

The "Every Doc Can Do Research" Workbook
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and the Madigan Faculty Development Fellows

INTRODUCTION - An old Army saying goes something like this: "Prior Planning Prevents Poor Performance." Planning is essential to ensure a successful research project. A common reason a research project fails is inadequate pre-study planning and organization.

The purpose of this workbook is to provide you with a practical approach to planning and organizing your research project. Hopefully we can get you started thinking about the major steps that need to be accomplished in the planning phase. We encourage you to use this workbook as a starting point. As you make your way through this workbook, we have made recommendations at various spots on who you should contact for assistance.

We intend for you to write in this workbook. However, we realize that in some areas the space may be insufficient to fill in all of the details. If this happens to you, having a few extra sheets of paper to write on may decrease some of your frustration. You might also want to keep a separate notebook or diary in which you write anecdotes, remarks or subjects, comments by others involved in the project, or any other facts or observations which might help you to make sense out of the study.

It is also important that you finish this workbook entirely before you begin collecting any data. You will need to contact the Clinical Investigation Committee at your institution to determine exactly what they need you to submit to them for approval (research protocol).

Using this workbook as a guide will get you well on your way toward completing that research protocol.

Good luck!

OTHER RESOURCES - Four books that you might find helpful in becoming more knowledgeable about research include:

- American Academy of Family Physicians - *Practice-Based Research in Family Medicine*, (can be ordered for nominal fee from the AAFP - we encourage you to buy this!)
- *Nursing Research - Principles and Methods*, Polit and Hungler ed, JB Lippincott Company
- *Epidemiology in Medicine*, Hennekens and Buring, Little, Brown & Company
- *Designing Clinical Research*, Hulley and Cummings ed, Williams & Wilkins

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Step #1 - Define Your Research Question

An essential ingredient in any quality research project is a well defined research question. The question should be simple and specific - a small, clearly defined project is always preferable to one that is large and vague.

Begin By Asking the General Research Question:

(e.g. Should we treat pregnant women who are carriers for Group B strep (GBS)?)

As you complete this workbook, you will find it useful to rewrite (refine) your research question several times. Each revision should have greater precision and narrower scope in your search for an answer.

Step #2 - Hit the Library (Lit Search)

The next step is to learn as much as you can about what others have done (literature search and review). A good literature review lets you find out what is out there, helps you define your research topic, updates your knowledge about the subject in which you are interested (makes you an "expert" in that area), and may give you methodological tools to use in your study. To get the most out of your search, you need an effective plan.

Begin your search by looking at the references cited in recent textbooks and the articles in your personal library. You should also browse the current issues of pertinent journals in your medical library, and ask other providers for a chance to look at their journals and textbooks. You should next use a computerized bibliographic database from the National Library of Medicine (NLM, MEDLARS). The NLM has several databases dealing with ethics, chemistry, toxicology, cancer, medical history, AIDS, and health planning and administration. Probably the most-often used database from the NLM is



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MEDLINE, which contains most of the medical journal articles from 1966 onward. Another useful NLM database is CATLINE, which contains lists of books, monographs, government documents, statistical sources, and historical material. Finally, don't forget to look at non-medical databases such as Science Citation Index and others dealing with subjects such as biology, psychology, sociology, and education.

A medical librarian has the expertise to help you with searching these databases and is a valuable resource you should not overlook. However, if you do not have immediate access to a librarian, you can do the search yourself using a personal computer and modem. You can now do your Medline searches for free by going straight to the home page of the National Library of Medicine (<http://igm.nlm.nih.gov/>); simple on-line instructions guide you through the process of using on-line Internet Grateful Med. Another useful home page of the National Library of Medicine uses PubMed (<http://www.ncbi.nlm.nih.gov/PubMed/>); using this search mechanism requires a bit more expertise. Both of these home pages have a link to Loansome Doc, a feature that allows users to order full-text copies of articles from a local medical library (local fees and delivery methods vary); users must register to use this service. If you don't have access to a computer or modem, you can always use the AAFP's **Huffington Library** (800-274-2237, ext 4402) which can help you with your search.

