

## Video 5 - Quasi-experimental studies

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## Learning objectives

- 1.To contrast the features of a quality improvement study with a research study
- 2.To describe the various quasi-experimental approaches

Here are the objectives for this week.

## Required reading

1. Chapter 6 (also re-read Chapter 5)

### Optional reading

Mike Evans. Quality Improvement in Healthcare. YouTube, November 26, 2014. Available as a [video \(11 minutes\)](#).

Health Resources and Services Administration. Quality Improvement. Available in [PDF format](#).

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This is what you should have read already. If you haven't done the reading yet, pause this video and read this material. You'll get more out of the video if you do so.

## What is quality improvement?

- Systematic approach
  - Commitment to teams
  - Organization-wide support
  - Passion for measurement
- Differences from research
  - Systems approach
  - Little or no attention to generalizability
  - Continuous and Cyclical process
  - Major reliance on quasi-experimental studies

Some of the material discussed on this page was taken from

<https://www.hrsa.gov/sites/default/files/quality/toolbox/508pdfs/qualityimprovement.pdf>

Quality Improvement (QI) is a systematic approach to changing how a health care organization works with the goal of providing better health care delivery. The QI process makes a strong commitment to teams and emphasizes the importance of broad representation on the team and careful elicitation of viewpoints from every perspective. While it is possible to run a QI team in a small corner of an organization, the QI process can only function well with organization-wide support, especially support from upper management. The QI process has a strong commitment to measurement, as measurement is the only way to evaluate the success or failure of changes made by the QI process.

There is substantial overlap between QI and health care research, but you should be aware of several important differences. QI takes a systems approach to solving problems. Some research takes a systems approach as well, but it's not really a research requirement. QI pays little or no attention to generalizability. The focus of QI

is on your particular organization, and attempts to generalize to other organizations is not a priority. The QI process is not a single step but a continuous effort. This effort is usually represented by the PDCA or PDSA processs (Plan, Do, Check/Study, and Act) and each time you reach the end of a PDCA cycle, you start over again with a new plan.

The final distinction and the reason I am talking about the QI process in this class is that QI relies heavily (but not exclusively) on quasi-experimental studies.

## The SMART approach

### – SMART

- Specific
- Measurable
- Achievable
- Relevant
- Time Bounded

### – [Who] will do [what] resulting in [measure] by [when]

- Minnesota Department of Health

Any problem identified by a QI should be written using the five criteria in the acronym SMART (Specific, Measurable, Actionable, Relevant, Time Bounded).

Specific means that you avoid multiple objectives (one verb, not two, according to the CDC) and keep the focus narrow.

Measurable means that you specify a quantitative variable that you will measure, a quantitative value representing where you currently are, and a quantitative value representing where you want to get to.

Achievable means that you have considered both the time and resources and the barriers that you face when setting your objective.

Relevant means that your objective addresses the problem directly.

Time bounded means that you set a calendar date by which you hope to achieve your objective.

As the Minnesota Department of Health puts it, your objective should state

[Who] will [what] resulting in [measure] by [when]

## The PDSA cycle

- Plan
- Do
- Study
- Act

The PDSA cycle is commonly used when describing QI teams. Some use the acronym PDCA with Check substituting for Study, but the intention is the same. It is a cycle, which means that as soon as you act on what you've learned, you starting a second cycle of planning.

The plan, do, study, act cycle is fairly straightforward, but I want to want you that a trap that some QI teams can fall into is to ignore two of the four parts.

A team, for example, might be trapped in a Plan, Do, Plan, Do cycle and never takes the time to learn from the work or to implement changes based on the work.

Or the team might be trapped in a Plan, Act, Plan, Act cycle and never take the time to see if the plans actually have a measurable impact.

This Fishbone diagram comes from QI study looking at wrong side imaging errors. The major bones on this diagram are Environment, Radiologist, Imaging Exams, and PACS+Voice Recognition.



Process measures

## The control chart

## Drawing a fishbone diagram (1 of 3)

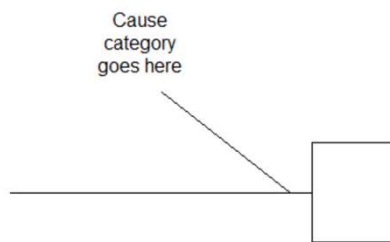


First step in drawing a fishbone diagram

The fishbone diagram (also called the Ishikawa diagram, or the cause and effect diagram) is a tool for identifying the root causes of quality problems. It was named after Kaoru Ishikawa, the man who pioneered the use of this chart in quality improvement in the 1960's. It is a graphical method for displaying possible causes of a quality problem.

