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Calculating Sample Size Using On-line Power Calculators: Examples

Sample size can be calculated by hand, but the calculations can be complicated. Most researchers choose instead to use power/sample size calculators. There are several software programs designed to analyze sample size (Egret, SIZ, PASS, Power and Precision, a web-based program). If you are designing a project with a more complex analysis (i.e. cluster randomized studies), you should invest in a software program that calculates sample size. However, for more simple analysis or to do a rough sample size calculation, there are many publicly available power/sample size calculators online. This worksheet explains how to calculate sample size using two of these on-line calculators.

We will use this example:

You are planning a one-year, randomized controlled trial of an intervention for diabetes prevention among those with pre-diabetes. The annual rate of progression to diabetes is 6.5% for individuals with pre-diabetes in this population, so we expect that the cumulative incidence of diabetes in the control group will be 6.5% by the end of the study. We expect that our intervention will prevent people with pre-diabetes from becoming diabetic and that the cumulative incidence of diabetes at year one will be 5.0% in the intervention group. That is a 1.5/6.5 = 23% relative risk reduction. The ratio of intervention to non-intervention (controls) is 1:1.

Note that you will need to postulate the expected risk reduction from the intervention. You have to base this on the literature and on your judgment, balancing study size and resources. You will need the expected event rate, which you will get from searching the literature.

1. www.openepi.com
    a. On the left-hand side under Sample Size, click on the type of study that you are conducting (for the example, Cohort/RCT).
    b. Click on Enter New Data.
    c. Fill in the appropriate boxes and click Calculate. For the example, you should enter the following responses:
        - Two-sided confidence level = 95
        - Power = 80
        - Ratio of unexposed to exposed in the sample = 1.0
        - Percent of unexposed with outcome = 6.5
        - Percent of exposed with outcome = 5.0

2. http://stat.ubc.ca/~rollin/stats/ssize/
    a. Click on the type of study that you are conducting (for the example, Comparing Proportions for Two Independent Samples)
    b. Click the circle for Calculate Sample Size
    c. Fill in the appropriate boxes and click Calculate. For the example, you should enter the following responses:
        - Value for p1 = 0.065
        - Value for p2 = 0.05
        - Alpha = 0.05
        - Power = 0.80
        - Click the Two-sided Test circle

These programs will also calculate sample sizes for surveys, case-control studies, cohort studies and other designs.

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Sample Budget and Budget Justification

