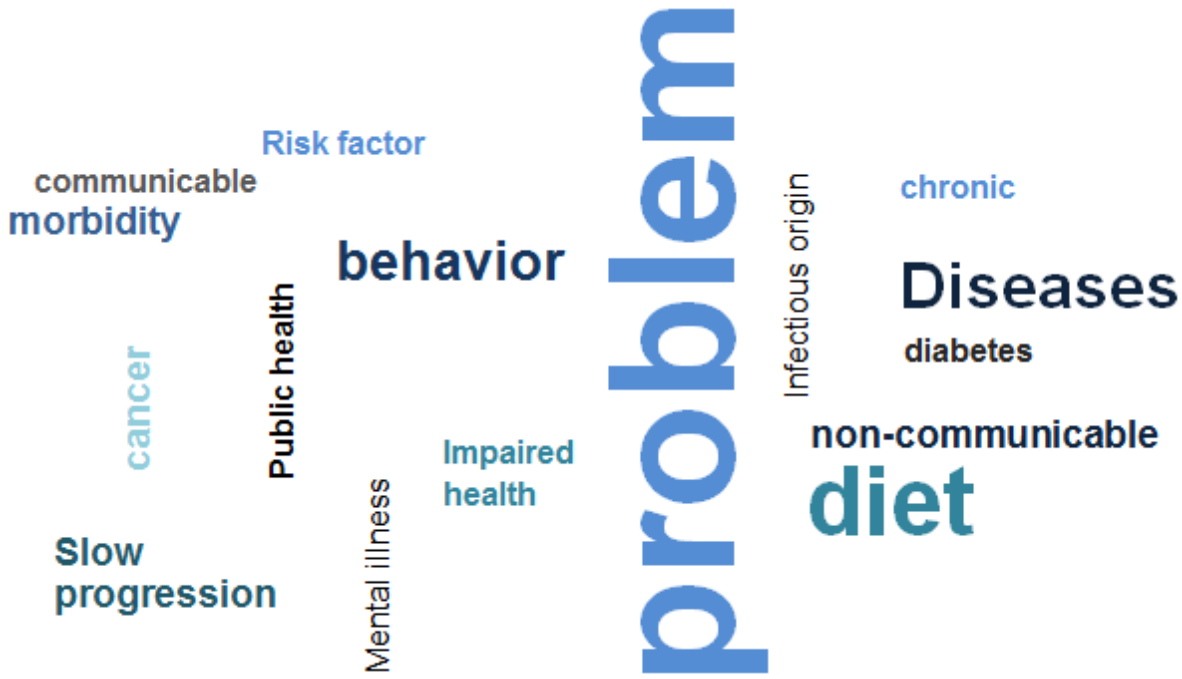
PARTICIPANT WORKBOOK



Developing a Protocol

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Developing a Protocol

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Section 1: Introduction

Overview of Developing a Proposal and a Protocol

A **proposal** is a **statement of work** for research or non-research study and must meet the requirements of the sponsoring and funding agencies. A typical proposal (also known as a concept paper or prospectus) can be as brief as 1-3 pages, but some proposals may be longer. It is common to write a proposal to obtain approval and/or funding and then use the approved proposal as a basis for developing a protocol.

A **protocol** can be defined as a **systematic description of procedures** to be used in research or non-research study. It must meet regulatory requirements to justify research and protect clients and is reviewed and approved by the appropriate regulatory body. A protocol can be quite long (e.g., 10-30+ pages in length, with attachments such as a copy of the questionnaire and informed consent form). Quality of science is often improved when you clearly think through and describe study objectives and methods.[1] A written protocol facilitates high quality science and is an invaluable tool to investigators as they develop and conduct studies.

Learning Objectives

1. At the end of the training, you will be able to:
   a. Write a proposal that includes the following:
      - Background
      - Justification for the study
      - Research question or hypothesis
      - Objectives of a study
      - Proposed methods
      - Expected benefit
   b. Assess the quality of a sample protocol.
   c. List the information to include in a protocol for a noncommunicable disease (NCD) study you are proposing.

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[1] *From the National Institute for Occupational Safety and Health: http://www.cdc.gov/niosh/nas/mining/pdfs/Protocol%20Checklist.pdf*

2. When you return to your job, you will be able to develop all sections of a protocol for an NCD study.

Estimated Completion Time

The workbook should take approximately 10 ½ hours to complete.

Target Audience

The workbook is designed for Field Epidemiology Training Program (FETP) residents who specialize in non-communicable diseases. However, you can also complete the module if you are tasked to develop a protocol or proposal to address other types of diseases.