Although searching the NLM databases is extremely important, you will probably not find all of the important articles you will need. Studies have shown that only half of the relevant articles are typically retrieved at the beginning. As such, it is important for you to look for additional references in the bibliographies of the articles you initially find. Another useful search method is the *invisible college*, which is the collection of "experts" in the field you are studying. Your search for the invisible college begins by asking the authors of the articles obtained in your initial search who they consider to be the experts in that field. You then ask those experts the same question, and repeat the process until you get to a handful of authorities, each of whom is aware of and refers to the others in that group as experts. This invisible college is probably the best source of unpublished and ongoing research in your area.

Once you have the list of articles from your search, your next step is to obtain and then review those articles. Reading the abstract will let you know if the

article is pertinent to your study, or irrelevant (and thus thrown out). Once you have the articles you feel are pertinent to your study, you should then use a systematic way to read them.

(continued next page)

Step #2 - The Literature Search (continued)

As you critically read each article, ask the following....

- what was the purpose(s) of the study?,
- what did the author(s) find from their literature review?,
- are the hypothesis and question(s) similar to yours?,
- are the subjects in the sample representative of the people who should be studied?, are they similar to your population?,
- is the methodology of the study similar to what you want to use, and are there helpful tools that you might want to use?,
- what problems were encountered, and what were the limitations of the study?, and
- do the conclusions and recommendations follow logically from their results?

You may want to make notes on the article itself, or on a separate sheet of paper. When you are done reading these articles, you should have a good idea of what has been accomplished, how it was done, the problems that others have had in their studies, and how the results of your study can add to the existing field of knowledge. At this time you may also want to write a summary of your literature search, which would later serve as a basis for the introduction and discussion sections of your paper.

For additional information on how to conduct a literature search, we recommend the following articles:

- Wallingford KT et al: Bibliographic retrieval: a survey of individual users of MEDLINE. *MD Computing* 7(3):166-71, 1990.
- Fox RN, Ventura MR: Efficiency of automated literature search mechanisms. *Nursing Research* 33(3):174-7, 1984.
- Williams HA: Searching the literature creatively: updating your skills in reviewing the literature. *J Ped Oncology Nursing* 10(1):33-6, 1993.

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Stop! Is there a problem with the reliability or validity of the instruments or data sources that you will be using? If so, you need to change something so that the data you obtain will be both reliable and valid. You may need to seek help in this area if you are unsure what to do.



Step #9 - Develop the Research Design

The design of the study refers to the way in which you will study the relationships between and among variables that you plan on measuring.

At this stage, we encourage you to call an experienced researcher, especially if all of this is new ground. It is wise to seek competent help in preparing a research design. Choices among the designs will always require compromises between the practical and the ideal. Well-designed research, like anything else designed well, should be more efficient and better suited to your needs than a haphazard approach. Poorly designed research may be inefficient or, even worse, may make it impossible for you to analyze the data legitimately.

The following are some of the more common research designs encountered in family practice research. These are listed to give you some ideas, but you may also want to refer to one of the research resources mentioned at the beginning of this workbook.

Descriptive Studies - Any research activity in which the investigator gathers data from a portion of the population (the sample) to examine characteristics such as what people do, what people plan to do, what people know, opinions, attitudes, values, etc. Information is also obtained from populations about the prevalence, distribution, and/or interrelations of variables. The researcher does not manipulate any variables, but only describes things. *Example: Surveying all AAFP members on their satisfaction with managed care.*