SUMMARY

ACME RESEARCH FOUNDATION
01/01/08 - 12/31/10

	PERIOD 1 01/01/08 - 06/30/08	PERIOD 2 07/01/08 - 12/31/08	PERIOD 3 01/01/09 - 06/30/09	PERIOD 4 07/01/09 - 12/31/09	PERIOD 5 01/01/10 - 06/30/10	PERIOD 6 07/01/10 - 12/31/10	TOTAL
ACME RESEARCH FOUNDATION							
Personnel							
Researcher A - salary (9.5%)	8,728	8,902	8,990	9,170	9,260	9,445	54,495
Researcher A - fringe	2,335	2,404	2,427	2,499	2,523	2,574	14,762
Researcher B - salary (2.5%)	1,169	1,193	1,205	1,229	1,241	1,266	7,303
Researcher B - fringe	313	322	325	335	338	345	1,978
Researcher C - salary (19%)	3,714	3,788	3,826	3,902	3,940	4,019	23,189
Researcher C - fringe	993	1,023	1,033	1,063	1,074	1,095	6,281
Total Personnel	***17,252***	***17,632***	***17,806***	***18,198***	***18,376***	***18,744***	***108,008***
Consultants							
Other ARF faculty	1,350	1,350	1,350	1,350	1,350	1,350	8,100
Total Consultants	***1,350***	***1,350***	***1,350***	***1,350***	***1,350***	***1,350***	***8,100***
Travel							
Subsidies for travel to India	2,550	0	2,550	0	2,550	0	7,650
Total Travel	***2,550***	***0***	***2,550***	***0***	***2,550***	***0***	***7,650***
TOTAL ARF DIRECT COSTS	**21,152**	**18,982**	**21,706**	**19,548**	**22,276**	**20,094**	**123,758**
SUBCONTRACT - FIELD SITE PARTNER							
Personnel							
Project coordinator	2,250	2,250	2,550	2,550	2,850	2,850	15,300
Interventionists (2)	1,125	1,125	1,620	1,620	1,740	1,740	8,970
Field workers (4)	2,250	2,250	3,240	3,240	3,480	3,480	17,940
Phlebotomists (4)	2,250	2,250	3,240	3,240	3,480	3,480	17,940
ECG technician	563	562	810	810	870	870	4,485
Data entry operator	675	675	990	990	1,080	1,080	5,490
Van driver	563	562	810	810	870	870	4,485
Total Personnel	***9,676***	***9,674***	***13,260***	***13,260***	***14,370***	***14,370***	***74,610***
Equipment							
Van	22,690	--	--	--	--	--	
LCD projector w/in-built computer	3,500	--	--	--	--	--	3,500.00
Blood pressure apparati (electronic) (6)	900	--	--	--	--	--	900.00
Bioimpedence analyzers (2)	500						500.00
Weighing scales (4)	240	--	--	--	--	--	240.00
ECG machines (2)	750	--	--	--	--	--	750.00
Total Equipment	***28,580***	***0***	***0***	***0***	***0***	***0***	***28,580***
Supplies							
Low-cost educational materials	2,500	2,500	--	--	--	--	5,000.00
IGT screening kits	4,500	4,500	3,000	3,000	--	--	15,000.00
Biochemical assays (baseline)	7,350	7,350	4,900	4,900	--	--	24,500.00
Biochemical assays (3 months)	5,600	5,600	8,400	8,400	--	--	28,000.00
Biochemical assays (6 months)	350	350	1,225	1,225	350	--	3,500.00
Biochemical assays (12 months)	--	--	8,400	8,400	5,600	5,600	28,000.00
Miscellaneous supplies	750	750	1,000	1,000	750	750	5,000.00
Total Supplies	***21,050***	***21,050***	***26,925***	***26,925***	***6,700***	***6,350***	***109,000.00***
Travel							
Maintenance and fuel for van	1,500.00	1,500.00	2,250.00	2,250.00	1,250.00	1,250.00	10,000.00
Total Travel	***1,500.00***	***1,500.00***	***2,250.00***	***2,250.00***	***1,250.00***	***1,250.00***	***10,000.00***
Other							
Dissemenation of findings	500	500	1,000	1,000	750	750	4,500.00
Incentives for participants	16,675	16,675	--	--	--	--	33,350.00
Total Other	***17,175***	***17,175***	***1,000***	***1,000***	***750***	***750***	***37,850***
TOTAL FSP DIRECT COSTS	**77,981**	**49,399**	**43,435**	**43,435**	**23,070**	**22,720**	**260,040**
TOTAL DIRECT COSTS	**99,133**	**68,381**	**65,141**	**62,983**	**45,346**	**42,814**	**383,798**

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Budget Justification

ACME RESEARCH FOUNDATION EXPENDITURES

Personnel:
Dr. Researcher A, MD, MSc, MBA (9.5% effort / 1.14 person months in all years), **Co-Principal Investigator**, is an international leader in diabetes/CVD epidemiology, translation research, and economic analysis, with experience in designing and implementing epidemiological and intervention studies, including several multi-center national studies. He will design and lead the study, and provide diabetes and epidemiological expertise.
Dr. Researcher B, PhD (2.5% effort / .3 person months in all years), **Co-Investigator** is a recognized authority in qualitative research techniques, with methodological expertise in qualitative research design, conduct, and textual data analysis. She will oversee the qualitative research component.
Dr. Researcher C, MPH (19.0% effort / 2.28% effort in all years), **Research Assistant**, has experience in study design, collecting and analyzing quantitative data, health promotion, and health policy. She will be in charge of protocol development, training, and data analysis. Additional effort (up to 50% effort, total) will be covered through in-kind contributions.

Consultants:
Consultant A ($45/hr x 4 hrs/wk x 26 wks/period each year), **Consultant**, is certified by the American Council on Exercise (ACE) as a Personal Trainer, a Group Fitness Instructor, and a Lifestyle and Weight Management Consultant. She is the owner of Acme Fitness. She is the lead instructor for a diabetes prevention project among South Asians in the US. She will help design the exercise portion of the intervention.

