

Designing a Study

Objectives and Hypotheses

The following chapter is excerpted from *Designing HIV/AIDS Intervention Studies: An Operations Research Handbook*, Andrew Fisher and James Foreit, 2002, Washington, DC: Population Council. ([More on OR Handbook](#))

OBJECTIVES AND HYPOTHESES

The objectives and hypotheses of a research study should flow logically from the earlier sections identifying the problem situation, defining the parameters of the problem, and justifying its importance. In this section, we explain how to narrow and focus the research. Specific objectives are written that describe the expected results arising from the study and the outcome variables that will be measured. Once objectives have been set, researchers can formulate specific, testable hypotheses that specify the relationship between program interventions and outcomes.

Ultimate Objectives

Most research studies include a statement of ultimate objectives that describes the expected implications or contributions arising from the study. The ultimate objective of many HIV/AIDS studies is to prevent the transmission of HIV and/or mitigate the impact of AIDS. This is an ambitious goal. It is unlikely that any single study will have a significant effect on reducing HIV transmission or a major effect on mitigating the impact of AIDS. A somewhat more reasonable ultimate objective is that the study will provide program administrators and policymakers with information useful for improving HIV/AIDS programs, scaling up these programs, or developing more effective policies.

Ultimate objectives relate the reasonable and expected contributions of the study to broad social, economic, or health concerns. In this way, the ultimate objectives contribute to the justification of why research on the problem is required. Note, however, that ultimate objectives are **expected contributions**. In a sense, they represent wishful thinking. The investigator does not promise that the contributions will occur and therefore usually does not try to measure them.

Examples of Ultimate Objectives

- “The ultimate objective of this intervention study is to contribute toward improving the quality of life for PLHA and the quality and effectiveness of prevention, care, and support activities offered by community-based organizations to PLHA.”
- “The ultimate objective of this intervention study is to develop a cost-effective model of service delivery in Kenya that can reduce the transmission of HIV from mothers to their newborn children.”
- “The ultimate objective of this study is to develop for Uganda a cost-effective and sustainable approach for integrating high-quality VCT services with related family planning and STD and TB prevention and care services in primary health care facilities.”
- “The ultimate objective of this intervention study is to reduce the transmission of HIV and other STIs by implementing a 100 percent condom use policy in brothels throughout the Dominican Republic.”
- “The ultimate objective of this intervention study is to promote in Cambodia the concept of dual protection against STIs and pregnancy through the use of male and female condoms.”

Comments on the Examples

Each of these ultimate objectives briefly states the overall expected outcome of the study. These objectives tend to be broad in nature. They represent the expected impact the researchers hope the study will have. Ultimate objectives relate the purpose of the study to larger health concerns, such as improving the quality of life for PLHA, reducing the rate of mother-to-child transmission (MTCT), or integrating HIV/AIDS services with other health care services.

Immediate Objectives

In contrast to ultimate objectives that state what is expected to happen, immediate objectives state what will happen. Immediate objectives relate directly to the research problem situation. They indicate the variables that will be examined and measured. An immediate objective represents a promise by the investigator that certain activities will take place and specific variables will be examined.

Whenever possible, the immediate objective should be stated in **behavioral** terms—in other words, in terms of what actions or behaviors will take place. The immediate objective should specify **who will do, how much of what, to whom, when, where, and for what purpose.**

Examples of Immediate Objectives

- “Over a 24-month period, the National HIV/AIDS Prevention Council in Uganda, together with Makerere University, will develop a youth-friendly program to provide comprehensive voluntary counseling and testing six days of every week to youth ages 14 through 24. This program will be evaluated in terms of the number of youth who use the service, the cost-effectiveness of the service, and the reduction of unsafe sexual risk behaviors by youth.”
- “Over a three-year period, the provincial health department, together with two local NGOs, will test and compare in terms of reduced STIs and in terms of cost-effectiveness two approaches to implementing a 100 percent condom use policy in brothels. One approach will be tested in Puerto Plata and the other in Santo Domingo. At each site, all commercial sex establishments will be enrolled in the study. All sex workers and brothel owners will receive extensive group counseling on the need to use condoms. Educational materials will be made widely available and condoms will be distributed free of charge.”

