P_1	P_2					
0.9	0.4	14	29	33	38	47
0.8	0.3	15	31	36	42	51
0.7	0.2	15	31	36	42	51
0.6	0.1	14	29	33	38	47
0.5	0.0	12	24	27	32	39
0.9	0.3	10	21	24	28	35
0.8	0.2	11	22	25	29	36
0.7	0.1	10	21	24	28	35
0.6	0.0	9	18	21	25	30

Module 28: Sample Size Determination

This module explores the process of estimating the sample size required for detecting differences of a specified magnitude for three common circumstances.

MASTER JULY [illegible]/MODULE 28

The General Situation

An important issue in planning a new study is the determination of an appropriate sample size required to meet certain conditions. For example, for a study dealing with blood cholesterol levels, these conditions are typically expressed in terms such as “How large a sample do I need to be able to reject the null hypothesis that two population means are equal if the difference between them is $d = 10$ mg/dl?”

The General Approach

We focus on the sample size required to test a specific hypothesis. In general, there exists a formula for calculating a sample size for the specific test statistic appropriate to test a specified hypothesis. Typically, these formulae require that the user specify the α-level and Power $= (1 - \beta)$ desired, as well as the difference to be detected and the variability of the measure in question.

Importantly, it is usually wise not to calculate a single number for the sample size. Rather, calculate a range of values by varying the assumptions so that you can get a sense of their impact on the resulting projected sample size. The you can pick a more suitable sample size from this range.

Three Common Situations

In this module, we examine the process of estimating sample size for three common circumstances:

1. One-sample t-test and paired t-test,
2. Two-sample t-test, and
3. Comparison of P_1 versus P_2 with a z-test.

The tools required for these three situations are broadly applicable and cover many of the circumstances that are typically encountered. There are sophisticated software packages that cover much more than these three and most professional biostatisticians have them readily available.

1. One-sample t-test and Paired t-test

For testing the hypothesis:

$$H_0 : \mu = k \;\; \text{vs} \;\; H_1 : \mu \neq k$$

with a two-tailed test, the formula is:

$$n = \left[\frac{(z_{1-\alpha/2} + z_{1-\beta})\sigma}{d} \right]^2$$

Note that this formula is used even though the test statistic could be a t-test.

A One-Sample Example

We are interested in the size for a sample from a population of blood cholesterol levels. We know that typically σ is about 30 mg/dl for these populations.

The following table shows sample sizes for different levels of some of the factors included in the equation for a one sample t-test for differences between a specified population mean and the true mean..

One-Sample Example

$\alpha = 0.05$, $\sigma = 25$, $d = 5.0$, Power = 0.80

$$n = \left[\frac{(z_{1-\alpha/2} + z_{1-\beta})\sigma}{d} \right]^2$$

$$n = \left[\frac{(1.96 + 0.842)25}{5} \right]^2$$

$$= [\mathbf{14.01}]^2 = \mathbf{196.28}$$

Sample Size for One-Sample t-test, $\alpha = 0.05$

Blood Cholesterol Levels

$\sigma = 25$

	$1-\beta/z_{1-\beta}$				
$\sigma = 25$	0.5	0.8	0.85	0.9	0.95
d	0	0.842	1.036	1.282	1.645
0.5	9,604	19,628	22,440	26,276	32,490
1.0	2,401	4,907	5,610	6,569	8,123
3.0	267	545	623	730	903
5.0	96	196	224	263	325
10.0	24	49	56	66	81
20.0	6	12	14	16	20
30.0	3	5	6	7	9

$\sigma = 30$

$\sigma = 30$	$1-\beta/z_{1-\beta}$				
	0.5	0.8	0.85	0.9	0.95
d	0	0.842	1.036	1.282	1.645
0.5	13,830	28,264	32,314	37,838	46,786
1.0	3,457	7,066	8,078	9,460	11,696
3.0	384	785	898	1,051	1,300
5.0	138	283	323	378	468
10.0	35	71	81	95	117
20.0	9	18	20	24	29
30.0	4	8	9	11	13

$\sigma = 35$

$\sigma = 35$	$1-\beta/z_{1-\beta}$				
	0.5	0.8	0.85	0.9	0.95
d	0	0.842	1.036	1.282	1.645
0.5	18,824	38,471	43,982	51,502	63,681
1.0	4,706	9,618	10,996	12,875	15,920
3.0	523	1,069	1,222	1,431	1,769
5.0	188	385	440	515	637
10.0	47	96	110	129	159
20.0	12	24	27	32	40
30.0	5	11	12	14	18

2. Two Sample t-test

For the hypothesis:

$H_0: \mu_1 = \mu_2$ vs $H_1: \mu_1 \neq \mu_2$

For a two tailed t-test, the formula is:

$$N = n_1 + n_2 = \frac{4\sigma^2 \left(z_{1-\alpha/2} + z_{1-\beta}\right)^2}{\left(d = \mu_1 - \mu_2\right)^2}$$

Sample Size for Testing $H_0: \mu_1 = \mu_2$ vs $H_1: \mu_1 \neq \mu_2$

Two sample t-test Two tailed t-test

How large a sample would be needed for comparing two approaches to cholesterol lowering using

$\alpha = 0.05$, to detect a difference of

d = 20 mg/dl or more with

Power = $1-\beta = 0.90$

The formula is:

$$N = n_1 + n_2 = \frac{4\sigma^2 (z_{1-\alpha/2} + z_{1-\beta})^2}{(d = \mu_1 - \mu_2)^2}$$