Pre-work and Prerequisites

Before participating in this training module, you must complete the pre-work assignment. The activities for the assignment include the following:

- Identifying an NCD health problem for which to conduct a study
- Searching the literature for information about the problem you are researching
- Determining whether other researchers/entities are currently engaged in similar or related research
- Identifying critical areas for research
- Identifying the incidence or prevalence of the problem, when and where it is occurring, who is affected by the problem and possible reasons for the problem

In addition, you should have completed training on the following topics:

- Data collection methods
- Study design
- Data analysis and interpretation

About this Workbook and the Activity Workbook

The **Participant Workbook** consists of three sections where you will read about how to develop a proposal and a protocol and complete four practice exercises using a sample proposal and protocol. You will also complete four Skill Assessments (i.e., exercises) in the **Activity Workbook** where you will practice by using the information you brought to class.

Icon Glossary

The following icons are used in this workbook:

Image Type	Image Meaning
 Tip Icon	Supplemental information
 Activity Icon	Activity, exercise, assessment or case study that participants complete
 Stop Icon	Stop and wait for further instruction for the facilitator

ACKNOWLEDGEMENTS

The content of this module is based on a training module developed by Christine Zahniser, BSN, MPH, Nurse Epidemiologist, Contractor/GEARS, Inc, Centers for Disease Control and Prevention, Office of the Director, Global Health Activities/Demographic Research and Program Evaluation Team. Thanks to Ms. Zahniser for providing detailed feedback and guidance.

Also, thank you to the following subject matter experts and reviewers:

- Antonio Neri, MD, MPH, National Center for Chronic Disease Prevention and Health Promotion, Division of Cancer Prevention and Control
- Mona Saraiya, MD, MPH, National Center for Chronic Disease Prevention and Health Promotion, Division of Cancer Prevention and Control

Many thanks to the authors who have shared their protocols which have been used as examples in this module.

- *"Assessing Risk Factors for Chronic Disease – Jordan, 2004"* MMWR, June 16, 2006. Vol 55/No. 23: 653-655 (A. Belbeisi, M Zindah, Jordan MOH; H Walke, B Jarrar, AH Mokdad, CDC).
- "*Study of prevalence and factors associated with tobacco consumption among adolescent students from middle level schools in Antigua*

*Guatemala, Sacatepéquez, Guatemala, 2012" (S*eventh cohort of the Masters Degree students at the Field Epidemiology Training Program, University of the Valley in Guatemala). Provided by Dr. Victor Caceres, Centers for Global HealthSection 2: Overview of Developing Protocols for a Study.

Section 2: Overview Of Developing A Protocol For A Study

WHY CONDUCT STUDIES AND WRITE PROTOCOLS?

There are several reasons for conducting studies, for example:

- To respond to a public health problem, such as an increase in prevalence of a disease or related risk factors, an epidemic, or an unexpected health outcome
- To plan or change a program or course of action
- To test a hypothesis
- To further study recent findings
- To evaluate effectiveness of an intervention
- To determine the value or return on investment
- To satisfy scientific or medical curiosity

Developing a protocol will help you clarify what you want to accomplish in a study. The process of writing this protocol allows you to clearly describe the problem you wish to address in your study, the data you will use, your planned analysis, and the resources you may need to conduct the study.

The format and content of protocols vary. These training materials will describe the standard information that is most commonly included in protocols.

STEPS IN WRITING A PROTOCOL

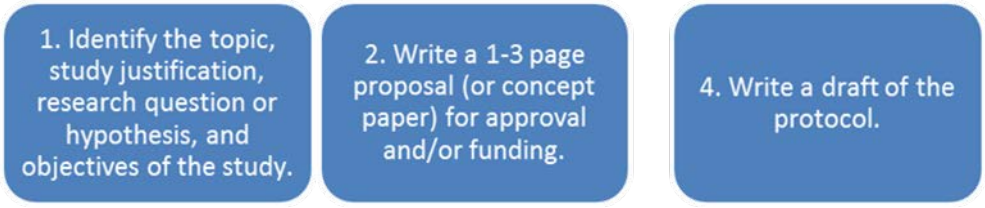
The following steps are recommended when developing a protocol:

1. Identify the topic, study justification, research question or hypothesis, and objectives of the study.
2. Write a 1-3 page proposal (or concept paper) for approval and/or funding.
3. Create tables for data collection to anticipate the data you will collect and how you will use it.
4. Write a draft of the protocol.
5. Prepare the data collection instruments.
6. Send the protocol (including data collection form, tables, and consent forms) to all applicable partners / stakeholders to review. This would also involve ensuring that administrative, bureaucratic, and funding requirements are met.

