Power Analysis and Sample Size Determination

Basic Ideas, Tools, and Examples

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Related Resources

- Two companion videos for this talk can be found here kaltura.uga.edu/media/t/1_scl60mqx and here kaltura.uga.edu/media/t/1_r5574d7h.
- An accompanying R script, powerExamps.R, is available as an attachment to each of the videos linked above. Follow the link to either video and click on attachments.
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- When planning a study, a fundamental design question is, *How many subjects?*
  - Too small and it will not generate enough information to learn anything definitive (low power).
  - Too large and we waste resources (money, time, opportunity).
  - Typically, we calculate the sample size necessary to have enough power to find the effect we are looking for.
- Sometimes the sample size is fixed. In that case, we may wish to calculate the power that our fixed sample size will achieve.
  - May tell us whether our study is worth doing at all.
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  - Forces you to think carefully about the design and the analysis.
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  - It requires assumptions about what we are researching, but we do the research precisely because we don't fully understand that subject.
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  - Given its imprecision and dependence on unknown inputs, often best to
    - get results over a range of inputs;
    - compute a conservative estimate (e.g., a lower bound on sample size needed to achieve 80% power);
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- to help operationalize and prioritize the research questions,
- to help with other design aspects that sample size/power will depend on,
- to figure out how to approach the power analysis and implement it,
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- Most general purpose commercial packages do power/sample size calculations.
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- R has some power functions in the `stats` package (e.g., `power.t.test()` as well as many specialized packages (`pwr` being the most useful).
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Basic Ideas

"Power" has a specific meaning tied to statistical hypothesis testing. So, let's review.

- Hypothesis testing:
  - Assume a null hypothesis H_0 is true,
  - gather evidence (data),
  - summarize evidence against H_0 (test statistic),
  - quantify strength of the evidence (p-value), and
  - make a decision (reject, fail to reject).
- Possible outcomes:

	The Truth	
Decision	H_0 is true	H_0 is false
Don't reject	Correct	Type II Error
Reject	Type I Error	Correct

$$\alpha = \Pr(\text{Type I Error}) \quad \beta = \Pr(\text{Type II Error})$$

$$\text{Power} = 1 - \beta = \Pr(\text{reject } H_0 \text{ given that it is false})$$

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Typical power analysis for a two-sample t test:

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1. Fix $\alpha = 0.05$ (or 0.01, or ...) and select 1- or 2-tailed alternative.
2. Assume a value of $|\mu_1 - \mu_2|$ based on clinical/practical significance and plausible magnitude of effect.
   - In this approach, μ_1 can be fixed at an arbitrary value.
   - Sometimes easier to assume a value for $\frac{\mu_2}{\mu_1}$ (percentage increase/decrease due to treatment) and a value for μ_1 from which $|\mu_1 - \mu_2|$ can be calculated.
3. Select minimum power you'd like to achieve (e.g., 80%).
   - Sometimes fixed by funding agency, but there may be wiggle room in 70–90% range.
   - 100 − power represents your tolerance of the risk of missing a real effect.
4. Assume a balanced design (which has best power) or, rarely, some degree of imbalance.
5. Compute power for range of n. Pick smallest n that achieves power target.

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Example: MOOC Study (Two-sample t Test and ANOVA)

An educational researcher want to improve MOOCs (massive open online courses) for students in developing countries.

- Planning 4 treatments, but for now, assume only A and D:

  $A =$ Standard MOOC in English

  $B =$ English MOOC with native language subtitles

  $C =$ English MOOC with native language dubbing and subtitles

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- $Y =$final exam score.
- He decides to use $\alpha = 0.05$, a balanced design, and wants 75% power.
- Basis of assumed effect size:
  - English-speaking past enrollees in A had $\bar{Y} = 78$, $SD(Y) = 10$.
  - Researcher believes non-native English speakers will score worse with more variability, so assumes $\mu_A = 70$, and $\sigma = 15$ in each treatment.
  - He thinks treatment D would be worthwhile if it increases scores by $\geq 10\%$ and believes such an increase is plausible. Thus,

$$\mu_D = 1.1\mu_A = 77.0 \quad \Rightarrow \quad \frac{|\mu_1 - \mu_2|}{\sigma} = \frac{7.0}{15} = 0.47.$$

