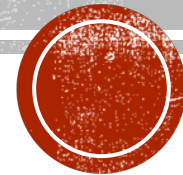


SAMPLE SIZE ESTIMATION & STATISTICAL POWER ANALYSIS IN EXPERIMENTAL DESIGNS



PURPOSE

- DECIDE HOW LARGE SAMPLE SIZE NEEDED TO ENABLE STATISTICAL JUDGMENTS THAT IS ACCURATE & RELIABLE
- HOW LIKELY STATISTICAL TEST WILL DETECT EFFECTS OF A GIVEN SIZE IN A PARTICULAR SITUATION



OUTLINE

- **POWER ANALYSIS AND SAMPLE SIZE CALCULATION IN EXPERIMENTAL DESIGN**
 - **SAMPLING THEORY**
 - **HYPOTHESIS TESTING**
 - **CALCULATING POWER**
 - **CALCULATING REQUIRED SAMPLE SIZE**



SAMPLING THEORY

- SAMPLE IS A SUBSET OF POPULATION
- STATISTIC IS AN ESTIMATE OF THE PARAMETER
- IN ANY SAMPLE, THERE WILL BE SOME SAMPLING ERROR OR VARIATION
- SAMPLING ERROR = DIFFERENCES OF SAMPLE TO THE PARAMETER ESTIMATE



HYPOTHESIS TESTING LOGIC

- PROCESS
- REJECT SUPPORT HYPOTHESIS TESTING
- NULL HYPOTHESIS IS EITHER TRUE OR FALSE
- STATISTICAL DECISION IS ONLY “ONE”



HYPOTHESIS TESTING LOGIC

		H0	H1
DECISION	H0	CORRECT ACCEPTANCE	TYPE II ERROR β
	H1	TYPE I ERROR α	CORRECT REJECTION



SIGNIFICANCE TESTING

- **TWO BASIC KINDS OF SITUATIONS**
 - **REJECT SUPPORT**
 - **ACCEPT SUPPORT**



REJECT SUPPORT RESEARCH - SUMMARY

1. RESEARCHER WANTS TO REJECT H_0
2. SOCIETY WANTS TO CONTROL TYPE 1 ERROR
3. RESEARCHER IS CONCERNED WITH TYPE 2 ERROR
4. HIGH SAMPLE SIZE WORKS FOR RESEARCHER
5. IF THERE IS “TOO MUCH POWER”, TRIVIAL EFFECTS BECOME HIGHLY SIGNIFICANT



ACCEPT SUPPORT RESEARCH - SUMMARY

1. RESEARCHER WANTS TO ACCEPT H_0
2. SOCIETY WORRY ABOUT CONTROLLING TYPE 2 ERROR
3. RESEARCHER MUST BE VERY CAREFUL TO CONTROL TYPE 1 ERROR
4. HIGH SAMPLE SIZE WORKS AGAINST RESEARCHER
5. TOO MUCH POWER, THE RESEARCHER'S THEORY CAN BE REJECTED BY A SIGNIFICANCE TEST EVEN THOUGH IT FITS THE DATA ALMOST PERFECTLY



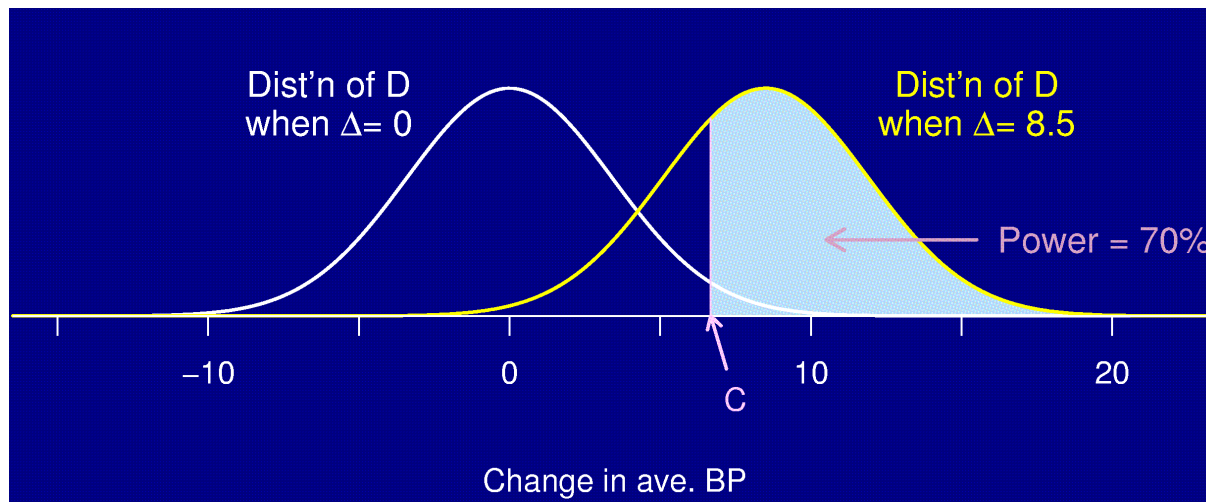
CALCULATING POWER

- FACTORS INFLUENCING POWER OF A STATISTICAL TEST:
 - KIND OF STATISTICAL TEST
 - SAMPLE SIZE, LARGER SIZE ~ LARGER POWER; WASTEFUL
 - SIZE OF EXPERIMENTAL EFFECTS
 - LEVEL OF ERROR IN EXPERIMENTAL MEASUREMENTS