7. Present the protocol to the ethics committee; revise as necessary until approved.

You will keep the approved protocol as a guide to use in the field and for the basis of your final report (i.e., manuscript).

In this workbook, we will focus on steps 1, 2 and 4:



Activity

Instructions:

1. Find a colleague with whom to complete this activity.
2. Spend 5 minutes discussing the components you include (or think you should include) in a proposal (or concept paper).
3. Continue reading the module on the next page.

Section 3: Writing a Proposal or Concept Paper

In this section, you will learn how to complete the first two steps of developing a protocol:

1. Identify the topic, study justification, research question or hypothesis, and objectives of the study.
2. Write a 1-3 page proposal or concept paper for approval and/or funding.

At the end of this section, you will read a sample proposal and answer questions about it. You will then develop a proposal using the information you brought to class for the pre-work assignment.

COMPONENTS OF A PROPOSAL

You will write a **proposal** to briefly describe your research or non-research study to obtain approval and possibly funding for your project. A good proposal should include the following components:

- project title
- background
- justification for the study
- research question or hypothesis
- objectives of the study
- proposed methods
- expected benefit
- references

Each of these components is described below.

Project Title

Your title should be able to stand alone as an explanation of the study and should be a summary of the main idea of your research or study. The title should include the following, if applicable:

- The topic being studied
- The geographic location (city, county, state, national) where the data were collected
- The measure of analysis (prevalence, incidence, mortality, etc.)
- The demographics (age etc.) of the population being studied
- The dates of data collection

Examples: **Study Protocol to Assess Risk Factors for Chronic Disease – Jordan, 2004**

Study of prevalence and factors associated with tobacco consumption among adolescent students from middle level schools in Antigua Guatemala, Sacatepéquez, Guatemala, 2012

Background

Describe relevant information about the health issue to be studied based on a review of the literature. Perform a literature review about the health problem, synthesize the current research of studies on the subject, and provide a clear description of what has been done previously. Include a bibliography of the sources used in the Reference section.

Tip

When you write a protocol, you will develop the background section to include more information from your literature review.

The following example of the background section is adapted from the following report: *"Assessing Risk Factors for Chronic Disease – Jordan, 2004"* MMWR, June 16, 2006. Vol 55/No. 23: 653-655 (A. Belbeisi, M Zindah, Jordan MOH; H Walke, B Jarrar, AH Mokdad, CDC). A complete example of the proposal can be found in Appendix A.

Background:

In 2002, Jordan Ministry of Health (MOH), with assistance from CDC and the World Health Organization (WHO), established a behavioral risk factor surveillance program to monitor risk factors associated with chronic diseases.

In 2003, chronic diseases were the leading causes of mortality in Jordan (Centers for Disease Control, MMWR Report); 38.2% of deaths were attributed to cardiovascular disease and 14.3% to cancer.

Source: "Assessing Risk Factors for Chronic Disease--- Jordan, 2004". Centers for Disease Control and Prevention and the Jordan Field Epidemiology Training Program. *Morbidity and Mortality Weekly Report*: 55(23)653-655.

Justification for the Study

The study justification is a critical part of the proposal. Studies are often expensive and time consuming. When funds are limited, it is especially important for the investigator to justify the proposed study carefully. Clearly communicate a balance of evidence-based proposed research with innovation. Explain the public health and scientific importance of the study and the health problem being addressed. In the context of previous studies, you may also want to describe the contribution this study will make. The author of the proposal needs to clearly communicate a balance of evidence-based proposed research with innovation. That is where value added is found.

As you write the justification, consider the following questions:

- How will the results of the proposed study be used to inform decision-making and/or make an impact on population health?
- Is the problem current and timely? Does the problem exist *now*?
- Does the problem have life-threatening or serious morbidity consequences?
- Does the problem affect (or potentially affect) a large number of people?
- Does the problem relate to on-going program activities? Does the problem have implications for current programs?
- Does the problem have broad social, economic, political, or health implications?

- Is the problem viewed as a concern by many different people? A problem of concern to many different people – administrators, politicians, health professionals, and the general public – may be *more* likely to receive funding than one viewed as a concern by only a small group.
- What gap in the literature would be filled by this proposed study? Have other studies already addressed the problem sufficiently? Would another study add significant new information?
- Have other funding agencies expressed an interest in funding studies on this topic?

Tip

You do not need to address ALL the questions. These are just suggested questions you may want to answer as you justify your proposed study.