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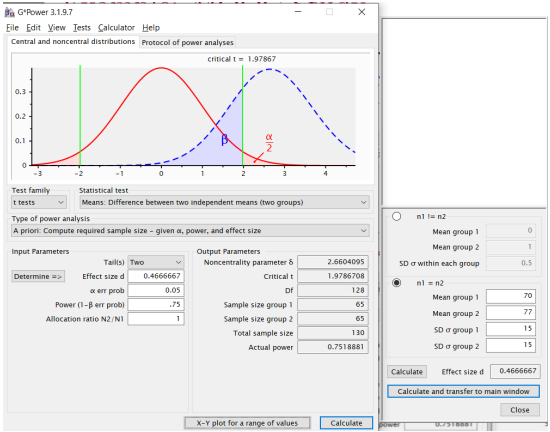

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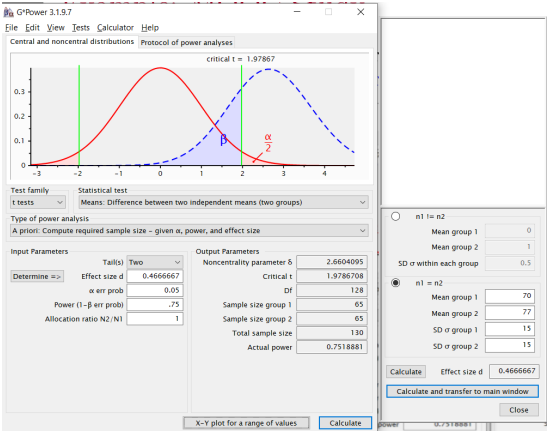

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Example: MOOC Study

What if the design includes all 4 treatments A–D?

- Now analysis is an ANOVA F test, not a two-sample t test.
- Effect size is determined by spacing of all four means. In fact, it is a function of sample variance of $\mu_A, \mu_B, \mu_C, \mu_D$.
- Conservative approach: assume a value for

$$\Delta \equiv |\mu_{\text{Max}} - \mu_{\text{Min}}|,$$

  and assume variance of all 4 treatment means is smallest (least favorable) subject to the assumed Δ.
- In MOOC example, we could assume $\Delta = 7$. Least favorable values for other means are half-way between best and worst. So means would be 70, 73.5, 73.5, 77.
- G*Power allows us to specify $\mu_A, \mu_B, \mu_C, \mu_D$ or their (population!) variance in order to determine effect size and the resulting power. Note: pop. variance of 70,73.5,73.5,77 is 6.125.
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Example: Secondhand Smoke Study (Repl. Latin Square)

St. Helen et al. (2012) designed an experiment to study secondhand smoke exposure in three outdoor environments:

- A: a **restaurant** patio,
- B: a **bar** beer garden,
- C: and a **control** setting (a park).

Design: Latin square replicated in two directions:

	Subject Number									
Week	1	2	3	4	5	6	...	n-2	n-1	n
1	A	B	C	A	B	C	...	A	B	C
2	B	C	A	C	A	B	...	B	C	A
3	C	A	B	B	C	A	...	C	A	B
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	.	.	.	.	.	.	...	.	.	.
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Response variables obtained as post-test minus pretest gain in two biomarkers for tobacco smoke exposure:

- Salivary cotinine
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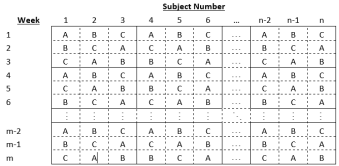

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Pilot study:

Parameter	Cotinine	log(NNAL/Creat)
Bar mean	1.432	0.638
Rest mean	0.766	0.134
Ctrl mean	0.141	0.130
SD: Occasions	0.344	0.207
SD: Subjects	0.582	0.285
SD: Error	0.356	0.176

- Analysis based on linear model for Latin square with fixed treatment effects, random subject and measurement occasion effects.
- Larger effects for cotinine, so we powered based on log(NNAL/creat).
- Large diff b/w Bar and Ctrl, so powered for Rest vs Ctrl contrast.
- Tiny difference in pilot data b/w Rest & Ctrl for log(NNAL/creat). But shouldn't always assume effect size that someone else obtained.
  - Pilot study small; much uncertainty in Rest vs Ctrl difference.
  - Should assume effect size that is plausible and clinically significant.
  - Cotinine: Rest vs Ctrl difference about half of Bar vs Ctrl diff. So, for log(NNAL/creat), assume Rest vs Ctrl diff at least one third of Bar vs Ctrl diff: $\mu_B - \mu_C = (0.638 - 0.130)/3 = 0.168$.

