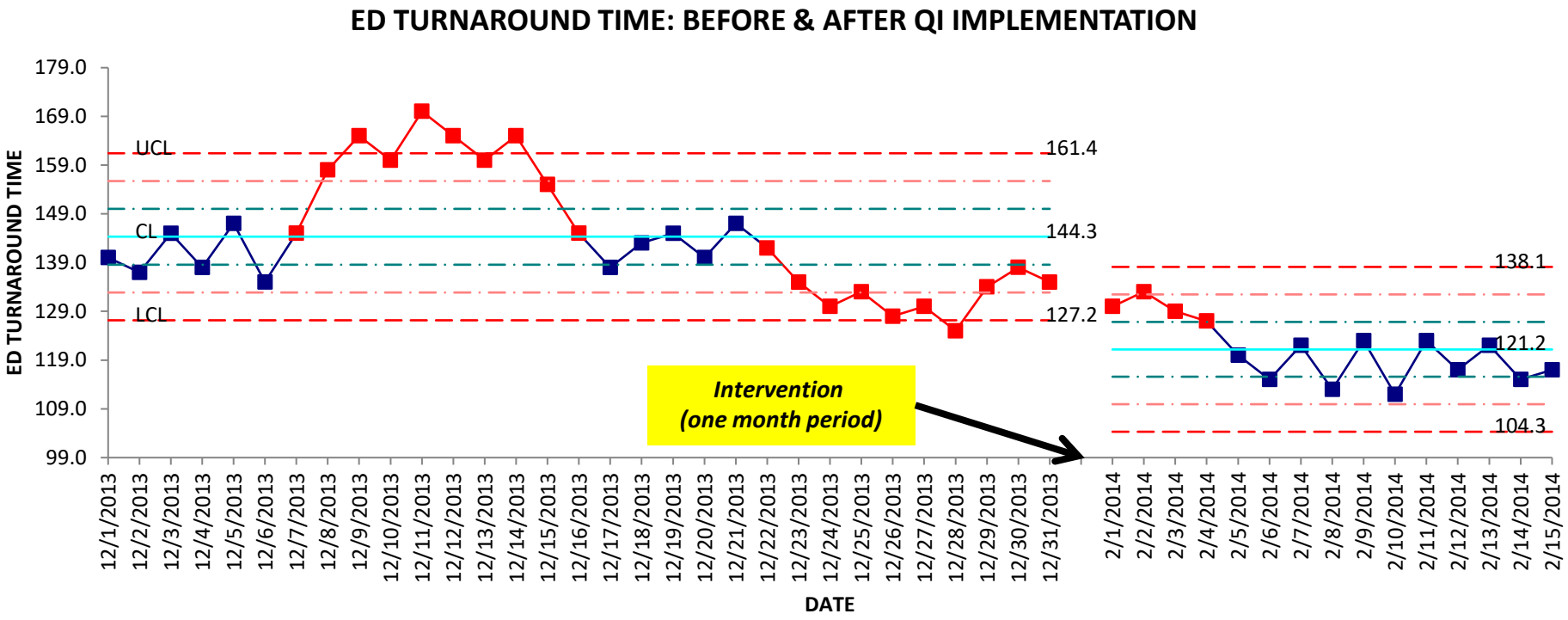


Practical Application: Quality Improvement Approach

- **After defining and analyzing the problem:**
  - ✓ **Do:** *What solution(s) are most appropriate for reducing ED turnaround time? How can we implement it/them successfully?*
  - ✓ **Check:** *Did the solution(s) work as expected? Why or why not?*
  - ✓ **Act:** *Should we stick with the solution(s), revise as needed, or try something else?*

Practical Application: Quality Improvement Approach

Do/Check/Act: Did it work?



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)*

WHICH APPROACH SHOULD I CHOOSE?

- If you want to make internal improvements within your unit/department/office on a smaller scale, with rapid plan-do-check-act cycles, choose a ***quality improvement approach.***

- If you want to formally test a hypothesis (using inferential statistical methods) to achieve widespread applicability/generalizability to a larger population, choose a ***quantitative research approach.***

- If you want to explore deeper insights and meanings based on people's subjective perceptions, choose a ***qualitative research approach.***

A Brief Overview of Qualitative Research

- **Purpose:** Explore participants' subjective attitudes, beliefs, and experiences, with an emphasis on descriptive details to reveal new insights or meanings.

- **Types:**
  - *Interviews*
  - *Focus groups*
  - *Ethnography*
  - *Case studies*
  - *Narratives (e.g., diaries, journals, writing exercises)*

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

Quick Comparison: Qualitative versus Quantitative Research

Qualitative	Quantitative

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Qualitative	Quantitative
Subjective data (e.g., words, images, sounds)	Objectively measurable data (i.e., numerical quantities)

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

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Keep in Mind

- Both qualitative and quantitative 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.

  - ✓ *For example, the descriptive, thematic-based results of qualitative research can help generate testable hypotheses for quantitative research.*

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 people 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

- **Suggested methodologies:**

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

Social Determinants of Health (SDoH) Example: Quantitative Research

- **Suggested methodologies:**

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

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

Social Determinants of Health (SDoH) Example: Quantitative Research

- **Suggested methodologies:**

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

   ✓ *Consider **controlling for variables other than the intervention** (e.g., age, gender, race/ethnicity) in order 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?

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https://www.surveymonkey.com/r/ResearchandQI

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Accreditation, Designation, and Disclosure

- Accreditation

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education through the joint providership of Ochsner Clinic Foundation and the AIAMC. The Ochsner Clinic Foundation is accredited by the ACCME to provide continuing medical education for physicians.

- Designation

The Ochsner Clinic Foundation designates this live activity for a maximum of 2.75 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

- Disclosure

The Ochsner Clinic Foundation relies upon everyone in control of content at all sponsored continuing medical education activities to provide information objectively and free from bias. In accordance with ACCME and institutional guidelines, the faculty for this continuing medical education activity has been asked to complete the CME Disclosure of Relevant Financial Relationships form. If anyone involved in control of content for the activity does disclose a relationship with an ineligible company, their materials have been peer reviewed to mitigate any potential bias.