The following is an example of a justification section adapted from the Jordan chronic disease study:

Justification:

Although many countries are improving their health infrastructure, chronic diseases continue to be a public health problem. In addition, the high cost of chronic disease treatment puts an additional strain on countries with developing economies. More global collaboration and partnerships in chronic disease prevention and control are needed; certain FETPs (e.g., in Egypt and China) have begun working to address the problem.

Previous studies have demonstrated that changes in lifestyle can prevent diabetes and obesity in selected groups of adults at high risk.

We are interested in the change in prevalence of chronic diseases between 2002 and 2004. The 2004 survey will contain additional questions on chronic disease risk factors, including diabetes, heart disease, seatbelt use, physical activity, oral health, eyesight, women's health, and screening.

Research Question or Hypothesis

All proposals and protocols should contain a formal and explicit statement of the study, and question(s) to be investigated or the study hypothesis(es) to be tested.

An exploratory or descriptive epidemiologic study does not involve hypothesis testing; descriptive studies focus on current health problem knowledge and past study findings. Make sure you formally state these study questions with clarity and specificity. In contrast, analytic epidemiologic studies are designed to make predictions about the relationships between variables and therefore tests hypotheses.

A hypothesis is a statement (not a question) about whether one or more independent variables being evaluated affect the outcome of a dependent variable. The statement should proceed logically from the description of the health problem and indicate:

- Under what conditions the hypothesis is expected to be true.
- All potential intervening variables that may affect the dependent variable.
- Operational definitions for all variables included in the hypothesis(es).

Read the following example of a study question and hypothesis:

Question for a Descriptive Epidemiologic Study:

- What is the current prevalence of behavioral risk factors in Jordan?

Hypothesis for an Analytic Epidemiologic Study:

- Low consumption of fresh fruits and vegetables and their nutrient biomarkers are associated with increased risk of Cardiovascular Disease (CVD).

Objectives of the Study

Objectives list clear, concise statements of what the study will demonstrate, test, evaluate, confirm, or compare.

These are often separated into two categories: 1) general objectives and 2) specific objectives. The general objectives are typically at a higher level, similar to goals. The specific objectives provide details of how you will achieve the general objectives.

Tip

Criteria for writing effective objectives:

- **Declarative statement:** describes the intended result or outcome of the study or program in a complete sentence
- **Concise:** communicates the complete idea of your goal simply and briefly, without unnecessary detail
- **Positive terms**: frames the intended outcomes in positive terms or in terms of a decrease in health risk behaviors or health outcomes
- **Easily understood**: uses language that is clear and jargon-free and that most people outside your organization understand

The following is an example of objectives adapted from the Jordan chronic disease study:

Objectives:

• To identify the prevalence of behavioral risk factors in Jordan associated with chronic diseases

• To develop a national plan to prevent and control chronic diseases in Jordan

Proposed Methods

Not all proposals need this much detail; however, if requested, you will want to include some or all of the following:

Study population

Specify the population in which you will undertake the study. Include political, geographic, social, economic, and demographic identifiers, if applicable.

Study design

The study design is determined by the primary purpose of the project. As a first step, determine whether the study will be *descriptive* or *analytic*.

A *descriptive study* is a statistical study to identify patterns or trends in a situation, but not the causal linkages among its different elements. Descriptive studies help in generating hypothesis on which further research may be based.

Descriptive studies provide accurate data on:

- the occurrence or prevalence of a characteristic or event related to a health problem,
- the people who are affected, and
- how they are affected.

As an example, a **cross-sectional** descriptive study, such as a population survey, is designed to estimate the prevalence of a disease or risk factor in a given time period.

An *analytic study* is used to explain the relationship between two or more variables by testing causal hypotheses that specify the relationship between the variables. Examples of analytic studies are case-control, cohort, or randomized controlled trial (described below)

Once you determine the primary purpose of the study, you will decide whether you will conduct a quantitative or qualitative study, or a combination of both.

Quantitative studies answer questions such as how much, how many, or how often. Examples of quantitative studies include:

- **Case-control:** a study method that compares differences in exposures between individuals who have a disease with individuals who do not have the disease in order to identify risk factors for the disease.
- **Cohort:** a study method that compares disease incidence over time between groups with different exposures in order to identify risk factors for the disease.
- **Randomized controlled trial:** a study method in which the investigator attempts to control certain study conditions and randomly assigns subjects to an exposed or unexposed group, then monitors both groups for occurrence of the health outcome of interest.