Travel:
An ARF Investigator will travel one time each year to Hyderabad to train staff and assess progress of project (3 one-week trips @ $2,550 each; includes airfare, hotel, and per diem of $50/day).

FIELD SITE PARTNER EXPENDITURES

Personnel:
Project Coordinator, (50% effort, $2,250 in first year, $15,300 total), has extensive research experience in conducting community-based studies. He will provide overall coordination of study activities at FSP.
Interventionists (2@20% each) ($2,250 first year, $8,970 total) will be the primary educators in the lifestyle intervention and will train and supervise lay interventionists.
Field workers (4@10% each) ($4,500 first year, $17,940 total) will recruit and screen study participants at community events and will provide community outreach, including home interviews. Field workers will administer all survey instruments.
Phlebotomists (4@10% each) ($4,500 in first year, $17,940 total) will draw blood for

study-related biomedical testing both in the field and at FSP.
ECG technician (1@10%) ($1,125 in first year, $4,485 total) will run the ECG machine for study-related testing and read the results.
Data entry operator (1@15%) ($1,350 in first year, $5,490 total) will enter data from study forms into a secure database. The data entry operator will audit data to ensure data quality.
Van driver (1@10%) ($1,125 in first year, $4,485 total) will operate the transportation van.

Equipment:
Transportation van ($22,690 in first year, $22,690 total) will be used to transport: participants to and from study classes; staff to recruitment and screening events; staff to home interviews when needed; and team members to meetings with community members and health policy makers to promote the program. Many people in the study area do not have access to personal transportation and this may be their largest barrier to participation in the program. Additionally, the van is required to transport study equipment (blood pressure machines, ECG machines, etc.) to screening events and study classes; it would be impossible to transport this equipment using personal cars or public transportation. The van will be used only for this project; therefore lack of transportation will never be a hindrance to the project.
LCD projector with in-built computer ($3,500 in the first year, $3,500 total) will be used for educational purposes such as teaching lifestyle classes and giving lectures and presentations to the community, other researchers, study team members, and policy makers.
Electronic blood pressure apparatuses (6 @ $150 each, $900 in the first year, $900 total) will be used to measure blood pressure and pulse rate, secondary study outcomes, and measures of exercise compliance. The World Health Organization recommends electronic blood pressure machines (instead of manual blood pressure cuffs) because of the absence of mercury and increased precision. Additionally, field workers and interventionists, who often have no medical training, can use the blood pressure machines easily and effectively.
Bioimpedence analyzers (2 @ $250 each, $500 in the first year, $500 total) will be used to measure percent body fat, a secondary study outcome.
Weighing scales (4 @ $60 each, $240 in the first year, $240 total) will be used to measure body weight, a secondary study outcome.
Portable electrocardiogram (ECG) machines (2 @ $375, $750 in the first year, $750 total) will be used to obtain resting 12-lead ECG's on study participants. These ECG's will be used to screen for pre-existing cardiac conditions such as prior myocardial infarction and chronic atrial fibrillation that might limit participants' exercise tolerance. Patients with these conditions will be excluded from the study.

Supplies:
Educational materials ($5,000 in first year, $5,000 total): Development and printing of low-cost, culturally appropriate prevention program materials (e.g., booklets, pamphlets, CDs) to be used for recruitment and patient and community education.

Oral glucose tolerance tests (impaired glucose tolerance screening kits) ($9,000 in the first year, $15,000 total) measure glucose tolerance and diabetes incidence, the primary study outcome.
Biomedical assays at baseline, post-intervention, post-maintenance, and at the end of the follow-up period ($24,500 in first year, $84,000 total): Covers supplies and kits for biomedical testing of secondary study outcomes (e.g., measurement of plasma lipids, hemoglobin A1C, and fasting glucose).
Miscellaneous supplies ($1,500 in first year, $5,000 total) include the cost of purchasing stationary and other office supplies, copying, and postage for study materials (study questionnaires, participant study booklets, study protocols, etc.).

Travel:
Van maintenance and fuel ($3,000 in first year; $10,000 total) for the study van and staff and participant transport. See "Equipment: Transportation Van" for more information.