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Example: Secondhand Smoke Study

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Parameter	Cotinine	log(NNAL/Creat)
Bar mean	1.432	0.638
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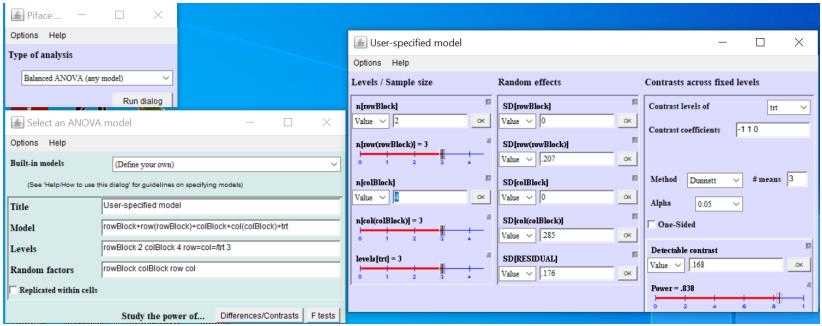
Russ Lenth's power applets are more useful for this example.



- Tried different values of m and n in multiples of 3. Power $\geq .80$ (0.838) for $m = 6$ measurement occasions, $n = 12$ subjects.

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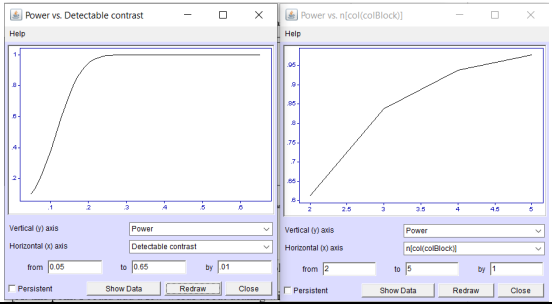
- When an input is especially speculative, its often advisable to compute power/sample size over a range for that input.
- This can also be useful just to visualize how the input affects power.
- E.g., in the SHS example, we assumed Rest vs. Ctrl difference was 0.168, one third the Bar vs. Ctrl difference. What if it were higher or lower?
- Below, we plot power versus the detectable contrast and versus # of replicated Latin squares in the column direction, which determines # subjects needed for the experiment.



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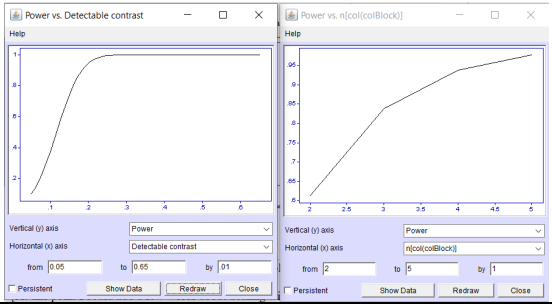

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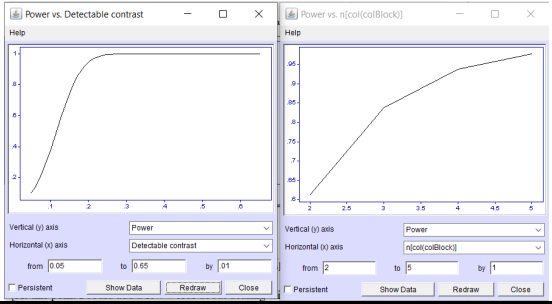

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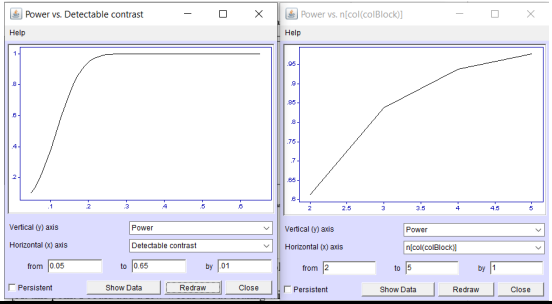

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Instead of using power/sample size software, simulation can be used to calculate power.