Qualitative researchers aim to gather an in-depth understanding of a topic. Some **qualitative** studies use open ended questions to elicit participants' descriptions or explanations. They answer questions such as why or how (to explain, describe, and capture the meaning and context of how people understand an issue). Interviews are usually tape recorded and transcribed. Some analyses involve researchers systematically reviewing transcripts to

determine common themes across and within interviews or focus groups. Examples of qualitative studies include:

- **In-depth interviews:** a study method that interviews one person at a time. They are useful for collecting individual opinions. Sensitive subjects are best explored with in-depth interviews because they provide confidentiality.

- **Key informant interviews:** a study method that uses interviewing techniques with one participant at a time. Key informants are people who are purposely chosen to be interviewed because they have particular knowledge or play a certain role (e.g., directors of community health organizations).

- **Focus groups:** a study method that uses discussion of a topic with a group of people. Focus groups are helpful for understanding a group's opinion about an issue. Dynamic group interaction is the hallmark of focus groups; therefore, they are most helpful for brainstorming or trying to understand group thought processes.

Operational definitions

Provide information regarding the key case definitions, criteria and / or control recruitment strategy.

Sampling procedure

Describe the type of sampling you will use, for example, simple random, systematic, cluster, multistage, non-probability (e.g., convenience).

Sample size

Briefly mention your sample size and the main assumptions you used to calculate it. This should contain enough information for the reader to redo the calculations to check the estimate.

Data collection

Briefly explain the type of data that will be collected, who will collect the data and how (telephone or in-person interview, paper form distributed at school or work, etc.), the timeline, and the quality assurance mechanism.

Analysis plan

Summarize the type of analysis (e.g., descriptive, analytical, stratified, multivariate) that you plan to carry out. Mention laboratory analysis if this will be part of the study.

The following is an example of the Proposed Methods section adapted from the Jordan chronic disease study:

Proposed Methods:

Study population:

Persons 18 years and older living in Jordan.

Study design:

This is a descriptive study. We will conduct a cross-sectional survey about behavioral risk factors in Jordan.

Operational definitions:

Overweight is classified as having a BMI of 25.0 – 25.9;

Obesity is classified as having a BMI of >= 30;

Cigarette smoking = ever smoked >= 100 cigarettes in lifetime and currently smoke every day or some days;

Vigorous activity = activity resulting in heavy sweating and large increase in breathing or heart rate for 20 minutes.

Sampling procedure:

The MOH will use sampling methodology comparable to that used in 2002. The sample will be based on the sampling frame provided by the Jordan Department of Statistics, used for quarterly, multistage, cross-sectional employment surveys. The study will be conducted among a nationally representative sample of adults aged >=18 years. In each household, one adult will be selected at random and interviewed in person.

Sample size:

3,334 adults will be interviewed for this study.

Data collection:

The survey will include questions on demographics, health status, health-care access, hypertension awareness, cholesterol awareness, diabetes, asthma, heart disease, tobacco use, seatbelt use, physical activity, nutrition, weight and height, oral health, eyesight, women's health, medical services, and screening.

In-person interviews will be conducted by MOH and Jordan FETP trained staff between October and December 2004.

Analysis plan:

We will do a descriptive analysis of selected behavioral risk factors by sex and age group.

Expected benefit

Describe the expected benefit of the study and how the results may influence prevention and control activities for the health problem.

The following is an example of the Expected Benefit section adapted from the Jordan chronic disease study:

Expected Benefit:

These results will allow us to develop and implement a national plan to prevent and control chronic diseases.

Budget

If you are using the proposal to seek funding, develop a preliminary budget that includes items such as:

- Study personnel
- Supplies and equipment
- Travel
- Miscellaneous

The following is an example of what a budget might look like:

Item	Cost/month of study	Number of months of study	Total costs for Year 01
Study Personnel (7)			
Coordinator (1)	$150 (US)	12	$ 1,800
Data manager (1)	$ 75	9	$ 675
Interviewers (5)	$ 30 x 5	6	$ 900
Supplies and Equipment			
Netbook	$150		$ 150
Travel			
Transport for Interviewers	$60 x 5	6	$ 1,800
Lodging in field	$40 x 7	4	$ 1,120
Miscellaneous cost			
Training (2 day for 7 people)	$125		$ 135
Total			$ 6,580

References

List bibliographic references you used in the proposal.

Stop

Let your facilitator or mentor know you are ready for the group discussion.

Practice Exercise #1

(estimated time: 30 minutes)

Instructions:

1. Complete this exercise with a colleague.

2. Read the case scenario below which shows an example of sections of a proposal, adapted from a study proposal: *Prevalence of and Susceptibility to Cigarette Smoking Among Female Students Age 13 to 15 years in Vietnam, 2007* by Van Minh, H., Tai Hai, P., Bao Giang, K., and Ngoc Kinh, L.