STATISTICAL POWER

Power = The chance that you reject H_0 when H_0 is false (i.e., you [correctly] conclude that there is a treatment effect when there really is a treatment effect).



POWER DEPENDS ON...

- The structure of the experiment
- The method for analyzing the data
- The size of the true underlying effect
- The variability in the measurements
- The chosen significance level (α)
- The sample size

Note: We usually try to determine the **sample size** to give a **particular power** (often 80%).



CALCULATING REQUIRED SAMPLE SIZE

- **MEASURES THAT AFFECT ACCURATENESS OF DATA:**
 - **MARGIN OF ERROR (CONFIDENCE INTERVAL)**
 - **CONFIDENCE LEVEL**



EASY SAMPLE SIZE CALCULATOR

	Confidence level = 95%			Confidence level = 99%		
	Margin of error			Margin of error		
Population size	5%	2,5%	1%	5%	2,5%	1%
100	80	94	99	87	96	99
500	217	377	475	285	421	485
1.000	278	606	906	399	727	943
10.000	370	1.332	4.899	622	2.098	6.239
100.000	383	1.513	8.762	659	2.585	14.227
500.000	384	1.532	9.423	663	2.640	16.055
1.000.000	384	1.534	9.512	663	2.647	16.317



Calculate sample size margin of error

After your survey is complete and you know the number of respondents you actually have, you can use this calculator to determine the actual margin of error.

Margin of error		
Population size:	<input type="text"/>	How many people are in the group your sample represents? (The sample size does not change much for populations larger than 20,000.)
Number of respondents:	<input type="text"/>	The actual number of respondents that answered your survey.
Confidence level:	95% <input type="button" value="v"/>	This tells you how sure you can be of the error of margin. It is expressed as a percentage and represents how often the true percentage of the population who would pick an answer lies within the margin of error.
Margin of error:	0.00%	



SAMPLE SIZE CALCULATOR

Population size:	<input type="text"/>	How many people are in the group your sample represents? (The sample size does not change much for populations larger than 20,000.)
Margin of error:	2% <input type="button" value="v"/>	This is the plus-or-minus figure usually reported in newspaper or television opinion poll results. For example, if you use a margin of error of 4% and 47% percent of your sample picks an answer, you can be "sure" that if you had asked the question to the entire population, between 43% (47-4) and 51% (47+4) would have picked that answer.
Confidence level:	95% <input type="button" value="v"/>	This tells you how sure you can be of the margin of error. It is expressed as a percentage and represents how often the true percentage of the population who would pick an answer lies within the margin of error.
Required sample size:	0	Number of respondents needed
Estimated response rate:	20% <input type="button" value="v"/>	What percent of those asked to participate in the survey will do so. Response rates vary greatly depending on many factors including the distribution method (e-mail, paper, phone...), type of communication (B2C, B2B...), quality of the invitation, use of incentives, etc.
Number to invite:	0	This is the number of individuals out of the population you need to ask to participate, in order to achieve the required sample size based on the expected response rate.



SAMPLE SIZE ESTIMATION

- $SS = (Z\text{-score})^2 * p*(1-p) / (\text{margin of error})^2$
- After calculation of sample size you have to correct for the total (estimated) population
 $SS_{\text{adjusted}} = (SS) / (1 + [(SS - 1) / \text{population}])$



SAMPLE SIZE ESTIMATION

Chart 1. Formulas for sample sizing to describe quantitative and qualitative variables in a population.

	Quantitative variable	Qualitative variable
Infinite population	$n = \left(\frac{Z_{\alpha/2} \cdot \delta}{E} \right)^2$	$n = \left(\frac{Z_{\alpha/2} \cdot \sqrt{p \cdot q}}{E} \right)^2$
Finite population (< 10000)	$n = \frac{N \cdot \delta^2 \cdot (Z_{\alpha/2})^2}{(N - 1) \cdot (E)^2 + \delta^2 \cdot (Z_{\alpha/2})^2}$	$n = \frac{N \cdot p \cdot q \cdot (Z_{\alpha/2})^2}{(N - 1) \cdot (E)^2 + p \cdot q \cdot (Z_{\alpha/2})^2}$

n – sample size; $Z_{\alpha/2}$ – critical value for the desired confidence degree, usually: 1.96 (95%); δ – population standard deviation of the variable; E – standard error, usually: $\pm 5\%$ of the proportion of cases (absolute precision), or $\pm 5\%$ of the mean value ($1.05 \times \text{mean}$); N – (finite) population size; p – proportion of favorable results of the variable in the population; q – proportion of unfavorable results in the population ($q=1-p$).



