11. Hypotheses Formulation for Drug Effectiveness Test

Null and Alternative Hypotheses for testing Drug Effect

1/1 point (graded)

As in the two-sample test in the first example in this lecture sequence, you are running a clinical trial to determine the effectiveness of a drug for treating an illness. You administer the drug to a **treatment group** and give a placebo to the **control group**.

However, in this problem, you will consider a different data set: at the end of the trial, you survey all participants with the yes or no question: "Did you recover from this illness?"

You model a "Yes" response as 1 and a "No" response as 0. Thus, we can model:

- the treatment group's responses as $X_1, \ldots, X_n \overset{iid}{\sim} \text{Ber}\left(p_{\text{drug}}\right)$;
- the control group's responses as $Y_1, \ldots, Y_n \overset{iid}{\sim} \text{Ber}\left(p_{\text{control}}\right)$.

Your goal is to use this data to answer the **question of interest**:
"**Is this drug effective in treating the illness?**"

It is standard practice in a clinical trial to take as the **status quo** (which represents a prior assumption) that the drug is no more effective than placebo. Hence, the data must show strong evidence to the contrary in order for this status quo to be rejected. Note that the placebo is considered to have *no* effect (*i.e.*, it is not possible for the drug to be *less* effective than the placebo).

Given this standard, that the drug is considered to be no more effective than the placebo until "proven" otherwise, how should the **null hypothesis** H_0 and **alternative hypothesis** H_1 be defined?

- $H_0 : p_{\text{drug}} > p_{\text{control}}, H_1 : p_{\text{drug}} = p_{\text{control}}$
- $H_0 : p_{\text{drug}} \leq p_{\text{control}}, H_1 : p_{\text{drug}} \leq p_{\text{control}}$
- **(selected)** $H_0 : p_{\text{drug}} = p_{\text{control}}, H_1 : p_{\text{drug}} > p_{\text{control}}$
- $H_0 : p_{\text{drug}} = p_{\text{control}}, H_1 : p_{\text{drug}} < p_{\text{control}}$

✔

Solution:

We examine the choices in order.

- The choice "$H_0 : p_{\text{drug}} > p_{\text{control}}, H_1 : p_{\text{drug}} = p_{\text{control}}$" is incorrect because it does not align with the status quo. Namely, we do **not** take as a prior assumption that the drug is more effective than placebo.

  Remark: From a practical standpoint, it makes sense to be skeptical and assume the status quo $p_{\text{drug}} = p_{\text{control}}$ because this will make it **harder** for scams or ineffective drugs to make it through clinical trials. Concretely, it seems like a bad idea to allow a drug to pass trial which does not show strong evidence of being an effective treatment.

- The choice $H_0 : p_{\text{drug}} \leq p_{\text{control}}, H_1 : p_{\text{drug}} \leq p_{\text{control}}$ is incorrect because the regions defined by H_0 and H_1 are not disjoint.

- The correct choice is $H_0 : p_{\text{drug}} = p_{\text{control}}, H_1 : p_{\text{drug}} > p_{\text{control}}$. In general, the status quo should be taken to be the **null hypothesis**. Since the status quo is that the drug is no more effective than the placebo and we have stated that it is not possible for the drug to be *less* effective than the placebo, the hypothesis $p_{\text{drug}} \leq p_{\text{control}}$ captures our prior assumptions. Moreover, to reject the null hypothesis, we would

need to use the data to show that our observations are very unlikely under the assumption $p_{\text{drug}} = p_{\text{control}}$. In this situation, we would deem that $p_{\text{drug}} > p_{\text{control}}$ is more likely, so moreover the **alternative hypothesis should be** $p_{\text{drug}} > p_{\text{control}}$.

- The choice $H_0 : p_{\text{drug}} = p_{\text{control}}, H_1 : p_{\text{drug}} < p_{\text{control}}$ is incorrect. While the null hypothesis is consistent with our prior assumptions, it is not possible for the drug to be less effective than the placebo. Thus the alternative hypothesis is incorrectly stated.

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Answers are displayed within the problem

Identify Null and Alternative Hypotheses Regions for a Two Sample Test

1/1 point (graded)

As above, you are testing for whether a drug is effective using data comprising of yes or no responses from both the treatment and control groups to the question “did you recover from the illness at the end of this clinial trial?"