3. Answer the questions that follow.

4. Ask a facilitator or mentor to review your work.

Background

Tobacco use is one of the leading causes of illness and death in the world. Tobacco use is associated with many chronic diseases, such as cardiovascular disease, cancer, chronic respiratory diseases, and diseases of the digestive tract. Though the prevalence of smoking among women is lower than among men worldwide (42% of men and 24% of women in developed countries and 48% of men and 7% of women in developing countries), the issue of smoking among women has attracted growing attention because recent reports have shown a high level of tobacco use among girls. Furthermore, women face additional health risks, including hazards during pregnancy (e.g., exposure to secondhand smoke that can lead to low birth weight or premature birth) and cancers of the female reproductive system (e.g., cancer of the cervix).

Study Justification

Many female smokers start smoking during adolescence, and girls have more difficulty than boys quitting smoking because they experience stronger dependence on the behavior and more negative emotions during attempts to quit. More concern now exists regarding smoking among girls because the tobacco industry has been extensively investing in advertising and marketing campaigns that associate tobacco use with independence, desirable body image, glamour, and romance, and these campaigns target girls and women.

Practice Exercise #1

(estimated time: 30 minutes)

Like other developing countries in Asia, Vietnam is affected by tobacco companies' girl-specific cigarette-promoting campaigns. Problems associated with smoking in Asia among women and girls will continue to be evident until well into the 21st century if no action is taken now to curb the smoking epidemic.

Research Question

What is the prevalence of and susceptibility to cigarette smoking among female students aged 13 to 15 years in Vietnam?

Objectives of the study

- To determine the prevalence of cigarette smoking among female students, ages 13-15 years in Vietnam
- To describe the susceptibility to cigarette smoking among female students, ages 13-15 years
- To identify other factors that promote cigarette smoking to female students ages 13-15 years
- To design appropriate prevention strategies to discourage adolescent girls from smoking

Discuss the following questions with a colleague and record your responses in the space provided.

1. Does the proposal include a clear description of the health problem? Circle some of the relevant sentences that helped you to understand the health . proposal include a clear description of the health problem? Circle some of the relevant sentences that helped you to understand the health

2. Did the proposal provide adequate justification for the study to be approved? Circle the sentences in this section that would help someone decide whether or not to approve or fund the study.

3. Did the authors provide a clear and concise research question that

Practice Exercise #1
(estimated time: 30 minutes)

the study will address and/or a hypothesis that they will test? Explain your answer. Do you have another research question that you would ask if you were conducting this study?

4. Did the study objectives include the following criteria? Place a check mark next to all that apply:
   - ☐ declarative statement
   - ☐ concise
   - ☐ positive terms
   - ☐ easily understood

Section 4: Writing a Draft of the Protocol

You will next learn how to complete all sections of a protocol.

Throughout this portion of the module, you will practice what you have learned by answering questions about a sample protocol (located in Appendix B). You will also complete three Skill Assessments in the Activity Workbook where you will write sections of a protocol based on the information you brought to class.

SECTIONS OF A PROTOCOL

You will use the feedback from your (approved) proposal and additional information to write a draft of your protocol.

A protocol contains the following five sections:

1. Overview of the Study
   a. Title
   b. Protocol abstract
   c. Investigators/collaborators/funding sources

2. Introduction
   a. Literature review/current state of knowledge of the research topic
   b. Justification for study

c. Anticipated use of study results
d. Study design and location(s)
e. Objectives
f. Hypotheses or questions
g. General approach or focus of the study

3. Procedures and methods
   A. Study design
      - How study design addresses research questions and objectives
      - Audience and stakeholder participation
      - Study timeline
      - Expedited review protocol

   B. Study population
      - Description and source of study population and the target study area
      - Case definition
      - Participant inclusion criteria
      - Participant exclusion criteria
      - Justification for excluding a population group
      - Estimated number of participants
      - Sampling, including sample size and statistical power
      - Enrollment

   C. Variables/interventions
      - Variables
      - Study instruments, including questionnaires, laboratory instruments and analytic tests
      - Intervention or treatment
      - Results and minimum significant differences
      - Training of all study personnel

   D. Analysis and data management
      - Data analysis plan, including statistical methodology
      - Data collection
      - Information management and analysis software
      - Data entry, editing and management, including handling of data collection forms, different versions of data, and the storage and disposal of data

- Quality control and assurance
- Bias in data collection, measurement and analysis
- Review and analysis during the process
- Study limitations

E. Management of adverse or unexpected events
   - Response to new or unexpected findings and changes in the study environment
   - Identifying, managing and reporting adverse events
   - Emergency care

F. Dissemination, notification, and reporting of results
   - Notifying participants of their individual results
   - Notifying participants of study findings
   - Anticipated products or inventions resulting from the study and their use
   - Disseminating results to public

4. References

5. Appendices
   a. Data collection forms
   b. Suggested tables and figures
   c. Other relevant documents

OVERVIEW OF THE STUDY

This section of the protocol includes the following components:

- Title
- Protocol abstract
- Investigators/collaborators/sources of funding

Title

Summarize the main idea of your research or study. Your title should be able to stand alone as an explanation of the study.