SAMPLE SIZE ESTIMATION

- Example 1: To describe the measurements of mean arterial pressure from a specific population of patients that has never been described before, with tolerable error of ± 5 mmHg, the sample size would have to be based on the standard deviation considering the values from this group. If a pre-test with 30 patients showed the standard deviation of 15 mmHg,

- $n = (1.96 \times 15 / 5)^2$

= 34.6 patients



SAMPLE SIZE ESTIMATION

- Example 2: To describe the prevalence of venous insufficiency of the lower limbs, with tolerable error of $\pm 5\%$, in the population of morbidly obese patients from a specific obesity outpatient clinic with 315 patients (630 limbs), the sample size calculation could be based on the results obtained by Seidel et al.6, who estimated the proportion of 69.3% of affected limbs

- $$n = \frac{630 \times 0.693 \times 0.307 \times (1.96)^2}{\{[(630-1) \times (0.05)^2] + [0.693 \times 0.307 \times (1.96)^2]\}}$$

$$= 215.5 \text{ limbs}$$



SAMPLE SIZE ESTIMATION

	Quantitative variable	Qualitative variable
Non-paired sample	$n = (S_a^2 + S_b^2) \cdot \left(\frac{Z_{\alpha/2} + Z_{\beta}}{d} \right)^2$	$n = \frac{(p_1 \cdot q_1 + p_2 \cdot q_2) \cdot (Z_{\alpha/2} + Z_{\beta})^2}{(p_1 - p_2)^2}$
Paired sample	$n_P = \left(\frac{(Z_{\alpha/2} + Z_{\beta}) \cdot S_d}{\bar{D}} \right)^2$	$n_P = \frac{(Z_{\alpha/2} + 2 \cdot Z_{\beta} \cdot \sqrt{p_a \cdot q_a})^2}{4 \cdot p_d \cdot (p_a - 0,5)^2}$

n – sample size (for each subgroup); n_P – number of pairs; $Z_{\alpha/2}$ – value of error α , usually: 1.96 (5%); Z_{β} – value of error β , usually: 0.84 (20%); d – minimum difference between the mean values; S_a and S_b – standard deviation of the variable in each group; S_d – standard deviation of the difference between the pairs; \bar{D} – mean value of the difference between the pairs; p_1 and p_2 – proportion of favorable results in subgroup 1 or 2; q_1 and q_2 – proportion of unfavorable results in subgroup 1 or 2; p_a – proportion of unmatched pairs for group 1; q_a – proportion of matched pairs for group 1; p_d – sum of the proportion of unmatched pairs for the two groups.



SAMPLE SIZE ESTIMATION

- Example 3: To compare the flow measurements of two limbs of dogs submitted to two different procedures of arterial revascularization, with the minimum tolerable difference of ± 50 mL/min to consider efficient one of the procedures, a pilot study would have to indicate the standard deviation of the differences between flows (e.g.: 60 mL/min).

- $n = [(1.96 + 0.84) \times 60 / 50]^2$
 $= 11.3$ animals



SAMPLE SIZE ESTIMATION

- Example 4: To compare the healing rates of two surgical procedures, the traditional method resulting in a 70% healing rate and the study procedure at least 10% better than the conventional system, the minimum sample size calculation of a clinical trial is?

- $$n = \{[(0.7 \times 0.3) + (0.8 \times 0.2)] \times (1.96 + 0.84)^2\} / (0.7 - 0.8)^2$$

$$= 290.4 \text{ patients (each group)}$$



SAMPLE SIZE ESTIMATION

Chart 3. Formula for sample sizing for linear correlation between quantitative variables.

$$n = 4 + \left(\frac{(Z_{\alpha/2} + Z_{\beta})}{0,5 \cdot \ln \left(\frac{1+r}{1-r} \right)} \right)^2$$

n – sample size; $Z_{\alpha/2}$ – value of error α , usually: 1.96 (5%); Z_{β} – value of error β , usually: 0.84 (20%); r – linear correlation coefficient (Pearson or Spearman).



SAMPLE SIZE ESTIMATION

- Example 5: To establish the correlation between the measurement of muscle force of quadriceps and the maximum distance covered by patients with history of intermittent claudication, the sample size calculation could be based on the study conducted by Pereira et al. 11, which described a linear correlation coefficient of 0.87.

- $$n = 4 + \left\{ \frac{1.96 + 0.84}{0.5 \times \ln(1 + 0.87)} \right\}^2$$
$$= 8.4 \text{ patients}$$

