



American Pharmacists Association[®]

Improving medication use. Advancing patient care.

Designing and Planning Your Project

Refining Your Topic

- Comes after conducting background research on the topic
 - Ensures there is a need for the project
 - Helps to focus study
- Once topic is set, must determine how to study your question
 - Background research is helpful here as well to see standard methods
 - Can help you avoid design flaws and pitfalls as well
- Ensure your project is feasible for the resources you have
- Ensure your project has enough breadth and depth that it matters beyond your practice

Select a Project Category

■ Exploratory

- This type of project allows you to obtain more information or understanding about a topic – testing the practicality of an idea or laying the groundwork for a larger study
- Can be valuable but seldom provides definitive answers and is useful mainly to give direction for further research
- Commonly referred to as a “pilot”
- Can test validity of research idea and methods

CONNECTING YOUR DATA AND OBJECTIVES

Major Reveal of Data	Corresponding Objective	Paragraph
NPs are managers (56%) (#3)	Identify managerial skills required in community pharmacy practice	1: General Demographics
NPs feel managerial skills are a necessary component of their job (#6)	Explore new practitioners' previous exposure to these skills	2: General Thoughts/Experiences with Management
NPs get managerial skills from experiential rotations and didactic but 1/3 do not feel they got from didactic (#43) → not practice ready	Explore new practitioners' previous exposure to these skills	4: Where do they gain managerial skills

CONNECTING YOUR DATA AND OBJECTIVES

Major Reveal of Data	Corresponding Objective	Paragraph
Significant growth in proficiency (low upon graduation) (#44,47) → not practice ready	Assess new practitioners' perceived preparedness to take on managerial responsibilities	2: General Thoughts/Experiences with Management
#45 and #46 identify where they have gotten managerial skills	Explore new practitioners' previous exposure to these skills	4: Where do they gain managerial skills
Feel skills can be improved (#48) and willing to get (#49)	Assess new practitioners' perceived preparedness to take on managerial responsibilities	2: General Thoughts/Experiences with Management
Various skills data	Assess new practitioners' perceived preparedness to take on managerial responsibilities Identify managerial skills required in community pharmacy practice	3: What Skills are Used, What is the Proficiency, How do Managers vs non-managers compare All about the skills

Select a Project Category (Continued)

- Descriptive

- Research describes something and helps define information for further research.
- Usually does not attempt to test a hypothesis or involve an experimental procedure
 - Considered less scientifically rigorous, but it can yield important information

Select a Project Category (Continued)

■ Explanatory

- This type of project seeks to answer a question, discover new information, test a hypothesis, or test an association
- The best explanatory research is prospective
 - Randomized, blinded, placebo-controlled studies
- Prospective studies may not be practical in real world situations and they are costly and time-consuming to perform

Select a Project Category (Continued)

- **Interventional**
 - A.K.A. Experimental
 - You are actively manipulating variables
 - More rigorous
- **Observational**
 - You are observing relationships between variables as they naturally occur

Identify the Proper Research Design

- Considerations:
 - Method that best answers your question
 - Your resources and research experience
 - Validity of methods for publication and policy consideration
 - Time constraints
 - Financial constraints

Interventional Research

- Experimenter determines and controls the intervention
- Randomized controlled trials are most well known and considered the gold standard
 - In these studies, patients are randomly assigned to a treatment group or a control group and followed forward in time to determine whether they have a particular outcome

Observational Research

- Involve observing without altering or influencing whatever is being observed
 - Primarily cohort or case-control
- Can be prospective or retrospective, but because subjects are not randomized, observational studies are not useful for determining cause and effect, only for detecting associations

Choose a Theoretical Model

- A theory behind a concept
- Describes the way you expect something to work based on current knowledge
- In health care, a theoretical model might have to do with patient adherence to medication regimens or patient education for chronic diseases
- Tip: draw a schematic diagram of how you think patients and procedures “flow” in your project, and the forces at play, using your theoretical model to guide you

