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Choosing a Study Design for the Polio Vaccine

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Overview of Lesson

This activity, based on real meetings during the 1954 Salk polio vaccine study, asks students to decide on an experimental design to test the polio vaccine. Students take one of multiple roles, such as statisticians, parents, and governments, that may lead to different design choices. Real-world study design involves balancing multiple interests; through small-group plan formation and large-group negotiation, students actively simulate the balancing process. After the discussion, students can compare their solution to the real-world decision and see results.

Type of Data

- Two categorical variables

Learning Objectives

- S-IC-1: Understand statistics as a process for making inferences about population parameters (rate of paralytic polio) based on a random sample from that population.
- S-IC-3: Recognize the purposes of and differences among sample surveys, experiments, and observational studies; explain how randomization relates to each.
- Apply definitions from study design, including treatment and control groups, placebo, blinding, consent, and non-response.
- In a real-world context, make a design decision based on statistical concerns (e.g., generalizability, causality) and societal concerns (e.g., consent, cost, safety), recognizing that different motivations may lead to different choices.

Audience

- Lesson tested in an introductory statistics class at the college level
- Also appropriate for high school students
- *Prerequisites:* Prior to this lesson, students should have been introduced to the following concepts: treatment and control groups, placebo, blinding, and non-response.

Time Required

30 to 50 minutes, depending on the amount of background provided to the students and the amount of time allocated for between-group discussion and negotiation. If rushed for time, eliminating negotiation between groups will keep time required around 30 minutes.

Technology and Other Materials

- Printed slips with information about each role (suggested)

Lesson Plan

Introduction

This lesson is designed to allow students to think as role-players in a very important historical study design, testing the effectiveness of polio vaccine. First, since few students know about the situation in 1954, describing context is necessary. This leads into an explanation of the study and the two available options, observed control and placebo control. Students then form small groups of two to four students and receive a group role. Students spend 5 to 8 minutes forming a recommendation in small groups. If time permits, there can be another round of group discussion, among either neighbor groups (in a smaller class) or groups with the same role (in a larger class). Small groups then report on their decisions and the reasoning behind their choices. To end the activity, results about design and effectiveness should be presented.

Describe the Context

Describing context is mandatory, since this activity is based on an actual meeting, the January 11, 1954 meeting of the Salk polio study advisory committee. It would be possible to assign background reading in advance, or coordinate lessons with a social studies teacher. If introduced in class, initial presentation takes 8 to 12 minutes. The video takes 3 minutes, I describe the situation for 5 to 7 minutes around the video, and then some student might have a polio experience or question.

I begin by asking students if they know anyone who suffered from polio. Occasionally someone knows a grandparent, and I ask the student to talk about what she or he knows for a minute. Students might have also heard about acute flaccid myelitis, a polio-like effect currently monitored in the USA (Centers for Disease Control and Prevention, 2019; Nawaz, 2019).

In almost all cases, I need to introduce polio's history. An attached word document contains additional information about polio and vaccine – likely more information than students need. Supplemental materials also include PowerPoint slides that I use. Key points are the following:

- Polio virus can be transmitted through coughing in the air, and many people were carriers without symptoms, so it was impossible to avoid risk.
- The virus had multiple forms. Because of better sanitation eliminating weaker forms, children in wealthier households were more likely to have damaging consequences.
- Polio paralysis struck without warning; people could be healthy one week and unable to breathe the next week. To show polio's effect, I play the first 2 minutes 40 seconds of the Brown (2017) video file, available at https://www.youtube.com/watch?v=gplA6pq9cOs
- Some epidemics were so massive that quarantines were invoked. In the 1916 epidemic, Pennsylvania established border controls with New Jersey to check children for symptoms.
- If the polio virus caused deaths at the same rate as it did in the early 1950s, about 1,500 children would die each year. This would make polio the second leading cause of child (non-infant) death, behind only accidents and ahead of cancer, suicide, homicide, and everything else.

Two Designs for Polio Vaccine Study

After establishing the seriousness of the problem, I take about 5 minutes to set the scene for the discussion. There had been two earlier ineffective vaccine attempts, but in 1953 the Jonas Salk team had shown promising results in a small-scale study; a larger study was planned to see if the Salk vaccine could reduce the polio infection rate. Because school-age children had the highest case rate, the polio foundation decided that the sample would consist of children in grades 1, 2, and 3, in 272 US counties with high rates of polio. During the winter of 1953–1954, advisory groups met to consider study design. The response variable was whether or not children contracted polio, with polio rate defined as the number of children per 100,000 that contracted polio. For instance, if 350,000 children were in a group, with 175 polio cases, the polio rate would be 50 per 100,000, since $\frac{175}{350{,}000} = \frac{50}{100{,}000}$. Two plans were offered, which I've labeled observed control and placebo control.