When $\sigma = 30$ mg/dl

$\alpha = 0.05$ so $Z_{1-\alpha/2} = 1.96$

Power = $1-\beta = 0.90$ so $Z_{1-\beta} = 1.282$

$\sigma = 30$ mg/dl

d = 20 mg/dl

$$N = n_1 + n_2 = \frac{4(30)^2(1.96 + 1.282)^2}{(20)^2}$$

$$= \frac{4 \times 900 \times (3.242)^2}{400} = \frac{37,838.03}{400} = 94.6$$

Hence about 50 for each group

$\sigma = 25$

	$1-\beta/Z_{1-\beta}$				
$\sigma = 25$	0.5	0.8	0.85	0.9	0.95
d	0	0.842	1.036	1.282	1.645
0.5	38,416	78,512	89,760	105,106	129,960
1	9,604	19,628	22,440	26,276	32,490
3	1,067	2,181	2,493	2,920	3,610
5	384	785	898	1,051	1,300
10	96	196	224	263	325
20	24	49	56	66	81
30	11	22	25	29	36

$\sigma = 30$

	$1-\beta / Z_{1-\beta}$				
$\sigma = 30$	0.5	0.8	0.85	0.9	0.95
d	0	0.842	1.036	1.282	1.645
0.5	55,319	113,057	129,255	151,352	187,143
1	13,830	28,264	32,314	37,838	46,786
3	1,537	3,140	3,590	4,204	5,198
5	553	1,131	1,293	1,514	1,871
10	138	283	323	378	468
20	35	71	81	95	117
30	15	31	36	42	52

$\sigma = 35$

	$1-\beta/Z_{1-\beta}$				
$\sigma = 35$	0.5	0.8	0.85	0.9	0.95
d	0	0.842	1.036	1.282	1.645
0.5	75,295	153,884	175,930	206,007	254,722
1	18,824	38,471	43,982	51,502	63,681
3	2,092	4,275	4,887	5,722	7,076
5	753	1,539	1,759	2,060	2,547
10	188	385	440	515	637
20	47	96	110	129	159
30	21	43	49	57	71

3. Two-sample proportions

$$H_0 : P_1 = P_2 \quad vs \quad H_1 : P_1 \neq P_2$$

$$N = n_1 + n_2 = \frac{4(z_{1-\alpha/2} + z_{1-\beta})^2 \left[\left(\frac{P_1 + P_2}{2} \right) \left(1 - \frac{P_1 + P_2}{2} \right) \right]}{(d = P_1 - P_2)^2}$$

Example: $d = P_1 - P_2 = 0.7 - 0.5 = 0.2$

$\alpha = 0.05$, so $z_{1-\alpha/2} = 1.96$

$\beta = 0.10$, so $z_{1-\beta} = 1.282$

$(P_1 + P_2)/2 = (0.7 + 0.5)/2 = 0.6$

$$N = (n_1 + n_2) = \frac{4(1.96 + 1.282)^2 [(0.6)(1 - 0.6)]}{(0.2)^2}$$

$$= \frac{4(3.242)^2 [(0.6)(0.4)]}{(0.2)^2} = \frac{10.09}{0.04}$$

$$= 252.25$$

Hence, we should consider using N = 260, or 130 per group

$P_1 - P_2$

Sample size for testing $P_1 - P_2$, with $\alpha = 0.05$						
		$1-\beta / z_{1-\beta}$				
		0.5	0.8	0.85	0.9	0.95
P_1	P_2	0	0.842	1.036	1.282	1.645
0.9	0.8	196	400	458	536	663
0.8	0.7	288	589	673	788	975
0.7	0.6	350	714	817	956	1,183
0.6	0.5	380	777	889	1,041	1,287
0.5	0.4	380	777	889	1,041	1,287
0.4	0.3	350	714	817	956	1,183
0.3	0.2	288	589	673	788	975
0.2	0.1	196	400	458	536	663
0.1	0.0	73	149	171	200	247

P_1	P_2					
0.9	0.7	61	126	144	168	208
0.8	0.6	81	165	188	221	273
0.7	0.5	92	188	215	252	312
0.6	0.4	96	196	224	263	325
0.5	0.3	92	188	215	252	312
0.4	0.2	81	165	188	221	273
0.3	0.1	61	126	144	168	208
0.2	0.0	35	71	81	95	117
0.9	0.6	32	65	75	88	108
0.8	0.5	39	79	91	106	131
0.7	0.4	42	86	99	116	143
0.6	0.3	42	86	99	116	143
0.5	0.2	39	79	91	106	131
0.4	0.1	32	65	75	88	108
0.3	0.0	22	44	51	60	74

$P_1 - P_2$

Sample size for testing $P_1 - P_2$ with $\alpha = 0.05$

		$1-\beta / z_{1-\beta}$				
	□	0.5	0.8	0.85	0.9	0.95
P_1	P_2	0	0.842	1.036	1.282	1.645
0.9	0.5	20	41	47	55	68
0.8	0.4	23	47	54	63	78
0.7	0.3	24	49	56	66	81
0.6	0.2	23	47	54	63	78
0.5	0.1	20	41	47	55	68
0.4	0.0	15	31	36	42	52