Protocol abstract

Give a concise overview or summary of the study. Describe the problem to be investigated, the study objectives, the research question or hypotheses to be tested, the population, and the methods that will be used. Write the

abstract so that whoever reads it can quickly and accurately identify the content of the project.

Tip

Although you will present the abstract as the first section of the protocol, you will write it after you complete all other sections.

Investigators/collaborators/funding sources

Include the names and degrees of all investigators and their roles on the project, and the participating institution(s). Note any possible conflict of interest for each investigator and acknowledge all funding sources.

INTRODUCTION

The introduction section of the protocol should include the following components:

A. Literature review/current state of knowledge of the research topic
B. Justification for study
C. Anticipated use of study results
D. Study design and location(s)
E. Objectives
F. Hypotheses or questions
G. General approach or focus of the study

Tip

A common error in protocols is a long and ineffective introduction.

A. Literature review / current state of knowledge of research topic

You should have performed a literature review when you prepared to write the background section of your proposal. In this section of the protocol, you

may expand on that information to include additional, relevant information about the state of knowledge of the research topic. Be sure to include in the Reference section of the protocol a bibliography of the sources used.

In this section, you can describe the health problem in more detail and include the following components:

- **What** is the health problem (e.g., breast cancer, heart disease)
- **Who** is being affected (e.g., women, students, adults)
- **How much** of the population is affected (e.g., 40% of adults)
- **When** did the problem occur or when was it identified (e.g., in 2009)
- **Where** does the problem generally occur (e.g., in the country/region/district)

B. Justification for the Study

The study justification is an important part of any proposal *and* protocol. In this section of the protocol, you may use the information you wrote in your proposal that explains the public health and scientific importance of the study and the health problem being addressed. In the context of previous research, describe the contribution of the present study. You should also consider what interventions have been tried and which ones were successful.

C. Anticipated Use of Study Results

Define the primary target audiences and discuss the expected applicability of study findings. For example, determine if the study results will be used by the Ministry of Health or other health-related groups or organizations and for what purpose. Consider all the stakeholders and what potential use they may have for the study results.

In this section, you can also include the method you will use to disseminate the study results, for example a report or a presentation.

D. Study Design and Location

Provide a brief description of the study design[2] and give the location where the study will be carried out.

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[2] *In the next main section "Procedures and Methods", you will describe the study design in more detail.*

E. Objectives

When you developed your proposal, you should have included clear, concise statements of what the study will demonstrate, test, evaluate, confirm, or compare. Include the objectives (general and specific) in the protocol.

F. Hypotheses or Questions

All protocols should contain a formal and explicit statement of the study question(s) to be investigated or the study hypothesis(es) to be tested. Use the study questions or hypotheses that you identified in your proposal and write them in your protocol.

G. General Approach or Focus of the Study

Determine whether the approach or focus of the study will be:

- **Descriptive**: information on time, place and person is collected
- **Exploratory**: hypothesis-generating
- **Confirmatory**: hypothesis-testing
- **Developmental**: focused on corrective action

Practice Exercise #2

(estimated time: 1 hour)

Instructions:

1. Complete this exercise individually or with a colleague.
2. Turn to **Appendix B** and read section **I: Introduction** of a protocol by the seventh cohort of the Masters Degree students at the FETP, University of the Valley in Guatemala: *Study of prevalence and factors associated with tobacco consumption among adolescent students from middle level schools in Antigua Guatemala, Sacatepéquez, Guatemala, 2012.*
3. Answer the questions below.
4. Ask your facilitator or mentor to review your work.

Questions:

1. Did the authors explain the public health and scientific importance of the study and the health problem? Circle the relevant sentences that support your findings.
2. Did the protocol provide adequate justification for the study? Circle the sentences in this section that support the justification.
3. Did the authors describe the contribution this study will make? Circle the relevant sentences that support your findings.
4. What is the study design and location (locality)?
5. Did the study objectives include the following criteria? Place a

Practice Exercise #2
(estimated time: 1 hour)

check mark next to all that apply:

- ☐ declarative statement
- ☐ concise
- ☐ positive terms
- ☐ easily understood

6. Did the authors provide a clear and concise research question that the study will address and/or a hypothesis that they will test? Explain your answer. Do you have another research question that you would ask if you were doing this study?