- E.g., in the SHS problem, we can generate many data sets at random with the assumed treatment means and variance components.
- For each data set, fit the model on which the analysis will be based, and test the hypothesis of interest.
- The proportion of the data sets for which the test is statistically significant is the power.
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Nonstandard Problems: Handle by Simulation and/or Simplification

Many problems are not implemented in power software. In those cases;

- try to simplify the analysis so that the problem is more tractable via simulation or via available software;
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- Partyka et al. interested in comparing echocardiographic measurements taken on koi fish under two conditions:
  - **A=Anaesthesia**, or
  - **B=manual restraint**.
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    $$\mathrm{SD}(Y_A - Y_B) = \left\{[\mathrm{SD}(Y_A)]^2 + [\mathrm{SD}(Y_B)]^2 - 2\underbrace{\mathrm{corr}(Y_A, Y_B)}_{\equiv\rho}\mathrm{SD}(Y_A)\mathrm{SD}(Y_B)\right\}^{1/2}$$

    and equal variance assumption to get $\mathrm{SD}(Y_A - Y_B) = S\sqrt{2(1-\rho)}$.
  - Power of test increases with ρ. Assume $\rho = 0.5$ (lowish).

Example: Koi Echocardiography Study

Assumptions, simplifications, and useful results:

- Power on paired t test, a simplification of the full crossover analysis.
  - Unless no order effect, crossover analysis will be more powerful.
- Need difference in means (=mean difference), and SD of difference b/w treatments.
- No literature on this topic. But some results giving summary stats on echo measurements in other non-anaesthetized fish of different species.
- Calculated power for range of % reduction under anaesthesia.
- Literature gives $\bar{Y}_B$, $\mathrm{SE}(\bar{Y}_B)$ for treatment B. We need $\mathrm{SD}(Y_A - Y_B)$.
  - Get $\mathrm{SD}(Y_B) = \sqrt{n}\mathrm{SE}(\bar{Y}_B)$.
  - Assume $\mathrm{SD}(Y_A) = \mathrm{SD}(Y_B) = S$ (equal variance).
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    $$\mathrm{SD}(Y_A - Y_B) = \left\{[\mathrm{SD}(Y_A)]^2 + [\mathrm{SD}(Y_B)]^2 - 2\underbrace{\mathrm{corr}(Y_A, Y_B)}_{\equiv\rho}\mathrm{SD}(Y_A)\mathrm{SD}(Y_B)\right\}^{1/2}$$

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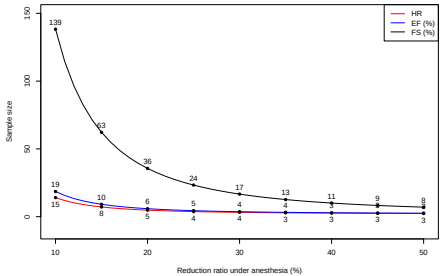
Example: Koi Echocardiography Study

Calculations can be done in G*Power or the Lenth applets. But we used the `power.t.test()` function in R.

```
# means and SD for the 3 responses in trt B:
meanB <- c(70,30,17); SD <- c(10,5,8)
# assume range of effect size (rr=reduction ratio)
rr <- seq(from=0.1,to=0.5,by = 0.01); effSize <- meanB%*%t(rr)
rho <- 0.5 ; sdDiff <- SD*sqrt(2*(1-rho))
# calculate sample sizes with power.t.test() function
sSize <- matrix(NA,ncol=3,nrow= length(rr))
for (j in 1:3){ for(i in 1:length(rr)){
    sSize[i,j]=power.t.test(delta = effSize[j,i],sd=sdDiff[j],
                            power = 0.8,sig.level = 0.05,
                            type="paired",alternative = "one.sided")$n } }
```



Example: COVID-19 Assay (Sensitivity and Specificity)

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- New assay to use yeast-based spike protein, cheaper than existing CDC assay that uses human-derived spike protein.
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Example: COVID-19 Assay (Sensitivity and Specificity)

Complications:

- Non-inferiority trial.
- Paired design.