Other:
Dissemination of findings ($1,000 in first year, $4,500 total): Mass education lectures to disseminate information on diabetes/obesity prevention and the findings of the intervention to the community and policy makers.
Participant incentives ($33,350 in first year, $33,500 total) will be used to promote the program before inception and during dissemination, reward volunteer lay interventionists, improve participant adherence, and reward participant successes. Study participants will be provided with walking shoes (350@$40, $14,000 in the first year, $14,000 total). Exercise is not a cultural norm in India; therefore, many participants would not have proper exercise equipment such as walking shoes, and this could be a barrier to participation. Also, proper equipment minimizes injury to the participant. Other incentives might include one-year gym memberships, exercise DVD's, water bottles, "gym" bags, or other give-aways to encourage diet and exercise changes. Smaller, inexpensive items such as water bottles or writing pens used for both incentive and promotional purposes will have the study logo predominantly displayed.

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Translation Research Grant Development
Additional Resources

I. Translation Research

1. National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases: Translational Diabetes and Obesity Research Conference. From clinical trials to community: the science of translating diabetes and obesity research. Bethesda, MD: National Institutes of Health; 2004. http://www2.niddk.nih.gov/NR/rdonlyres/864EE73D-C876-4B30-A0EB-14E3911E2499/4589/Confpublication.pdf.
2. Garfield SA, Malozowski S, Chin MH, Narayan KM, Glasgow RE, Green LW, Hiss RG, Krumholz HM. Considerations for diabetes translational research in real-world settings. Diabetes Care. Sep 2003;26(9):2670-2674.
3. Narayan KM, Benjamin E, Gregg EW, Norris SL, Engelgau MM. Diabetes translation research: where are we and where do we want to be? Ann Intern Med. Jun 1 2004;140(11):958-963.
4. Narayan KM, Gregg EW, Engelgau MM, Moore B, Thompson TJ, Williamson DF, Vinicor F. Translation research for chronic disease: the case of diabetes. Diabetes Care. Dec 2000;23(12):1794-1798.

II. Quality of Life and Cost-effectiveness

1. Russell LB, Gold MR, Siegel JE, Daniels N, Weinstein MC. The role of cost-effectiveness analysis in health and medicine. Panel on Cost-Effectiveness in Health and Medicine. Jama. Oct 9 1996;276(14):1172-1177.
2. Siegel JE, Weinstein MC, Russell LB, Gold MR. Recommendations for reporting cost-effectiveness analyses. Panel on Cost-Effectiveness in Health and Medicine. Jama. Oct 23-30 1996;276(16):1339-1341.
3. Weinstein MC, Siegel JE, Gold MR, Kamlet MS, Russell LB. Recommendations of the Panel on Cost-effectiveness in Health and Medicine. Jama. Oct 16 1996;276(15):1253-1258.
4. Rubin RR, Peyrot M. Quality of life and diabetes. Diabetes Metab Res Rev. May-Jun 1999;15(3):205-218.
5. Zhang P, Engelgau MM, Norris SL, Gregg EW, Narayan KM. Application of economic analysis to diabetes and diabetes care. Ann Intern Med. Jun 1 2004;140(11):972-977.

III. Study Design and Reporting

1. Glasgow RE, Klesges LM, Dzewaltowski DA, Bull SS, Estabrooks P. The future of health behavior change research: what is needed to improve translation of research into health promotion practice? Ann Behav Med. Feb 2004;27(1):3-12.
2. Morabia A. Strobe for the international comparison of health determinants. Int J Public Health. 2008;53(1):11-12.
3. STROBE statement--checklist of items that should be included in reports of observational studies (STROBE initiative). Int J Public Health. 2008;53(1):3-4.

4. Moher D, Cook DJ, Eastwood S, Olkin I, Rennie D, Stroup DF. Improving the Quality of Reports of Meta-Analyses of Randomised Controlled Trials: The QUOROM Statement. Onkologie. Dec 2000;23(6):597-602.

IV. Quantitative Data Analysis/Epidemiology

1. Eldridge S, Ashby D, Bennett C, Wakelin M, Feder G. Internal and external validity of cluster randomised trials: systematic review of recent trials. Bmj. Apr 19 2008;336(7649):876-880.
2. Gigerenzer G, Edwards A. Simple tools for understanding risks: from innumeracy to insight. Bmj. Sep 27 2003;327(7417):741-744.
3. Loong TW. Understanding sensitivity and specificity with the right side of the brain. Bmj. Sep 27 2003;327(7417):716-719.
4. Paling J. Strategies to help patients understand risks. Bmj. Sep 27 2003;327(7417):745-748.

