

## **Designing a Study**

### ***Intervention Description***

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](#))

## INTERVENTION DESCRIPTION

If your study includes an intervention, such as a test of a new training procedure or a comparison of two new approaches to service delivery, you need to fully describe the nature of the intervention in your proposal. You should elaborate on the questions you answered when writing the immediate objectives, namely, **who will do, how much of what, to whom, when, where, and for what purpose.**

More specifically, it is important to answer in some detail the following questions:

**Who will be responsible for implementing the intervention?**

Indicate the organization(s) that will be responsible for implementation and their capacity to implement the study. Also, indicate the categories of people (for example, nurses, doctors, midwives, or field motivators) who will be involved and the role of each of these persons.

**Where will the intervention activities take place?** Be as specific as you can about the actual location of the study intervention. Will the intervention be implemented in an entire province, in one district, in ten villages, in 30 factories, or in four clinics? Be sure to mention the location of the study sites.

**What activities will be initiated?** You should describe the sequence of events that will take place. For example, a study intervention might start with the training of peer educators. The nature and duration of the training should be described. Next, a series of village meetings might be held. The frequency and purpose of these meetings should be noted. Finally, the educators will visit at least five homes each day for a period of one year. The purpose of the visits and the expected activities during the visits should be described. In describing the activities that will be implemented, it is important to indicate the level or intensity of each activity.

For example, if the intervention being tested is an IEC campaign, you should describe in detail the nature of the campaign. Indicate the type of media that will be used (television, radio, newspapers, pamphlets, wall posters, group meetings, plays, or songs). Mention the intensity of the media effort (100 wall posters, 1,000 pamphlets, three radio spots per day for six months, one TV program a week for three months). Specify who will produce the posters, pamphlets, radio and TV scripts, plays, songs, and so forth; what kind of training (if any) will be needed; and what special equipment will be required.

## Example of a Study Intervention Description

“An Experimental Operations Research Study in The Gambia to Provide HIV/AIDS Education and Condoms in the Workplace”

### Study Intervention Sites

This employment-based HIV/AIDS prevention study will be implemented by The Gambia Rotary Club. All employment sites will be located in and around Banjul. Potential sites will include those with at least 100 employees, of whom 20 or more are female workers (the Rotary Club wants to increase women’s access to HIV/AIDS education and condoms). It is estimated that some 25 employment sites will meet these criteria and approximately 15 to 20 of these will agree to participate in the project. Thus, at a minimum, the 15 employment sites should have approximately 1,500 employees (15 sites x 100 employees), of whom 300 (15 x 20) should be female employees. In fact, the number of total employees and female employees is expected to be far greater.

Although The Gambia does not have large industrial enterprises, several of them employ more than

100 workers, including breweries, hotels, the port authority, and commercial farm operations. The Rotary Club has already contacted a number of work sites to determine potential interest in participating in the study, and all enterprises contacted have expressed an interest.

To ensure active and informed participation in the study, site visits and seminars will be organized by the Rotary Club for management and workers’ representatives before the study intervention begins. The purpose of the seminars will be to outline the project design and objectives and to convince management of the short- and long-term advantages of participating in the activity. The seminars will be organized in collaboration with the Ministry of Labor and the Department of Medicine and Health.

### Study Activities

Employment sites willing to participate in the project will be stratified on the basis of the number of employees. Two strata will be created: (1) employment sites with 149 employees, and (2) sites with 150 or more employees. From within each stratum, employment sites will be randomly assigned to one of three groups: stationary services, mobile services, and the control group, which will receive the usual company services. The activities to be initiated in the two experimental groups are described below.

#### STATIONARY SERVICE SITES

At the stationary service sites, one peer educator for every 40 workers will be selected by the workers themselves, with the approval of management. The distributors will receive a total of ten days of training on sexually transmitted infections, including HIV/AIDS. Five days of training will be completed before the intervention phase of the study begins. The remaining five days of training will be spread over the duration of the intervention period, one day at a time.

The primary job of the distributor will be to provide fellow workers with information on STIs, sell condoms on a commission basis, and make referrals to the Department of Health clinics for STI treatment and voluntary counseling and testing for HIV. Each distributor will be given three bright-colored T-shirts with the Rotary Club logo to help other workers identify them. In addition, they will be given a bag to store condoms and record-keeping forms.

The stationary service sites will receive monthly supervisory visits from a Department of Health educator, who is a trained midwife. One of the primary functions of the supervisor will be to sell the distributor condoms for resale to clients and to provide support to the peer educator. The distributor will be allowed to keep half of the final sale price. Currently, a strip of four condoms sells for approximately 12 cents. Thus, for each strip of four condoms sold, the distributor earns 6 cents and the Department of Health recovers 6 cents.

In addition to resupplying the distributors, the midwife will also hold group meetings with the workers to discuss STIs, safe-sex education, and VCT. Work site managers will be requested to allow 15 minutes of work time every two weeks for educational sessions. The workers will be asked to give an equal amount of time for these educational sessions during their work break.

### **MOBILE SERVICE SITES**

Work sites assigned to the mobile services group will receive visits every two weeks by a Department of Health educator/midwife. She will hold group meetings with the workers to discuss STIs, including HIV/AIDS, safe sex, VCT, and sources of condoms. Work site managers will be requested to allow 15 minutes of work time every two weeks for educational sessions. The workers will be asked to give an equal amount of time for these educational sessions during their work break. In addition, the educator/midwife will sell condoms. The full price of the sale will be reimbursed to the health department. As in the stationary service sites, the

midwife/educator will make appointments for workers at the nearest health department clinics for STI diagnosis and treatment, VCT, and/or other desired services.

## **Recruitment and Training of Field Staff**

The Department of Health has a cadre of educator/midwives who are responsible for carrying out HIV/AIDS information, education, and communication programs. From this cadre, four will be selected to work on this OR study. They will be responsible for conducting the field activities, scheduling the on-site education visits, monitoring condom distribution activities, and collecting routine service statistics on sales and the number of referrals to clinics. They will also provide in-service education and training for the work site distributors. Two educator/midwives will be responsible for the activities in the stationary service group, and the other two will be responsible for those in the mobile service group.

Although the educator/midwives have already been trained in the substantive areas of HIV/AIDS prevention, a short orientation program on this OR study will be organized for them. This orientation will provide an opportunity to discuss the design of the project and to review the requirements and responsibilities of the educators and workplace distributors. The midwives will be randomly assigned to a pair of study groups. Each pair will include one mobile site group and one stationary site group.

A member of the Rotary Club staff will serve as a research assistant. The research assistant will interview workers and collect service statistics and other relevant data from the workplaces. Training for the research assistant will be provided by the Department of Health.

The principal investigator will coordinate recruitment of workplace distributors with assistance from the educator/midwives. Employees in the work sites will be encouraged to participate in selecting the peer educator for their site. Selection criteria will be provided to assist them in identifying suitable peer educators. Those selected should show an interest in becoming involved in the project, demonstrate positive attitudes toward HIV and STI prevention, and be respected by workers and management.

Peer educators will participate in a required initial five-day training session and in a subsequent series of five one-day training sessions to be conducted by the Department of Health. These training sessions will be scheduled on days that are convenient for the participants and the trainers.

## What To Do: Intervention Description

1. Be as detailed and complete as possible in describing the study intervention.
2. Be sure that the theoretical rationale for selecting the intervention is clear.
3. Describe the activities in the order in which they will occur.
4. Be sure your description of the intervention answers the three basic questions:
  - Who will be responsible for implementation?
  - Where will the intervention take place?
  - What activities will be initiated at what level of intensity?