Observed control: This was the originally proposed plan. All Grade 2 students whose parents consented would receive a vaccine injection. The vaccinated children's polio rate would be calculated from Grade 2 vaccinated children. This polio rate would be compared to the observed polio rate among Grade 1 and Grade 3 students, plus Grade 2 students not vaccinated. If the vaccinated children's polio rate was lower, the vaccine would be considered successful.

Placebo control: This plan was suggested by an expert statistician hired onto the project. Every child in Grades 1, 2, and 3 whose parents consented would receive some type of injection. Half of the children, randomly selected, would receive vaccine. The other half of the children would receive a placebo injection of saline (salt water). Vaccines would be identified by codes known only to the analysts; children, parents, and medical staff would not know. There are three groups to compare in this plan – children who received vaccine; children who received placebo saline; and children whose parents did not consent.

Small Group Discussion (among students assigned the same role)

Meeting attendees came from multiple groups, including statisticians, government health officials, clinical polio specialists, virologists, and pediatrician doctors. Each group met to offer a recommendation for study design. The students' task is to role-play as a specific group, making a recommendation based on their role. I have not had trouble with disengaged or non-participating students, because this activity occurs in the first week of class and the students see the real-world importance of polio vaccine. With younger students, I would consider more discussion guidance, such as a reminder to discuss advantages and disadvantages of both plans, make sure each person speaks and responds to others, and then decide on a group decision. Generally, student groups take 5 – 8 minutes to decide on a recommendation with rationale. To reduce complexity, I ask groups to choose only observed control or placebo control. Many other possible plans exist, but creating strategies would take more time. Also, in real life, the planning time available was very limited. This meeting was in January; vaccine needed to be shipped in March. Observed control and placebo control were considered implementable; other suggestions might not be.

I use up to six group roles, assigning roles to groups of 2 to 4 students. Each group gets a slip of paper with information about their role. In this document, after each role title, I include what I provide on the slip of paper. Comments in [brackets] are instructor information and should not go on the student paper. After the group descriptions, I offer suggestions about assigning roles.

Statisticians: Your primary goal is to maximize statistical power, the ability to determine if the polio vaccine is actually effective. To a statistician, good design includes large sample sizes, similar characteristics across groups, and randomized groups.
[Comments: Power does not involve numeric analysis; it's a very informal definition. Statistician groups almost always pick placebo control because of randomization into similar groups.]

Government of New York: Because of the 1916 outbreak and other outbreaks, polio fear is high. Demand for an effective vaccine is high. You have a strong public health office and the ability to persuade people towards the best statistical design, even at higher cost.
[Comments: New York groups almost always pick placebo control because they see the advantages of randomization, and they have the support of a nervous state population.]

Government of Indiana: Polio fear exists, but is not high. You have a relatively weak public health office, other disease demands, and relatively low budget. Indiana's original choice was observed control; it took substantial effort to get even those funds.
[Comments: This explanation encourages observed control, because it's cheaper and doesn't require a change of plans. 34 of the 45 participating states picked observed control, for reasons like Indiana's, so having this role is very realistic.]

Parents of Children in Grade 2: You are upper-middle class parents, who know a child in your neighborhood who contracted polio and now must use a wheelchair. Your primary concern is the health of your children.
[Comments: Unlike other roles, responses vary here. There's a tension between individual benefit to their child, individual risk to their child, and group benefit from a statistically stronger placebo control study. Most Grade 2 groups have preferred observed control because it guarantees vaccine for their children, but one group preferred the statistically stronger option.]

Parents of Children in Grade 3: You are upper-middle class parents, who know a child in your neighborhood who contracted polio and now must use a wheelchair. Your primary concern is the health of your children.
[Comments: Because grades 2 and 3 are different in the observed control plan, parent groups often reach different conclusions. Grade 3 groups generally select placebo control because it gives their child a 50% chance of receiving vaccine while observed control offers a 0% chance.]

Ethicists: Your primary goal is to improve human welfare (as you define it). You remember the 1935 polio vaccine trials, where not only was the treatment ineffective, it caused several cases of polio. A few virus scientists are worried that the process to make Salk's killed-virus vaccine occasionally leaves polio virus still alive. Additionally, you are worried about administering a placebo injection, causing pain to a child, without any protective benefit.
[This role is deliberately less defined to let groups decide about human welfare. Students might get stuck, but explanations from ethicist groups have been the most complex and sometimes surprising. For example, one ethicist group decided on placebo control, because one-half of the children would receive vaccines instead of one-third, and attempting to reduce polio death was the most ethical thing. Another group chose based on the advantage of fewer injections in observed control. Although interesting, this role might not work well with less mature students.]

When forming groups, groups of size 3 perform best. Sizes 2 and 4 also work; larger groups don't allow each student enough speaking time. Groups could be formed by the teacher, random draw, students physically near each other, or other approach. Because this activity occurs during the first week of my course, I let students form groups with neighbors. Getting students to communicate with each other early in a course is not a bad thing.