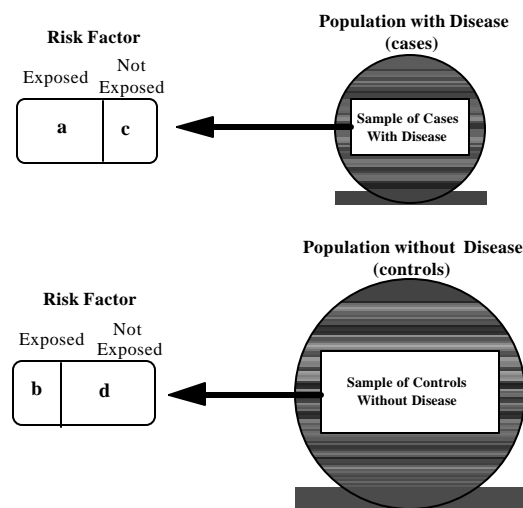


Observational Studies - As in descriptive studies, the investigator does not alter or manipulate any variables and does not randomly assign subjects to

groups, but does analyze the data using statistical tests. There are three (3) major types of observational studies: (a) *case-control*, (b) *cross-sectional*, and (c) *longitudinal (cohort)*.

Case-Control Studies: Typically retrospective, you identify groups of subjects with and without the disease you are studying, and then look backward in time to identify the presence or absence of risk factors. *Example: Vaginal cancer and maternal exposure to DES,*

Disadvantages include: (1) potential bias from sampling two populations, (2) does not yield prevalence or incidence, (3) selection of controls may be a problem, and (4) exposure data may be subject to biased recall. Strengths include: (1) useful for studying rare conditions, and (2) relatively inexpensive and quick to complete.



Case-Control Study

A retrospective study in which the investigator selects a group with disease (cases) and one without disease (controls) and looks back in time at exposure to potential risk factors to determine causation. Data are typically analyzed using the odds ratio.

Odds Ratio (OR) is the measure of strength of association. It is the odds of exposure among cases to the odds of exposure among the controls.

	Cases	Controls	
Exposed	a	b	OR =
Not Exposed	c	d	

$$= \frac{(a/a+c)/(c/a+c)}{(b/b+d)/(d/b+d)} = \frac{a/c}{b/d} = \frac{ad}{bc}$$

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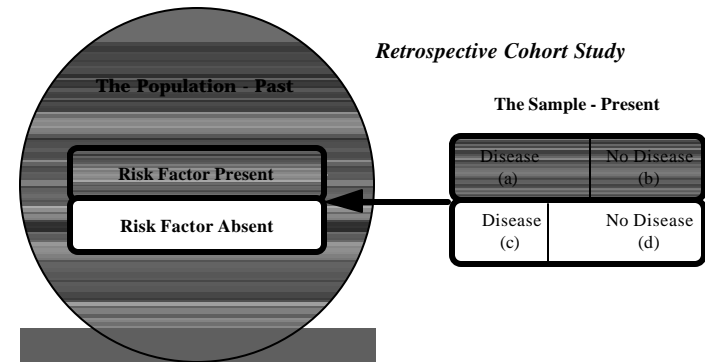
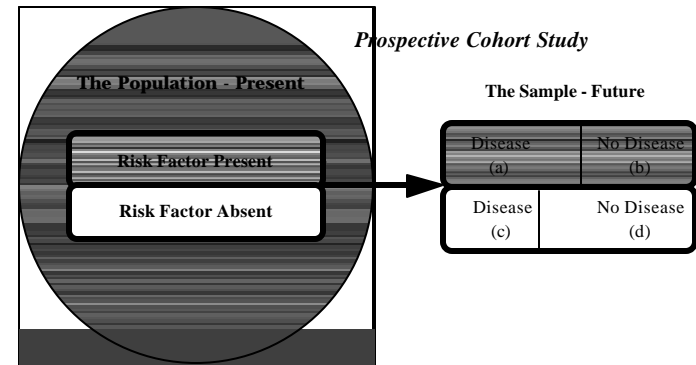
Cross-Sectional (Prevalence) Studies: You make all your measurements at once (one point in time) looking at both disease status and exposure factors. *Example: What is the prevalence of GBS early-onset disease in my hospital and which infants are at risk?*

Disadvantages include: (1) you can't establish causality - you don't know if the exposure preceded the outcome, (2) does not yield incidence of disease, and (3) not feasible for rare conditions. Strengths include: (1) yields prevalence, (2) may study several outcomes, and (3) relatively inexpensive and quick to complete.