Avoid Threats to Internal Validity

- Maturation
- History
- Instrumentation
- Statistical regression
- Placebo or Hawthorne effect
- Dropout bias
- Recall bias
- Selection bias

Maturation

- Were changes captured in the study outcome measures due to the normal course of a disease?
- Solution: Randomly assign control and intervention groups that start equally and “mature” equally over time
 - Be sure to have an equal mix, rather than all newly diagnosed patients in one group and “maturely” diagnosed people in another

History

- Did other events occur in the study that could affect study outcome measures?
- Solution: Make sure that both the control and intervention groups are exposed to the same events during the study

Instrumentation

- Did measurement methods change during the study or did something about the measurement method alter the outcome?
- Solution: Provide the same measurement to both control and intervention groups equally over the course of the study.

Statistical regression

- Did “regression toward the mean,” which naturally occurs when the study subjects are selected based on high or low values, affect the results?
- Solution: Participants should be randomly assigned to the study group or control group and each group should regress toward the mean equally over time

Placebo or Hawthorne effect

- Did simply knowing that they are in a study cause patients to react in a way that affects outcomes?
- Solution: In providing the treatment, use a blinded approach so patients do not know if they are in the intervention or the control group

Dropout bias

- Did some subjects drop out?
- Solution: Try to keep all subjects in the study to completion
 - At the end of the study, when you analyze your data, check for dropout bias
 - May require statistical analysis investigation

Recall bias

- Do the subjects have to recall events in the past where memories may be blurred or experienced differently?
- Solution: Use prospective study design when possible, carefully test wording of questions to get at your variable of interest

Selection bias

- Were the subjects self-selected or assigned by the researcher in a way that skews the results?
- Are participants likely to select participation or select lack of relevance based on materials provided?
- Solution: Assign subjects to groups randomly so the groups are generally equivalent at the beginning of the research
 - Send materials to as specialized of group as possible to meet inclusion criteria

Develop a Project Plan

- A document that spells out how you will carry out all the relevant activities in your study.
- When creating your plan, work through it both forward and backward, thinking of everything you will need to accomplish by the end of your project.
- Your project plan should include:
 - Formulate a research question
 - Develop study objectives
 - Determine the study design
 - Establish the research methods
 - Select the study population
 - Choose outcome measures
 - Design the intervention
 - Develop a statistical analysis plan
 - Create a project timeline
 - Develop a budget
 - Complete necessary Institutional Review Board (IRB) documentation

Formulate the Research Question

Exploratory	Descriptive	Explanatory
Define the project in one sentence: What are the components of patient satisfaction with the pharmacist's services?	Define the project in one sentence: How are screening services use in a community pharmacy?	Define the project in one sentence: Do community pharmacy provided point-of-care testing for diabetes management improve diabetes control?

Develop the Study Objectives

Exploratory	Descriptive	Explanatory
Summarize the question(s) the research intends to answer. Must be narrow and measurable.	Summarize the question(s) the research intends to answer. Must be narrow and measurable.	Summarize the question(s) the research intends to answer. Must be narrow and measurable.

Select the Study Population

Exploratory	Descriptive	Explanatory
<p>Describe the people you are studying and how they represent the larger population potentially affected by your program. Are you studying people with a particular disease or healthy volunteers? Does your study population include people taking certain medications or coming to a particular pharmacy?</p>	<p>Describe the people you are studying and how they represent the larger population potentially affected by your program. Are you studying people with a particular disease or healthy volunteers? Does your study population include people taking certain medications or coming to a particular pharmacy?</p>	<p>Determine how you will select your control and intervention groups.</p>

Establish Research Methods: Determine Study Design

Exploratory	Descriptive	Explanatory
<p>Determine whether you are gathering data prospectively or retrospectively. Describe how you will get the information you need to accomplish the project's purpose.</p>	<p>Determine whether you are gathering data prospectively or retrospectively. Describe how you will get the information you need to answer the research question or accomplish the project's purpose.</p>	<p>Determine whether you are gathering data prospectively or retrospectively. Describe how you will get the information you need to answer the research question.</p>

Establish Research Methods: Select the Study Population

Exploratory	Descriptive	Explanatory
Describe the people you are studying and how they represent the larger population of people potentially affected by your program.	Describe the people you are studying and how they represent the larger population of people potentially affected by your program.	Determine how you will select or identify control and intervention groups.