A course leader might want to drop one or two roles. I recommend keeping statisticians, New York, Indiana, and Grade 2 parents, because these four roles have different perspectives that illustrate real-world anxieties. For less mature students, I might remove the ethicist role because of the complexity around "human welfare" even though those discussions might be interesting. The Grade 3 parent role has similarities to the New York role encouraging placebo control; although Grade 2 parents and Grade 3 parents can contrast perspectives, Grade 3 parents might provide the smallest expansion of rationales.

If there are more than six groups, some roles will need to be repeated. To provide a few examples based on different participant counts:

- For a class with more than 12 groups, roles will be repeated multiple times. In a class with about 55 students, I had 19 groups. I printed four copies of each role and had groups just pick role papers.
- For classes with 9 to 12 groups, likely 25 to 35 students, roles should be repeated once. Dropping a role is an option. For example, in one class, I had 9 groups. I did not use the Ethicist role, instead choosing to repeat statisticians, New York, Indiana, and Grade 2, with one group role-playing as Grade 3 parents. Combined discussion (mentioned in the next section) I considered more helpful than hearing about Ethicists.
- For classes with 7 or 8 groups, I suggest repeating Grade 2 parents and ethicists, because those role have provided the greatest diversity of reasoning in my experience.
- For classes with 6 or fewer groups, under 20 students, repetition is not necessary. For a class of 11 participants, I used statisticians, New York, Indiana, and Grade 2 parent roles.

Discussion of Recommendations

If the class had more than one group assigned to each role, allowing groups with the same role to create a combined recommendation is a nice idea. Groups should try to create short, strong summaries. This takes another 5 minutes, so this step can be omitted if time is tight or groups will have trouble moving around the room. I do not use this step in 50+ student classes.

After groups have decided on a recommendation, either individually or in combined roles, ask for the recommendation from each role. I ask about roles in the order above, beginning with more defined statisticians and ending with less defined parents and ethicists. It's important not just to hear each choice, but a summary of the reasoning behind each choice. Even though some groups are designed to lean towards one design, there's no overall obvious right answer; reasons can be thoughtful and unexpected.

Students less experienced with statistical reasoning might struggle with explanation. When this occurs, I ask for the most important reason that they made their choice. Even a phrase is enough, such as "randomization is important" or "observed control is cheaper". Positive instructor feedback helps. Sometimes an encouraging instructor response will lead to further comments from a student; in all cases, it establishes the value of student logic on this complex topic.

Group Discussion (among students assigned different roles) – optional

A final participatory option is to allow students in different roles to interact for a few minutes. The purpose is not to create a single recommendation; this did not occur in reality. Both plans were used in some states. The purpose is to have students explain to each other. This phase could occur before whole class discussion, but I tend to place it after because groups less sure about their reasoning can use phrases and sentences from other groups.

How this step occurs will vary. In 70 student college lectures, this might be skipped. A 14 student AP Statistics class might discuss recommendations as a single committee, like the actual meeting. In between no combining and just one group, one possibility is to match roles that chose the same plan, allowing them to create a combined rationale. When combining, students should think about relative strength of argument and try to select the best reasons. A more adversarial approach would match related roles with different assumptions: Statisticians with Ethicists, Governments of New York and Indiana, and the two groups of parents. This requires more oversight to prevent shouting and non-productive argument, but some student populations might gain from debate.

Presenting Real-World Results of the Polio Study

After students speak, finish the activity by providing the real-life results. In the accompanying slides, which take 3 to 5 minutes to cover, I emphasize that the polio vaccine was a success, including the following:

- Both observed control and placebo control were used, so all recommendations were taken and supported in some parts of the USA
- Most states (34) remained with observed control; only 11 states switched to placebo control.
- Parental non-consent was substantial, over 40% in placebo control and about 30% in observed control. Vaccine fear was a factor.
- The vaccine was a success, with polio rates reduced by at least 40%, as shown here and in the slides.

Placebo control	Vaccinated	28 per 100,000 children
	Placebo	69 per 100,000 children
	Nonparticipating	46 per 100,000 children
Observed control	Grade 2 vaccinated	25 per 100,000 children
	Grade 2 unvaccinated	43 per 100,000 children
	Grades 1 and 3	54 per 100,000 children

- The announcement about results was nationally televised.
- Polio vaccine was a major historical success. The last US polio case occurred in 1979. Around the world, civil wars have established vaccination truces. In 2018, there were only 133 confirmed polio cases worldwide. It's a (pretty) happy ending.

Additional Materials

- Class slides that give information about polio and provide instructions for discussion
- Word document containing background information about polio and vaccines

References

There are hundreds of references about the polio virus and the field trial; articles and webpages listed are ones I found helpful in creating this activity.

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