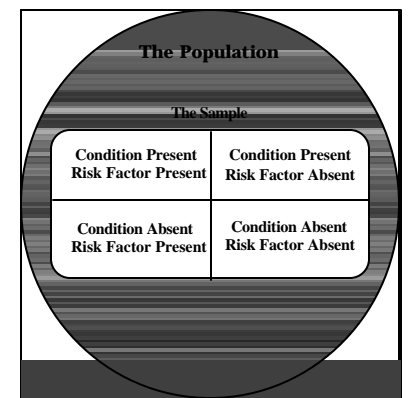
Step #9 - Research Design (Continued)

Cohort Studies: A cohort is a group of subjects who are followed over a period of time. There are two (2) basic types: (1) prospective cohort study (the investigator defines the sample and measures variables before any disease has occurred), and (2) retrospective cohort study (the investigator defines the sample and measures the variables after the diseases has occurred). *Example: Women born in 1950's currently on oral contraceptives, variable = smoking; outcome = myocardial infarction.*

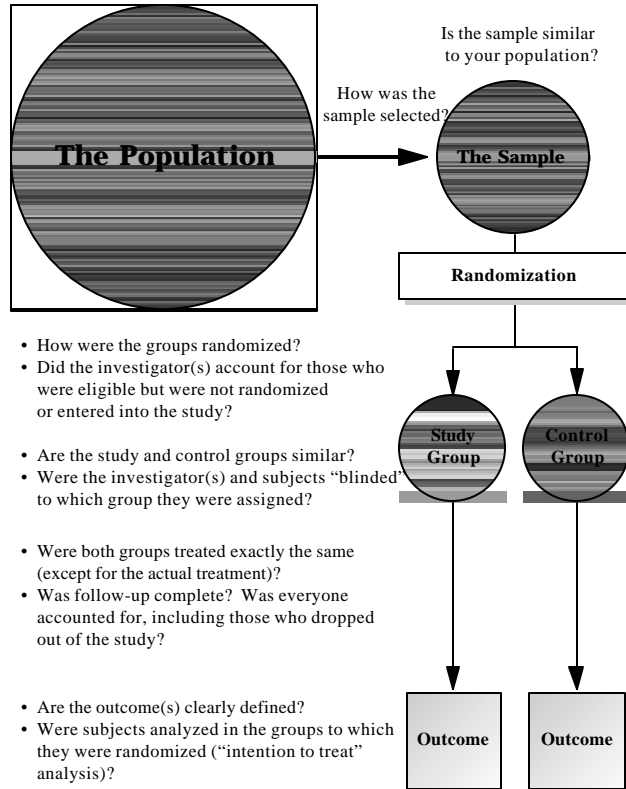
Disadvantages include: (1) need large numbers, especially for rare diseases, (2) potentially very expensive, (3) time consuming, and (4) attrition may be a problem. Strengths include: (1) time sequence of exposure and outcome is known, (2) can directly measure the risk of a bad outcome, (3) can study many outcomes of a single variable, and (4) good for occupational diseases.



Experiments: Often considered the "gold standard", the randomized, double-blind trial is the best way to establish the effects of an intervention. The investigator, through the study design, has control over which study subjects are exposed to the factor of interest, and makes exposure assignments for purposes of the study. This is the strongest design for establishing causal relationships. However, experiments are also the more difficult and expensive of the types of studies. Also, some experiments can't be ethically done - for example, one can't randomly select subjects to enter a smoking group.



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There are many other types of research designs, but these are by far the most common, and should give you a good foundation when collaborating with others on which study design is best to answer your research question.

You can also help identify the issues which your design should address by considering carefully each of the items in steps #10-12 below.

Step #10 - Select Your Sample(s)

Describe the characteristics of the people (or the subjects) who will be eligible for participation in your study. (e.g. all singleton term (38-42 weeks) pregnant women who are known R-V GBS carriers, who have no known risk factors, and who deliver at our hospital during the study period).

Describe the characteristics of the people (or the subjects) who will be excluded from participation in your study. (e.g. OB patients who are preterm (before 38 weeks), have a fever, have multiple gestation, who have PROM, etc).