Inputs:

- Non-inferiority margin (decided on $\delta = 0.05$).
- Significance level ($\alpha = 0.05$).
- Power (80%).
- Correlation between results from the two assays (0.9).
- True sensitivity of each test (assumed 0.96, published value for CDC assay).
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Example: COVID-19 Assay (Sensitivity and Specificity)

```
library(mvtnorm); library(PropCIs)
# The following function computes a multinomial prob vector for a 2x2 table assuming dichotomized bivariate
# normal random variables generated the table. rho is corr b/w the bivariate normals, and sens is the cut-point
# for dichotomization (i.e, the positivity rate of each assay).
mnorm.pi <- function(rho,sens){
  zsens <- qnorm(sens)
  sigma <- diag(2); sigma[1,2] <- sigma[2,1] <- rho
  p11 <- pmvnorm(lower=c(-Inf,-Inf),upper=c(zsens,zsens),mean=c(0,0),sigma=sigma)
  p01 <- pnorm(zsens)-p11; p10 <- pnorm(zsens)-p11; p00 <- 1-p11-p01-p10
  pi <- c(p00,p01,p10,p11); pi
}
# Now a function to compute the reject rate based on nsim simulated data sets, each of size n,
# where underlying continuous responses are bivariate normal with correlation rho, and where each
# dichotomous response (each test's results) has prob of a positive response (i.e., sensitivity
# when used on cases) equal to sens, and where the non-inferiority margin is delta.
simPowerNoninfSens <- function(nsim=2000,n,rho,sens,delta=0.05,level=.05){

  rcounts <- rmultinom(nsim,n,mnorm.pi(rho=rho,sens=sens))
  rejectVec <- numeric(nsim)
  for(i in 1:nsim){
    rejectVec[i] <- as.numeric(
      scoreci.mp(b=rcounts[2,i],c=rcounts[3,i],n=n,
                 conf.level=1-2*level)$conf.int[1] > -1*delta)}
mean(rejectVec)
}
```

Example: COVID-19 Assay (Sensitivity and Specificity)

- Functions above were used to calculate power

```
set.seed(149689)
# Now compute power at various choices of n_1 assuming sensitivity of 0.96.
# (n_1=117 gives power <.8, n_1=118 gives power>.8)
simPowerNoninfSens(nsim=5000,n=117,rho=.9,sens=.96,delta=0.05)
```

```
[1] 0.7898
```

```
simPowerNoninfSens(nsim=5000,n=118,rho=.9,sens=.96,delta=0.05)
```

```
[1] 0.8342
```

```
# Now compute power at various choices of n_0 assuming  specificity of 0.993.
# Same function can be used, just use specificity value in sens argument.
# (n_0=67 gives power <.8, n_0=68 gives power >.8)
simPowerNoninfSens(nsim=5000,n=67,rho=.9,sens=.993,delta=0.05,level=.05)
```

```
[1] 0.7976
```

```
simPowerNoninfSens(nsim=5000,n=68,rho=.9,sens=.993,delta=0.05,level=.05)
```

```
[1] 0.8008
```

- $n_0 = 68$, $n_1 = 118$.

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Final Comments

Cohen's Effect Sizes:

- Based on the social science literature, Cohen (1988) published guidelines for small, medium, and large standardized effect size in various types of power analyses.
  - E.g., for a one-way ANOVA, Cohen's small, medium and large standardized effect sizes ($f = \sigma_W/\sigma_B$) are 0.10, 0.25, and 0.40.
- A deeply flawed strategy is to assume one of these "T-shirt" effect sizes, which allows sample size to be determined without separate consideration of the magnitude of effect on the scale of measurement to be used, the error variability, and the experimental design.
- Essentially, assuming a canned standardized effect size without consideration of the factors that determine it is *pretending to do a power/sample size analysis.*
  - E.g., for 80% power, all balanced one-way layouts come in one of 3 sizes:
    - Small ($f = 0.10 \Rightarrow n = 393$)
    - Medium ($f = 0.25 \Rightarrow n = 64$)
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Post-Hoc Power Analysis

- When a completed study fails to find the significant result it was designed to reveal, the question often arises:
  - *Was the null result because my study was underpowered?*
- To answer this, many investigators embark on retrospective power analysis. This is a fool's errand.
  - If the result was non-significant, then the test necessarily had low power for the *observed effect*. No further calculation is needed.
  - But that does not imply the study was underpowered. It may be that the true effect was trivial or null.
  - And if retrospective power for a *clinically significant effect* is low, this doesn't imply that the null result is less valid or that p would reach significance if study had been larger.
  - The reverse claim is more common: if a non-significant p-value was obtained and the study had high power for a clinically significant effect, then it is "more valid" to conclude H_0 is true.
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