Establish Research Methods: Determine Number to Enroll

Exploratory	Descriptive	Explanatory
<p>Depends on practical considerations, such as how many people with a certain disease fill prescriptions at the study site. Because there is no control group, statistics are less important than in explanatory studies, but they may help you understand how one group differs from another on certain variables.</p>	<p>Depends on practical considerations, such as how many people with a certain disease fill prescriptions at the study site. Because there is no control group, statistics are less important than in explanatory studies, but they may help you understand how one group differs from another on certain variables.</p>	<p>Must be based on statistical considerations, especially when you are trying to explain why an outcome occurred in the intervention group and whether it is different from the outcome of the control group. The more reliable and precise you want the results to be, the more people you must enroll. Because of threats to internal validity in observational studies, statistics are very important.</p>

Establish Research Methods: Decide How to Select and Enroll Patients

Exploratory	Descriptive	Explanatory
<p>Participants must meet all criteria for the study—such as age, gender, pregnancy status, and other disease states present—and formally agree to participate.</p>	<p>Participants must meet all criteria for the study—such as age, gender, pregnancy status, and other disease states present—and formally agree to participate.</p>	<p>Participants must meet all criteria for the study—such as age, gender, pregnancy status, and other disease states present—and formally agree to participate. Study criteria must be set to reduce bias in patient selection but should not be so restrictive that you have difficulty enrolling patients.</p>

Establish Research Methods: Represent the Target Population

Exploratory	Descriptive	Explanatory
Patients enrolled in the study group must accurately represent the target population in terms of demographics, existing medical conditions, etc.	Patients enrolled in the study group must accurately represent the target population in terms of demographics, existing medical conditions, etc.	Patients enrolled in the study group must accurately represent the target population in terms of demographics, existing medical conditions, etc.

Establish Research Methods: Determine How to Measure Results

Exploratory	Descriptive	Explanatory
<p>Outcome(s) to measure and the system for collecting and interpreting the data must be determined, based on the study objectives.</p>	<p>Outcome(s) to measure and the system for collecting and interpreting the data must be determined, based on the study objectives.</p>	<p>Outcome(s) to measure and the system for collecting and interpreting the data must be determined, based on the study objectives.</p>
<p>Often used descriptive measures and statistics</p>	<p>Primarily descriptive measures and statistics, but able to incorporate statistical tests to test for significance</p>	<p>Minimal use of descriptive measures and statistics. Study powered to detect projected difference between interventions.</p>

How to Measure Results: Instruments to Gather Data

- Utilize existing instruments when available to save time and minimize risk of error
- Instruments used in related studies conducted previously may be ideal for your study
 - Examples of these include questionnaires assessing satisfaction with care in the community pharmacy setting, compliance with drug regimens, or quality of life
 - Especially critical in survey research – best practice is to use a validated study
 - Data collection from patient care often utilizes Microsoft Excel

How to Measure Results: Data Sources

- Where will your project data come from?
- Examples include self-reporting, face-to-face or phone interviews, laboratory tests, patient charts, pharmacy records, and investigator observation.
- Keep in mind you may need to use multiple data sources
- Tip: when writing your project plan, design the data tables you want to have in your final project report

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How to Measure Results: Measurement Frequency

- Think about whether you need to take measurements before, during and/or after the study.
- Pre- and post- interventions used frequently so patients can be their own control
 - Allows to test the impact of educational interventions
- How many measurements of each variable are needed and how frequently?
 - Allow enough time to see impact of intervention
 - Ideal to show sustained improvement without active intervention

How to Measure Results: Data Collection Surveys and Forms

- Be clear about the information required for your study
- Consider your audience and what matters to them
- When designing surveys and patient materials, keep statements or questions simple and precise
 - Have content experts review surveys for completeness, accuracy
 - Pilot test with mock audience for readability
- Test the final product to ensure clarity and reliability
- Develop a data summary sheet to organize your data before you begin collecting it