Describe the population (beyond your sample) to which you wish to generalize conclusions. (e.g. the results of this study will apply to all term, pregnant women with GBS who are otherwise considered low-risk; etc).

Determining Sample Size (How Many Need To Be In Your Study?)
 One of the most frequent questions asked is "how many do I need to include in my study?" Before this can be answered, you need to answer several questions. Two of the most important considerations in determining sample

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size are how much money you have to spend, and how much time you can commit. The larger the sample, the more it will cost, both in dollars and time.

Increases in sample size increase the precision of the research. A large sample should allow you to detect more subtle (but perhaps less clinically important) relationships.

It's time to talk to someone who can help you determine the sample size. A statistician at your institution, someone with a strong background in research, or someone from the Clinical Investigation Committee of the AAFP should be able to help you with this.



How many will you need in your study?

Some things you'll need to determine when figuring out the sample size are the following:

- How sure do you want to be that the results you find did not occur by chance alone? (e.g. are you willing to take a 5% chance (that is, $p < 0.05$) - most people arbitrarily set this at either 0.05 or 0.01.

- If you find no difference in relationships, how sure do you want to be that you had a large enough sample? - this is referred to the power of the study; most people set this at 0.80

- What size difference do you expect to find between the two groups? You will need a larger group to find a significant difference in weight of 2 grams as opposed to 2 kilograms. This expected difference may come from pilot studies, other research, or your best guess.

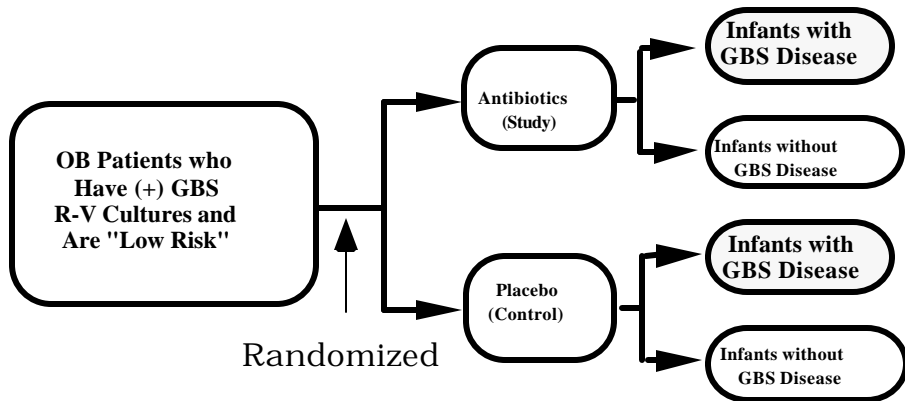
Step #11 - Develop the Research Protocol

How Will You Select the Sample? Will you sample all those who attend a certain meeting (convenience sample) or will you randomly pick them, and if so, how will you do the randomization? (e.g. All OB patients presenting to L&D with the entrance requirements over a one-year period of time).

Will You Divide Your Sample Into Groups? If So, How? What criteria are you going to use to determine who goes into what group, etc? and how will you make sure that the groups are similar except for the variable that you are studying? (e.g. Once identified and agree to enter the study, she will be randomly placed into either a treatment group or a control group using a pre-determined table of randomization).

Describe what will happen to each group. (It helps to draw a flow diagram, an example of which is....

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Describe what will happen to each group:

Who Will Gather The Data, and How? (e.g. Upon entry into the study, the nurses will complete a data sheet; the investigators will then review the maternal and newborn charts after delivery .)

Step #12 - Eliminate or Control the Biases

Bias refers to sources of systematic error that may affect your study results. Unless adequately controlled, bias may render your results uninterpretable. You need to give specific attention to each of the following potential sources of bias. As you control for the most serious of these biases, your study design will evolve.

Effects of Historical Events - Can you anticipate events such as personnel changes, remodeling plans, interference by nonparticipants, etc, that will take place during your data collection phase and which might affect the results? If yes, describe.