- “Over a three-year period, researchers at Kenyatta National Hospital will develop and implement a comprehensive training program for staff, and an HIV/AIDS voluntary counseling and testing service for pregnant women attending the antenatal unit at the hospital. Women who test positive will be offered antiretroviral medication plus breast milk substitutes. The effect of these activities will be measured in terms of reduced rates of mother-to-child HIV transmission, cost-effectiveness, acceptability to staff, and participation by pregnant women and their partners.”
- “Over a four-year period, the Amber and Victoria Gold Mining Company, together with three local NGOs, will implement a comprehensive STI control program among miners and sex workers. This program will consist of behavior change communication using peer educators, condom promotion and distribution through social marketing, and STI services, including periodic presumptive treatment among sex workers. The effect of these activities will be measured in terms of reduced prevalence of STIs among miners and sex workers, greater condom use, increased safe sex practices, and increased knowledge about HIV/AIDS transmission.”

Comments on the Examples

Note that, in each of these objectives, the investigator promises to undertake a **specific activity**: to develop a program activity and measure the effect; to test and compare two different program strategies for implementing a 100 percent condom program; to develop, implement, and measure the effect of an MTCT program; and to implement and measure the effect of an STI reduction program among miners and sex workers. The situation or context involved in the research is also specified. **Who** will conduct the study, **where** it will be conducted, and **when** it will be conducted are stated. Finally, and most important, the key variables of interest are indicated, such as accep-

tance by youth of VCT, cost-effectiveness, sexual risk reduction, reduction of STIs, reduced transmission of HIV from mother to child, and increased condom use.

Each of these variables needs to be carefully defined in operational terms later in the proposal, but at least as stated here in the immediate objectives, they indicate the focus of the proposed research and some of the key variables that will be examined.

Hypotheses

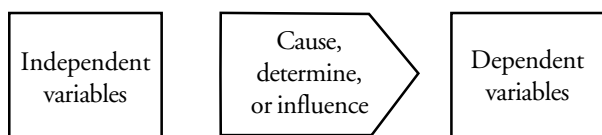
A hypothesis is a statement about an expected relationship between two or more variables that permits empirical testing. While ultimate objectives identify the anticipated contributions arising from a study, and immediate objectives (stated in behavioral terms) specify what will be done or measured in the study, hypotheses specify the **expected relationship** among the variables. Hypothesis statements are most appropriate for field intervention or evaluative studies. Diagnostic or exploratory studies do not normally require hypothesis statements because they generally do not test relationships between variables.

Study hypotheses serve to direct and guide the research. They indicate the major independent and dependent variables of interest. They suggest the type of data that must be collected and the type of analysis that must be conducted in order to measure the relationship among the variables.

A single hypothesis might state that variable A is **associated** with variable B, or that variable A **causes** variable B. Sometimes a hypothesis will specify that, **under conditions X, Y, and Z**, variable A is associated with or causes variable B. A well-written hypothesis focuses the attention of the researcher on specific variables.

When writing hypothesis statements, it is important to keep in mind the distinction between **independent** and **dependent variables**. An independent variable **causes, determines, or influences** the dependent variable. An example of the basic relationship between these two types of variables is shown in Figure 4.1. This model shows a **direct relationship**. In other words, whenever the independent variable changes, the dependent variable changes. The dependent variable **depends** on the independent variable.

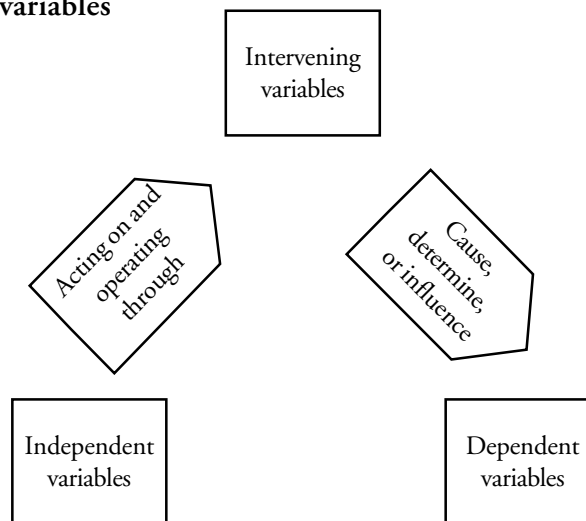
FIGURE 4.1
A direct relationship between independent and dependent variables



This type of direct relationship is usually the model used to develop study hypotheses, but in some cases, a study will hypothesize a model in which the relationship is indirect. The independent variable acts on the dependent variable through **intervening variables**. These intervening variables serve to either increase or decrease the effect the independent variable has on the dependent variable.