If you want to use a Fishbone Diagram, first list the main problem on the right hand side of the paper. Then draw a horizontal line to represent the "backbone" of the diagram. This line is not labeled.

## Drawing a fishbone diagram (2 of 3)



Second step in drawing a fishbone diagram

Off of the backbone, draw and label major bones: 4 to 7 major categories of causes. A commonly used list of major causes is

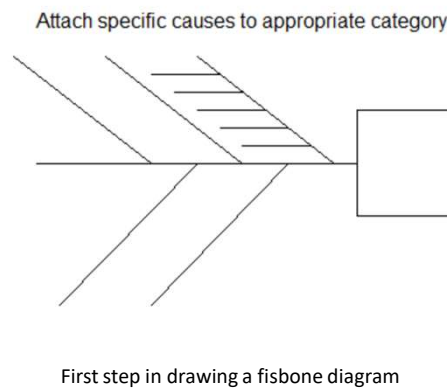
Management,  
Manpower,  
Machines, and  
Materials.

Another possible list is

Policies,  
Procedures,  
Plant, and

People.

## Drawing a fishbone diagram (3 of 3)



Then attach specific causes to the appropriate category.

Some people allow the individual causes to have subcauses, which would be attached to the minor bones. This is intended to get at the fundamental or root causes of the problem. Other people do not include this level of detail on their fishbone diagrams.

The process of developing a fishbone diagram can be done by an individual, but more commonly it is done by a team. You can use standard brainstorming approaches for the fishbone diagram. For example you could go around the table repeatedly asking each person to list a cause. Only after all the possible causes are listed do you review and possibly winnow down the list. Then arrange the remaining causes on the fishbone.

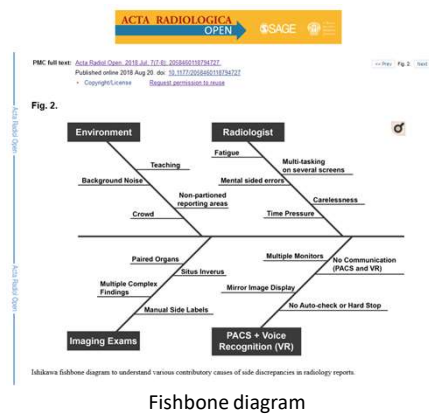
If you do use a team to develop a fishbone diagram, make sure that all relevant parties are included. No fair getting input only from doctors and ignoring nurses, for example, in a health care setting. The rule should be that at least one person from any group that is associated with the work process should be included.

When you are done, look at the entire diagram. Does it have reasonable balance

across the major bones? Are any common themes emerging? Can you identify causes that are measurable and fixable and which you believe are likely to have a large impact on the problem?

In some situations, you may find that a flow diagram of the work process may be more valuable and informative.

## Fishbone example (1 of 4)

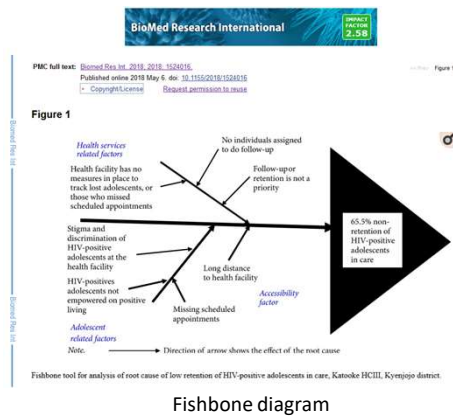


As you will see, there is no standard format or structure for a Fishbone diagram.

Here is an example of a Fishbone diagram in a published research study. The problem, shown only in the legend, is side discrepancies in radiologic reports. The major bones are Environment, Radiologist, Imaging Exams, and Voice Recognition. Two specific causes on the environment bone are background noise and crowd.

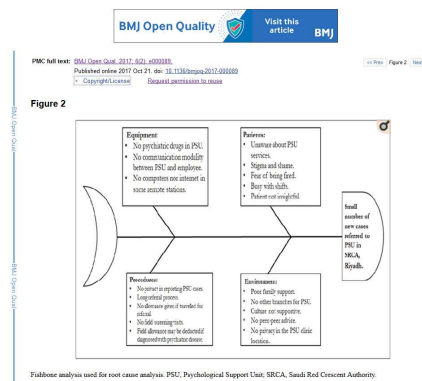


## Fishbone example (2 of 4)



Here's a second example. The problem is non-retention of HIV-positive adolescents in care. The major bones are Health Services factors, Adolescent factors, and Accessibility factors. Two of the specific causes on the adolescent factor bone are stigma, and lack of empowerment.