Effects of Maturation - If subjects are to be observed over time, are there changes that might result merely by normal development, growth, natural course of illness, etc? If yes, describe.

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Effects of Repeated Measurement - If the same measurements are repeated on subjects, are they likely to remember past responses, prepare differently for the next session, relax procedures? If yes, describe.

Instrument Decay - Is it likely that the test equipment will wear out, observers get bored, protocols get short-cut by investigators, etc? If yes, describe.

Effects of Statistical Regression - If subjects are chosen because they lie at the extremes of a distribution (e.g. severe hypertension, low compliance with medicine), subsequent measurements will tend to be more nearly average, for purely statistical reasons. Are your subjects chosen or assigned to groups on the basis of their "extremeness"? If yes, describe.

Subject Selection - Is there anything in the selection of your sample or assignment of subjects to groups that makes one group of subjects unintentionally different from other groups? If yes, describe.

Loss of Subjects - Subjects lost to attrition (e.g. moved, died) may be different from those who remain. Is your study jeopardized by this possibility? If yes, describe.

Investigator Bias - Are you in a position to unintentionally "shade" results to confirm your hypothesis or to influence subjects by your attention, attitude, etc? If yes, describe. (note: blinding the investigator will minimize this bias).

Stop! Look at the above biases - can you change your study design so that you minimize them? The more bias you can control through your study design, the more "faith" you can have in accepting your results as being true.

Step #13 - Identify the Limitations of Your Study

After struggling to develop a study design that is feasible and minimizes the most troublesome sources of bias, you may still be left with inadequate control over other sources of bias. Use the space below to identify the remaining potential sources of bias.



Potential Sources of Bias Remaining

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Even unbiased studies have limitations in their generalizability. For example, a study done on lower income patients may not apply to higher income patients. To what kinds of people beyond your study sample can you justify generalizing your conclusions? (It may be easier to identify individuals for whom your conclusions do not necessarily apply).

Limitations to Generalizability

Step #14 - Develop Data Collection Forms

Spend some time developing the forms that you will use to collect your data. Look at what data you need to record (go back to Step # 8). When developing your form, you may also want to start thinking about what type of computer data base program you want to enter the information into, and develop the data base and the form so that you can easily transcribe the information from the form into the computer. Before launching into the study, it also helps to "pilot" the form on a few subjects/records to work out any

bugs, etc. For example, if you are collecting data from an OB chart, you might want to have the information on the form follow the information as it is laid out in the chart, so you can easily go from the front of the chart to the back of the chart (and not have to flip back and forth through the chart). It also helps to code your form so that you can easily enter the information into the computer data base. For example, 1 = male, 2 = female.

Use separate sheets of paper to develop your data collection forms, and have others go over your form to make sure it is easy, simple, complete, and accurate.

Step #15 - Reporting of Results

Are you collecting the right type of information? Based upon the data you want to record (Step #8), and your data collection form (Step #14), use the space below to sketch summary data tables and/or graphs which you would expect to use in presenting your results. You may include simulated results of the kind you hope to find.

Step #16 - Pick Your Statistics

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Other sources of grants that may be applicable to family physicians include the following.....

<u>Grant Source/Name</u>	<u>Short Description</u>	<u>Phone #</u>
Academic Research Enhancement Award	Supports new research projects or expands ongoing research activities proposed by faculty members of eligible institutions in areas related to the health sciences.	(301) 594-7248
William T. Grant Faculty Scholars Program	Provides support to junior faculty members in research relevant to the well-being, and health development of children, youth and adolescents.	(212) 752-0071
NRSA Fellowships for Research Training in Primary Care Disciplines	An NIH grant that supports additional research training in the primary care field.	(301) 496-7441
Mental Health Services in General Health Care Research Grants	Encourages research on mental disorders in primary care, particularly research that focuses on the nature, recognition, classification, treatment and outcomes of people with mental disorders.	(301) 443-1330

To obtain additional sources for grants, your medical librarian can help you find a grant directory that lists other granting organizations.