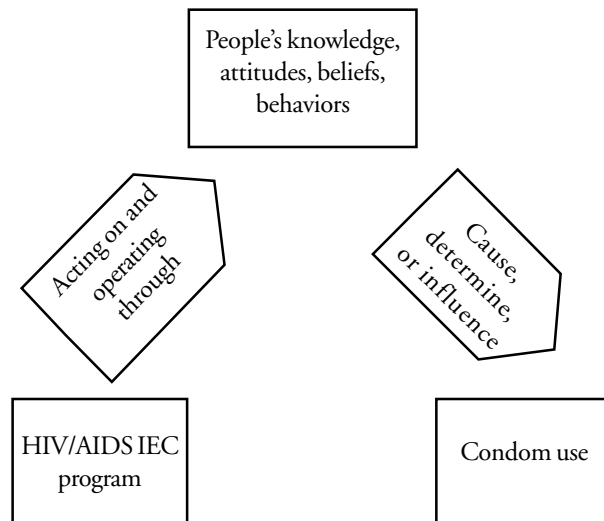
Intervening variables are sometimes referred to as **test** or **control** variables. In longitudinal field experiments, the design of the study (with random assignment of cases to experimental and comparison areas) usually controls the intervening variables. In cross-sectional surveys, intervening variables are measured and then controlled in the statistical analysis. Many HIV/AIDS behavioral and epidemiological research studies are based on a model that includes intervening variables (see Figure 4.2).

FIGURE 4.2
Intervening variables



For example, in an effort to increase condom use (the dependent variable), an HIV/AIDS program might initiate a large information, education, and communication campaign (the independent variable). Alone and by itself, an IEC program cannot increase condom use. The program must act on and operate through a set of intervening variables, which in turn cause, determine, or influence condom use. There may be many of these intervening variables, but the most likely ones that might be influenced by an IEC program would be people's knowledge about HIV transmission, their attitudes about the use of condoms, their sexual risk behaviors, and their beliefs about their vulnerability to AIDS. A possible research model for an evaluation study of the effects of an IEC program is shown in Figure 4.3.

FIGURE 4.3
The effects of intervening
variables in an IEC program



In HIV/AIDS operations research, the hypotheses of most importance usually are those that consider program activities as the independent variable. The HIV/AIDS program input, such as an IEC effort, a voluntary counseling and testing service, an STI prevention program, or a condom promotion program, is the independent variable. The objective of the research is to determine the extent to which the independent variable affects the dependent variable. The dependent variable is usually the central concern of a research proposal's problem statement. The intervening variables are important because they tend to either increase or decrease the strength of the relationship between the program (the independent variable) and the outcome effect (the dependent variable). It is therefore important to gather information on possible intervening variables.

Most research studies will examine many independent variables and many intervening variables but only a few dependent variables. In writing study hypotheses, always think in terms of the expected relationship between variables. Think first about the central problem your study will address (the dependent variable). Next, consider what factor or factors (the independent variables) might cause, determine, or influence the dependent variable. Finally, ask yourself if the relationship between the independent and dependent variables is direct or indirect through a set of intervening variables.

Examples of Hypotheses

- Students who participate in a school-based life skills education program will have more knowledge about HIV risk behaviors and prevention practices and more positive attitudes about safe sex practices than comparable students who do not participate in the life skills program. As a result, they will be more likely to delay sexual debut and use condoms than comparable students who do not participate in the life skills program.
- PLHA who receive comprehensive counseling on antiretroviral therapy that includes discussion of the side effects and their management before ARV treatment begins are more likely to adhere effectively to treatment after a year than PLHA who have not received counseling on ARVs before they begin therapy.
- Peer educators who receive a five-week, field-based training course will have higher knowledge about HIV/AIDS and be more highly motivated than peer educators who have received a three-week, classroom-based training course. As a result, work performance of the peer educators who have been trained for five weeks will be significantly higher than peer educators who have received a three-week training course that was based in the classroom.