How to Measure Results: Data Summary Sheets

ID	Pt. Name*	Group	Date of Birth	Gender	Pharmacy	Q1	Q2
1	Joyce Jones	1	12031970	1	1	2	3
2	Mary Smith	2	01031945	1	2	4	2
3	Adam Roberts	1	10231978	0	3	1	3

The data spreadsheet program's dictionary would explain:

Group refers to control= 1 experimental = 2

Date of Birth mmddyyyy

Gender F = 1, M = 0

Pharmacy where enrolled in study: 1 = professional pharmacy, 2 = Doctors pharmacy, 3= Value Pharmacy

Question 1 is score on satisfaction scale, 1-5

Question 2 is annual household income 1 = < \$10,000, 2 = \$10,001-\$25,000, 3 = > \$25,000



*name is usually a medical record number or some other identification that preserves the participant's confidentiality.

Plan Survey Research

- A survey is a mechanism for collecting data in any type of research project
- Collect descriptive data
- Medium
 - In person
 - Postal mail
 - E-mail
 - Web

Survey Features

- Open-ended Questions
 - Allow people to respond in their own words
- Checklists
 - Give participants a list of items and ask them to check all that apply
- Two-way Questions
 - Ask participants to answer in one of two ways, such as yes/no, true/false, helpful/not helpful, etc.
- Multiple-choice Questions
 - List several responses and ask participants to identify the best one
- Ranking Scales
 - Ask participants to attach a value to a series of words or statements

Survey Design

- Often underestimated research design
 - Several factors need to be considered for research validity
- Sample size (Response rate goal: ~70-80%)
- Sample population
- Construct validity
- Medium selected
- Duration of survey being open
- Reminders
- Helpful Resource: The Tailored Design Method

Establish Research Methods: Design the Intervention

Exploratory	Descriptive	Explanatory
<p>There usually is no intervention in exploratory studies and no control group.</p>	<p>There may be no intervention in a descriptive study. If there is one, it must be well described. However, because there is no control group, no conclusions can be drawn about the actual value of the intervention</p>	<p>In a prospective study, the intervention must be well designed and follow an established protocol. Any practitioners participating in the project need training to provide the intervention in a standardized way. Patients in the control group should never receive the intervention. If a retrospective study is being done, people receiving the “intervention” need to be identified carefully.</p>

Establish Research Methods: Consider Statistical Needs

Exploratory	Descriptive	Explanatory
Usually doesn't have statistics.	Looks for differences between groups or subgroups to determine if their needs, perceptions, attitudes, or characteristics are different. Planning for statistical analysis begins when you start developing your research plan.	Goal is to determine if an intervention will make a difference on practice decisions and/or patient outcomes. Planning for statistical analysis begins when you start developing your research plan. In retrospective studies, because control and experimental groups are not randomly assigned, statistical techniques are more complicated to use.

Establish Research Methods: Designing the Statistical Analysis Plan

- Best practice is to consult a biostatistician if you are not comfortable
- Need to design a plan and have appropriate software to run tests
 - Will save time if you collect data in manner that is compatible with statistical analysis software
- Determine what type of data you have
 - Nominal, Ordinal, Interval, Ratio
 - Nonparametric tests: nominal, ordinal
 - Parametric tests: Interval, Ratio
- Have a plan of how you want to compare your variables when meeting with the biostatistician

Select Statistical Tests

- Statistical tests have rules that determine when they can and cannot be used.
- Data Scales
 - Nominal: A measurement scale in which numbers are used to classify, name or label an individual, attribute, or category
 - Ordinal: Data are represented by individual values that can be ordered or ranked on a scale
 - Interval: Data are divided into ranges or set on a continuum, and the distance between the intervals is meaningful
 - Ratio: Measurements originate at absolute zero and represent amounts in terms of equal intervals, such as time, glucose level, heart rate or blood pressure