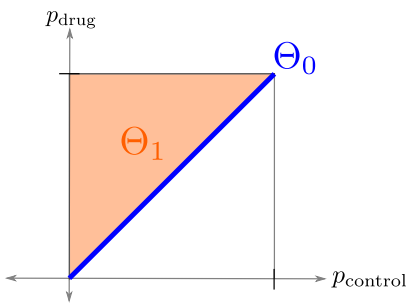
As above, you model

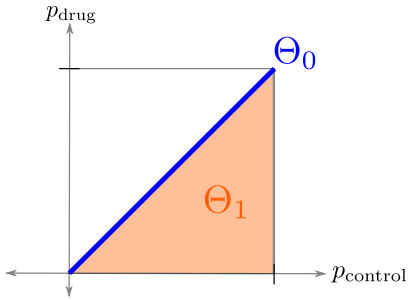
- the treatment group's responses as $X_1, \ldots, X_n \overset{iid}{\sim} \text{Ber}\,(p_{\text{drug}})$;
- the control group's responses as $Y_1, \ldots, Y_n \overset{iid}{\sim} \text{Ber}\,(p_{\text{control}})$.

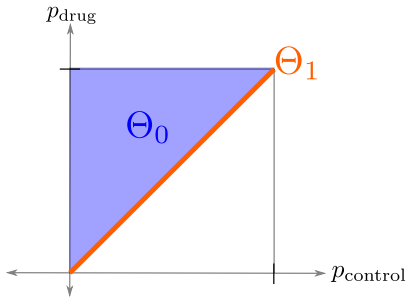
where $X_i = 1$ means the response is “Yes", and $X_i = 0$ mean “No", and similarly for Y_i. You assume the two sets of responses are independent of one another.

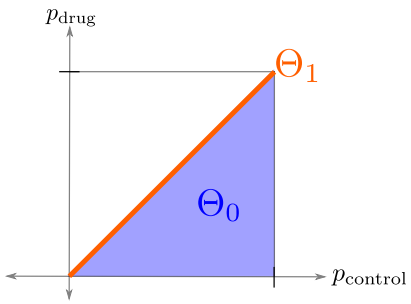
The statistical model for the example in the drug testing is $\left(\{0,1\}^2, \{P_{(p_{\text{control}}, p_{\text{drug}})}\}_{(p_{\text{control}}, p_{\text{drug}}) \in (0,1)^2}\right)$.

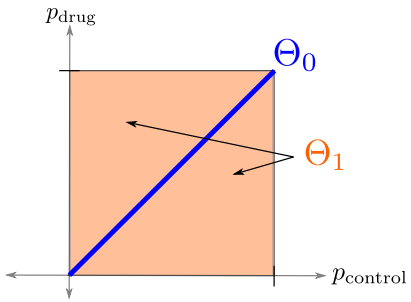
In the problem above, you formulated the null and alternative hypotheses. Which of the following depicts the regions Θ_0 (corresponding to the null hypothesis) and Θ_1 (corresponding to the alternative hypothesis)?


p_{drug}
Θ_0
Θ_1
p_{control}


p_{drug}
Θ_0
Θ_1
p_{control}


p_{drug}
Θ_1
Θ_0
p_{control}





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Solution:

First, the parameter space is

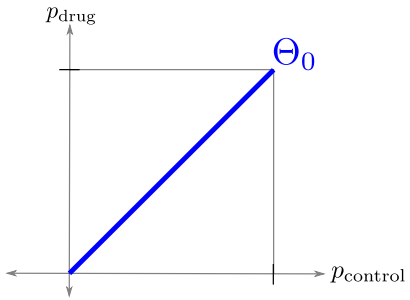
$$\Theta = \{(p_{\text{control}}, p_{\text{drug}}) : p_{\text{control}} \in (0,1), p_{\text{drug}} \in (0,1), \} = (p_{\$}0,1)^2.$$

Since $\Theta_0, \Theta_1 \subset \Theta$, only the figures in which the shaded regions Θ_0 and Θ_1 are within the unit square can be correct.

The null hypothesis is $H_0 : p_{\text{drug}} = p_{\text{control}}$, hence

$$\Theta_0 = \{(p_{\text{control}}, p_{\text{drug}}) \in (0,1)^2 : p_{\text{drug}} = p_{\text{control}}\}$$

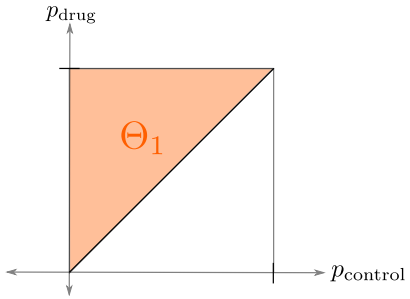
which defines the diagonal line in the unit square:



The alternative hypothesis is $H_1 : p_{\text{drug}} > p_{\text{control}}$, hence

$$\Theta_1 = \{(p_{\text{control}}, p_{\text{drug}}) \in (0,1)^2 : p_{\text{drug}} > p_{\text{control}}\}$$

which defines the region above the diagonal line in the unit square:



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"it is not possible for the drug to be less effective than the placebo"....why?
I know it's just an assumption for the problem, but in the real world it's not uncommon for new drugs to have so many adverse effects that they are effectively worst than doi... 3

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