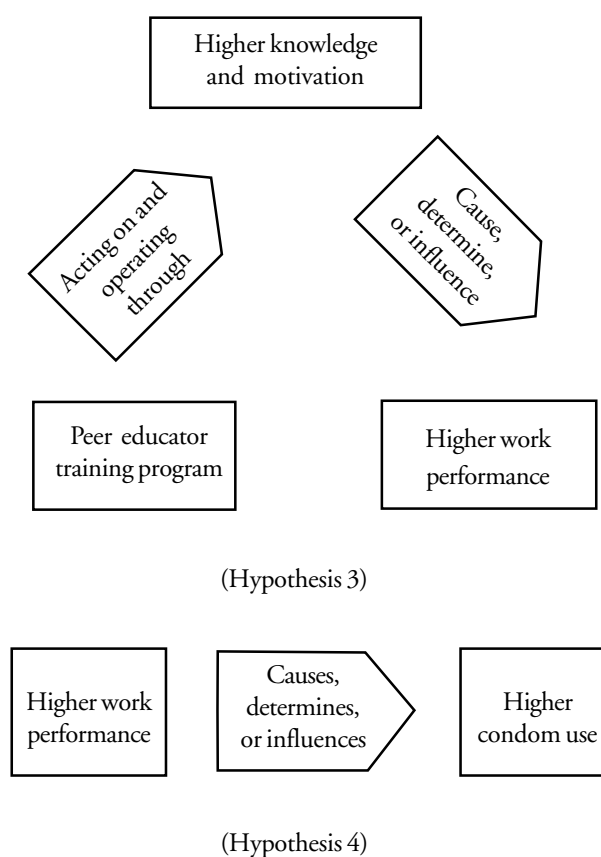
- Higher levels of peer educator work performance will lead to higher rates of consistent condom use among youth.
- Voluntary counseling and testing programs that are linked to community-based HIV/AIDS organizations will be more successful in reducing stigma and discrimination directed at PLHA than VCT programs not linked to community-based HIV/AIDS organizations.
- Reduced levels of stigma and discrimination against PLHA will lead to more people seeking voluntary counseling and testing.
- Community-based HIV/AIDS organizations that actively involve PLHA in the planning and implementation of programs will be more likely to achieve their objectives than similar organizations that do not involve PLHA in the planning and implementation of programs.
- Dual protection programs that focus on counseling women together with their male partners will be more successful than dual protection programs that focus only on counseling women.

Comments on the Examples

Note that in each hypothesis there is a statement of an expected relationship between two or more variables. In the first hypothesis, the expected relationship is between attending a life skills education program (the independent variable) and knowledge about HIV/AIDS, and more positive attitudes toward safe sex (the intervening variables). These intervening variables are then hypothesized to have a relationship with the delay of sexual debut and on condom use (the dependent variables). In the second hypothesis, the relationship is between comprehensive counseling on ARVs (the independent variable) and adherence to ARV treatment after a year (the dependent variable).

The third and fourth hypotheses go together. In the third hypothesis, the relationship is between a five-week, field-based training program (the independent variable) and greater knowledge about HIV/AIDS and higher motivation (the intervening variables). These intervening variables are then hypothesized to have an effect on work performance (the dependent variable). Hypothesis 4 carries this causal process one step further by suggesting that work performance (which is now the independent variable) will have an effect on condom use (the dependent variable). Taken together, the model for these two hypotheses would look like Figure 4.4.

FIGURE 4.4
A model for two hypotheses about the effect of a peer educator training program on higher rates of condom use



Similarly, hypotheses 5 and 6 go together. In hypothesis 5, VCT programs linked to community-based organizations (the independent variable) are hypothesized to reduce stigma and discrimination against PLHA (the dependent variable). In hypothesis 6, reduced stigma and discrimination become the independent variable, and use of VCT centers becomes the dependent variable.

For all the hypotheses listed in the examples, the important point is that they show a relationship between an independent and a dependent variable, and it is this relationship that is tested empirically through a research study.

To summarize, all research studies should include a statement of (1) ultimate objectives, (2) immediate objectives, and (3) hypotheses (except in the case of purely exploratory or descriptive studies). Each of these statements serves a different purpose:

1. **Ultimate objectives** state the **anticipated (hoped-for) contributions** of the study.
2. **Immediate objectives** state **what will be done** in the study.
3. **Hypotheses** state the **expected relationship** between two or more variables.

What To Do: Writing Ultimate Objectives, Immediate Objectives, and Hypotheses

1. List the major variables of your study under the headings: Independent Variables and Dependent Variables. Intervening variables can be listed under both headings. The dependent variable(s) should relate directly to your problem statement.
2. Review the list of dependent variables and then write a statement of ultimate objectives that relates to them. Ask yourself, “If I knew the factors that caused, determined, or influenced the dependent variable(s), how would this knowledge help policymakers, program administrators, or others?” How will the results from the study help improve service delivery, improve training programs, or assist in the design of educational materials? In other words, what are the anticipated contributions of the study?
3. Now write the immediate objectives for your study. Focus your attention on the specific actions that you will perform. Exactly what do you plan to do? What variables do you plan to measure? Write behavioral objectives that answer the following questions:
 - Who will do?
 - How much of what?
 - To whom?
 - When?
 - Where?
 - For what purpose?
4. Finally, write the hypotheses that your study will test. Review once again your list of independent and dependent variables. How are these variables related? Are there special conditions that must be present before they are related? Write hypothesis statements in **positive**, not negative, terms. Write a hypothesis for each major relationship that you expect to test in your study.