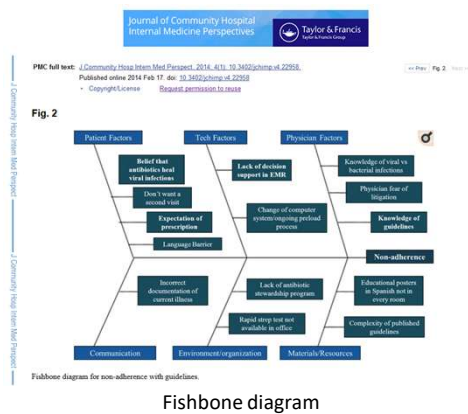
## Fishbone example (3 of 4)



Fishbone diagram

Here's a third example. The problem is the small number of cases referred to the PSU. The major bones are equipment, patients, procedures, and environments. Two specific causes on the patients bone are lack of awareness and stigma.

## Fishbone example (4 of 4)



Here's one last example. The problem is non-adherence. The major bones are patient factors, tech factors, physician factors, communication, environment/organization, and materials/resources. Two of the specific causes on the physician factor are fear of litigation and knowledge of guidelines (I presume they mean lack of knowledge of guidelines).

## The Pareto chart

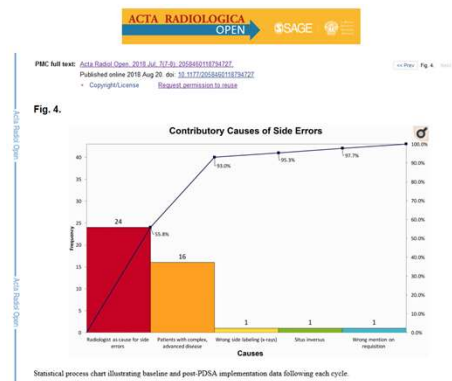
- Based on the Pareto 80-20 principle.
  - The “frequent few”
- Proportion of cases associated with a specific cause.
  - Combined with cumulative frequency

The Pareto chart is an attempt to focus attention on the most common causes of a problem. It is based on the Pareto Principle which talks about the “frequent few”. The Pareto Principle states that most of the troubles that you see (around 80%, but this is just a ballpark estimate) are limited to just a few causes (20%, but again just a ballpark).

It is typically displayed as a bar chart of causes with a percentage of cases in each cause displayed. You put the bars in order from largest to smallest and include a line showing the cumulative frequency of causes.

You should focus your QI efforts on the left side of the Pareto chart.

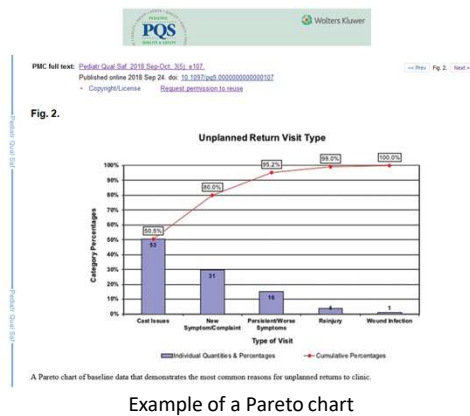
## Example of Pareto (1 of 3)



Example of a Pareto chart

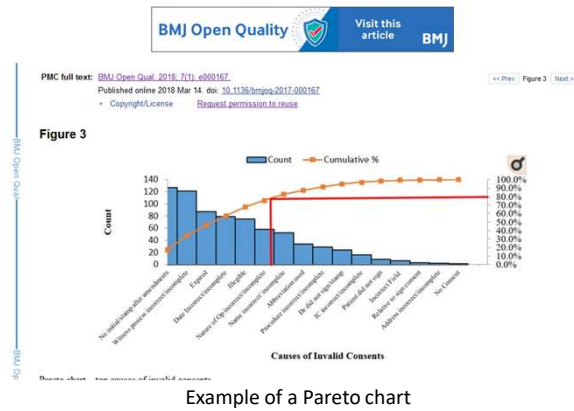
This is an example of a Pareto chart published in the peer-reviewed literature. The problem is side errors in radiology and the first two causes (radiologist, and complex, advanced disease) account for 93% of the problems.

## Example of Pareto (2 of 3)



This is second example. The problem is unplanned return visits and the first two causes (cast issues and new symptoms) account for 80% of the problems.