Select Statistical Tests Continued

■ Tests of Significance

- Parametric tests: involve population parameters and basic assumptions that the distribution is normal
 - Examples: t-test (unpaired data), Paired t-test (paired data), Analysis of variance (more than two comparators)
- Nonparametric tests: make no assumptions about the distribution of a statistical population
 - Used when the data are skewed or have a non-normal distribution
 - Examples: Chi-square test (nominal data), Mann Whitney (unpaired data), Wilcoxon-Signed Rank test (paired data)

Develop a Project Timeline

Exploratory	Descriptive	Explanatory
Do not underestimate the time needed to enroll subjects, analyze data, and prepare your final manuscript.	Do not underestimate the time needed to enroll subjects, analyze data, and prepare your final manuscript.	Do not underestimate the time needed to enroll subjects, analyze data, and prepare your final manuscript.

Project Timeline: Sample

Month	Activity
July	Begin developing research plan; Develop timeline and budget
August	Finish research plan; Submit IRB application; Secure funding
September	Revise protocol as needed; Develop intervention; Promote project
October	Revise protocol as needed; Begin enrolling subjects; Submit abstract to APhA for Annual Meeting presentation
November-February	Continue enrolling subjects; Begin data aggregation and analysis; Develop poster/presentation for APhA Annual Meeting
March	Present at APhA Annual Meeting; Continue enrolling subjects; Continue data aggregation and analysis
April-May	Finish data aggregation and analysis; Complete project evaluation; Begin preparing final report and manuscript
June	Finish Final Report; Finish manuscript for publication

Develop a Budget

Exploratory	Descriptive	Explanatory
Think through each step in your project and the associated costs.	Think through each step in your project and the associated costs.	Think through each step in your project and the associated costs.

Budget: Sample

Item	Quantity	Total Cost
Office Supplies	1 box, envelopes, 1 box mailing labels, 3 reams paper, 1 package pens	\$40
Copying	500 copies @ \$.07 each	\$35
Mailing	100 stamps @ \$.39 each	\$39
Educational brochure	\$15.00 per 100	\$30
Mileage for Site Visits	100 miles @ \$.23 per mile	\$23
IRB approval	-	-
Content expertise	2 hours @ \$55/hour	\$110
Statistical expertise	3 hours @ \$55/hour	\$165
Preperation for poster presentation at APhA Annual Meeting	Poster, PowerPoint Presentation, color pictures, copies	\$200
Publication costs	Copying and binding report	\$200
Total Project Budget		\$842

Apply for Institutional Review Board (IRB) Approval

Exploratory	Descriptive	Explanatory
May not require formal IRB approval, but review that the project “is not research”. May require exempt review or expedited for full review.	May not require formal IRB approval, but review that the project “is not research”. May require exempt review or expedited for full review.	Will require at least expedited review or full review.
All work shared outside of one’s institution should be submitted to an IRB.	All work shared outside of one’s institution should be submitted to an IRB.	All work shared outside of one’s institution should be submitted to an IRB.

- Contact IRB chair if you have not submitted an IRB proposal before
 - Need to complete CITI (Collaborative Institution Training Initiative) training
 - Varies institution to institution

IRB Approval Criteria

- The criteria that IRBs use to approve a study are:
 - Sound protocol and existing diagnostic and treatment procedures to minimize subjects' risks
 - Acceptable risk-benefit ratio
 - Equitable subject selection
 - Informed consent obtained and documented
 - Research plan provides for necessary safety monitoring
 - Privacy of subjects and confidentiality of data is protected
 - Additional safeguards are put in place to protect vulnerable populations

Categories for IRB Review

- Exempt Studies
 - Use an accepted practice or method
 - No potential for harm
 - No intervention with potential for impact or harm on subjects
- Expedited Reviews
 - Involve minimal risk to the subjects
- Full IRB Reviews
 - Conducted when there is measurable or significant risk to the subjects, or when a new medical practice is being investigated

Key Activities in Designing and Planning Your Project

- Select a project category
- Identify the proper research design
- Choose a theoretical model
- Avoid threats to internal validity
- Develop a project plan