For information on epidemiology, consult these textbooks:

1. Rothman KJ, Greenland S, Lash TL. Modern Epidemiology. 3rd ed; 2008.
2. Kleinbaum DG, Sullivan KM, Barker ND. ActivEpi Companion Textbook. A Suplement for Use with the ActivEpi CD-ROM. New York: Springer-Verlag; 2003.
3. Kleinbaum DG, Sullivan KM, Barker ND. A Pocket Guide to Epidemiology. New York: Springer; 2007.
4. Hennekens CH, Buring JE. Epidemiology in Medicine. Boston: Little, Brown and Company; 1987.
5. Gertsman BB. Epidemiology Kept Simple. New York: Wiley-Liss; 1998.

V. Qualitative Research

1. Ahern, K. Ten Tips for Reflexive Bracketing. Qualitative Health Research. May 1999; 9(3):407-411.
2. Penrod, J. Getting Funded: Writing a Successful Qualitative Small-Project Proposal. Qualitative Health Research. July 2003;13(6):821-32.
3. Morse, J. A Review Committee's Guide for Evaluating Qualitative Proposals. Qualitative Health Research. July 2003;13(6):833-851.
4. Belgrave, L., Zablotsky, D., and Guadango M. How Do We Talk to each Other? Writing Qualitative Research for Quantitative Readers. Qualitative Health Research. 2002;12(10):1427-1439.

For information on qualitative research methods, consult these textbooks:

1. Ritchie, J. and Lewis, J. (eds) (2003) Qualitative Research Practice: A Guide for Social Science Students and Researchers. Sage Publications: London.
2. Rubin, J. and Rubin, S. (2005) Qualitative Interviewing. The Art of Hearing Data. Second Edition. Sage Publications, Thousand Oaks, California.
3. Hennink, M. (2007) International Focus Group Research. Cambridge University Press.

4. Emerson, R., Fretz, R., & Shaw, L. (1995). Writing Ethnographic Fieldnotes. University of Chicago Press, Chicago.
5. Corbin & Strauss (2008) Basics of Qualitative Research. Third edition. SAGE Publications.
6. Patton, M. Q. (2002). Qualitative research and evaluation methods (3rd ed.). Thousand Oaks, CA: Sage

VI. Websites

1. Survey Instruments
   a. General information and survey databases:
      1. http://orpheus.ucsd.edu/famed/hoap/MEASURE.html
      2. http://www.healthmeasurement.org/Measures.html
      3. http://www.proqolid.org/proqolid/about_proqolid
      4. http://www.rand.org/health/surveys_tools.html
   b. Examples:
      1. Euroqual (EQ-5D) – http://www.euroqol.org/
      2. SF-36: http://www.sf-36.org
      3. Diabetes Symptom Checklist: http://www.mapi-research.fr/t_03_serv_dist_Cduse_dscr.htm
2. Sample Size/Power Calculators
   a. http://www.openepi.com/Menu/OpenEpiMenu.htm
   b. http://stat.ubc.ca/~rollin/stats/ssize/
3. Human Subject Information
   a. United States Department of Health and Human Services, Office of Human Research Protection: www.hhs.gov/ohrp/

VII. Other Useful References

1. Behavioral Theories:
   a. Stages of Change: Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. J Consult Clin Psychol. Jun 1983;51(3):390-395.
   b. Health Belief: Rosenstock, I. Historical Origins of the Health Belief Model. Health Education Monographs. 1974:2(4).
   c. Locus of Control: Rotter, JB. Social learning and clinical psychology. New York: Prentice-Hall; 1954.
   d. Diffusion of Innovation: Rogers, EM. Diffusion of Innovations, Fifth Edition. New York, NY: Free Press; 2003.
2. Shojania KG, Ranji SR, McDonald KM, Grimshaw JM, Sundaram V, Rushakoff RJ, Owens DK. Effects of quality improvement strategies for type 2 diabetes on glycemic control: a meta-regression analysis. Jama. Jul 26 2006;296(4):427-440.
3. Wagner EH. Chronic disease management: What will it take to improve care for chronic illness? Effective Clinical Practice. 1998;1(1):2-4.