## Example of Pareto (3 of 3)



This is third example. The problem is invalid surgical consents, and it does not quite follow the Pareto principle because the causes are quite varied. The top five causes (No initials after amendments, Witness initials incomplete or absent, Consent forms were expired, Dates incomplete or absent, Illegible handwriting, and use of abbreviations) account for 80% of the invalid consents.

## What is a quasi-experimental study?

- Could but does not use randomization
- Never sneer at quasi-experimental studies
  - Make a loud mistake
- Problems with randomization
  - Cost
  - Logistical constraints
  - Contamination
  - Small n
  - Difficult to get buy-in

A quasi-experimental study uses an active independent variable, but does not use a formal process of randomization to control that variable.

The choice to forgo randomization is usually a deliberate choice. Many people, including the authors of your book, dismiss the quasi-experimental design as an inferior alternative to a randomized design, but that are wrong. In some settings, randomization puts you at a disadvantage. If you decide to use a quasi-experimental design, recognize that you are choosing this design because it is superior to a randomized trial.

I dated a piano major in college and I tried, with very limited success, to learn how to play the piano myself. She told me, “If you’re going to make a mistake, make a loud mistake.” You don’t want to play the piano nervously and hesitantly. The same is true in research.

If you deviate from a well-established research norm, do so boldly and explicitly. Say something like “Although this quasi-experimental study has some limitations, it avoids many of the well-documented problems with a randomized trial” And then elaborate. Don’t apologize for your research design. Brag about how it is the best



approach for this particular problem and explain what advantages it offers over a randomized trial.

What are the problems with randomization? First, it is expensive. It takes a lot of money (and a lot of time=remember that time is money). The machinery associated with randomization does not come cheap.

Contamination is the tendency for a particular intervention to “bleed over” into the control group. You may ask a health care provider to use a new approach for patients, but it is sometimes very easy to let some of the new approach slip in when that person is treating a randomly selected control patient.

Certain interventions, such as changes to the physical layout of a work area are one directional and cannot be undone. This is also true of certain training interventions (Uh-oh! A control patient is next on my randomization list. Time to forget everything that I’ve just learned.)

The sample size available to randomize may be too small to assure that randomization would work. This is especially true when you are looking at an intervention that can be implemented only at a very broad scale, such as with an entire floor or wing of a hospital.

Even when you have enough control to randomize, the people that have to implement your randomization process may rebel. This is especially true in a difficult and hectic environment like an emergency room. Randomization is one more distraction that they just don’t need. They are more likely to support your research if you implement the intervention without randomization.

## Notation for research designs

- O means a measurement is made
- X means an intervention is given.
- ~X means no intervention or a control intervention
- R means randomized assignment
- NR means non-randomized assignment
- E means the experimental group
- C means the control group

There is a fairly standard notation with the letter O representing a measurement and the letter X representing an intervention.

The symbols here mean all subjects were assigned to an exposure group, that two measurements were made, then an intervention was given and then two more measurements were made.

## Example of a design

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R E: O1 X O2 O3  
R C: O1 O2 X O3
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This is an example of a waiting list control group. The patients are randomly assigned to E or C. They both get a baseline, O1. Then the E group gets an intervention X that does not happen for the control group just yet. The second measurement is done, and after the second measurement, the same intervention is offered to the control group. Then both groups are measured a third time. The comparison of O2 between the experimental and control groups is the key measure, and you can adjust for baselines using a change score or analysis of covariance. But there are other interesting comparisons. With the experimental group, the comparison of O2 with O3 represents an assessment of whether the effect of X persists over a longer period of time.

## Single group post-test only design

NR E: X O

- Simplest design
- Useful for pilot work

The simplest possible design is a single group post-test only design. There is no randomization. The treatment given to everyone and you get a measurement only after the treatment.

It reminds me of a story, that I have not been able to verify. If you find a link to this story, let me know. The famous philosopher Karl Popper asked his wife “How much do you love me?” She responded “I love you eleven”.

Eleven compared to what? Maybe she loves bagels fifteen? Maybe he only loves her eight? There’s no comparison to be made at all.

Although no comparisons can be done. It could be useful for pilot or feasibility studies.

## Single group comparison post-treatment to baseline

NR E: O1 X O2

- Allows a comparison.
- Confounded with temporal trends.

One group, pre-test versus post-test. You can look at change before and after the intervention. You still don't know if the change would have occurred even without this intervention.

There are effects such as maturation or carry-over effects that could easily account for any difference seen in this design.

You can improve this design by including extra outcome variables. Half of these outcome variables would be expected to be changed by the intervention and half would be expected to be unchanged, even if the intervention is successful.

If you see that the first half changes from baseline and the second half does not, then you have some assurance that there is no temporal trend, at least no trend that might influence all the outcome variables that you are considering.

So a teaching intervention, for example, might teach lessons in X1 and X2, but not X3 and X4. Test all four areas prior to the intervention and afterwards. If you see a change in just X1 and X2 great! If you see a change in all four, though, you're in trouble.

## Two group comparison, without a baseline

NR E: X O

NR C: O

- Nonrandomized comparison
- Confounded with baseline imbalance

If you have two groups, assigned without randomization, you do have a comparison, but without a baseline measurement, you can't be sure that the difference that you do see is the same as the difference that existed between the two groups prior to the intervention.

Here's where randomization would have helped a lot. Randomization controls for unmeasured covariates and the baseline value in this study is an unmeasured covariate.

The three quasi-experimental studies described so far are called pre-experimental because you cannot draw any conclusions without making some untestable assumptions.

This sounds terrible, but we make untestable assumptions all the time in science. For example, Carbon-14 dating relies on the assumption that the rate of decay of carbon-14 is the same now as it was a thousand years ago. There's no good way to test this assumption, but we accept it as reasonable.

It's okay to make untestable assumptions if there is no way that you could collect the

extra data that you would need to turn it into a testable assumption. Just be explicit about what assumptions you are making and your readers can for themselves whether they agree with you that the assumption is reasonable.

One way to indirectly test the assumption that the two groups were comparable at baseline is to compare the two groups by some demographic variables like age or gender that might be associated with your baseline. If the demographic variables are comparable, then you have some assurance that the baselines would have been comparable, if you had an opportunity to measure and test them.

## Two group comparison with a baseline

NR E: O1 X O2

NR C: O1 O2

- Best design so far.
- Can check for
  - temporal trends in the control group.
  - baseline imbalances
- Cannot check for unmeasured covariates
- Cannot check for treatment interaction



## Interrupted time series design

NR E: O1 O2 O3 X O4 O5 O6

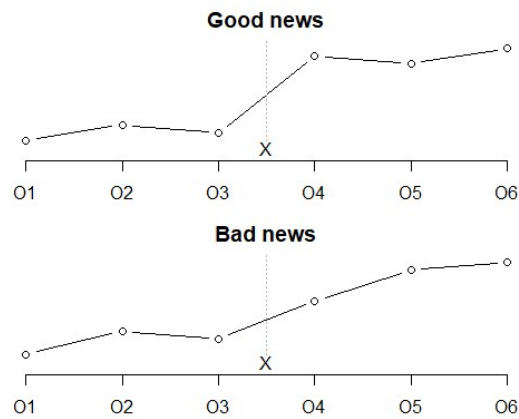
- Best with three or more measures at baseline
- Check for most temporal trends

If you have the option of taking multiple measurements over time, then this can help avoid the problems with using a single group.

If the measurements are flat from O1 through O3, show a jump from O3 to O4, and then becomes flat again from O4 through O6, then you have pretty good evidence against most temporal trends, except for a temporal trend with the bad luck of occurring right at the time of your intervention.

If you see a jump between O3 and O4, but you also see jumps at most of the other time points, that's bad news.

## Hypothetical patterns in the interrupted time series design

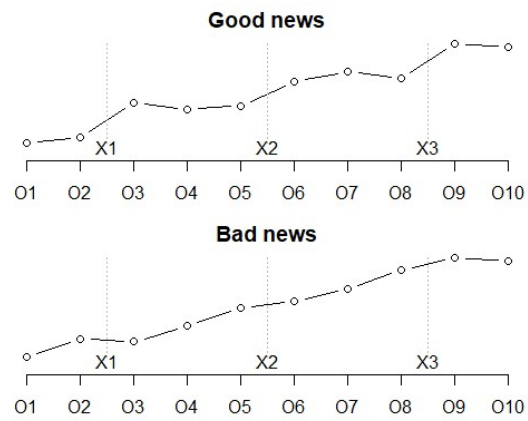


## Phased design

NR E: O1 O2 X1 O3 O4 O5 X2 O6 O7 O8 X3 O9 O10

- Split intervention into three or more pieces
- Phase in the intervention piece by piece

## Phased design



## Assignment

Prepare a summary of one of the quality improvement studies listed below or a study you find on your own. Did the team use a SMART aim? Describe the research design that the team used. Was it quasi-experimental? How might the design have been improved?

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## Discussion questions

1. What kind of clinical research questions are you interested in pursuing?
2. Do you have previous experiences that factor into the research questions you are interested in?
3. What kind of design do you think would be most appropriate for the topic you are interested in?

Additional slides