7. Did the authors explain the approach they will use? If so, what is their approach?
   If not, which of the following approaches would you use if this was your study?
   - ☐ descriptive: information on time, place and person is collected,
   - ☐ exploratory: hypothesis-generating,
   - ☐ confirmatory: hypothesis-testing, or
   - ☐ developmental: focused on corrective action.

Stop

Activity

Let your facilitator or mentor know you are ready for the debrief. You will then complete Skill Assessment #2.

PROCEDURES/METHODS

In this section, you will provide a thorough description of the study design methodology for selecting the subjects and for collecting the data. The content of this section will vary depending on the purpose of the study and study design; however, this section should specify, at a minimum, the following:

A. Study design

B. Study population

C. Variables/interventions

D. Analysis and data management

E. Management of adverse or unexpected events

F. Dissemination, notification, and report of results

A. Study design

In this section, include some or all of the following components:

- **How the study addresses the stated research questions and objectives:** Justify using the proposed study design for addressing the stated research questions and objectives. Distinguish between research procedures that are new to this area of study and those that have are well-established in addressing the research questions and objectives. Identify the specific study methodology (i.e., (Quantitative (e.g., descriptive, randomized controlled trial, cross-sectional, case-control, or cohort) or Qualitative (e.g., structured interviews or focus groups).
- **The public and stakeholders:** Define the audience for the research. Assess who the stakeholders are and describe the ways in which they can participate in the study. Explain the process by which they can express their opinions, state their needs, and contribute to the project.
- **Timeline of the study:** Outline the steps (i.e., activities) and their sequence in the entire study process. A corresponding calendar should indicate the amount of time each step will require. The steps might include:
    - Selecting the sample
    - Drafting the questionnaire
    - Training interviewers and supervisors
    - Pre-testing the questionnaire
    - Revising the questionnaire

- Printing the questionnaire
- Carrying out fieldwork/interviews
- Coding the data
- Entering the data
- Performing quality assurance on data entry
- Editing the data
- Tabulating the data
- Analyzing the data
- Writing the final report
- Printing the final report
- Presenting the research findings at conferences

Example of a timeline:

Activity	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7
Hire interviewers/staff							
Develop tools							
Train staff							
Pre-test tools							
Data collection							
Data entry, coding, cleaning, analysis							
Report writing							
Dissemination							

B. Study population

In this section, include some or all of the following components:

- **Description and source of the study population and the target study area:** Define the population from which the participants, the samples, or the subjects under surveillance were taken and to which inferences will be made. Include demographics and details relevant to the public health condition / disease of interest.
- **Case definition:** Provide criteria for the disease, condition, or health event that define whether a participant will be judged to have the condition of interest.
- **Inclusion criteria:** Describe the characteristics or conditions used to identify and recruit potential participants for the study.

- **Exclusion criteria:** Describe the characteristics that disqualify potential study subjects from participating, or other ways that they could be ineligible for inclusion in the study.
- **Justification for excluding a population group:** Provide the reasons for excluding any subgroup of the population from the study (for example, defined by race/ethnicity, gender, or age).
- **Estimated number of participants, including sample size and statistical power:** Estimate the number of participants that will be necessary to answer the research questions and to test the hypothesis based on available information from pilot studies or previous reports. Utilize statistical power calculations to determine the number of participants you will need in each group to determine a given difference. Explain conditions in which you would need to revise the sampling estimates. If the study is establishing or using data from a surveillance system, this section can include the anticipated number of reported cases for epidemic and non-epidemic periods.
- **Sampling:** Describe the sampling method (e.g. simple random, systematic, stratified, cluster, multistage or convenience sampling). Specify the sampling units (individuals, cluster, neighborhood, etc.) and the units of analysis. If you will collect group or aggregated data, explain how you will assemble the groups, or the procedures that you will follow to form appropriate groups. Make sure you select a sampling procedure that will maximize your data collection and response rate.
- **Enrollment:** Describe how you will contact potential participants, check them for compliance with inclusion criteria, and enroll them in the study. Describe the procedures for tracking the number of people who drop out of the study. Explain the procedures for assigning participants to different groups. Include a discussion of how you will deal with and document any deviation from enrollment procedures.
- **Consent Process:** Describe the procedures you will use to inform the participants about the study and to obtain consent. Include methods for assuring the reading level or speaking level is at an appropriate level for the potential participant to fully understand what he or she is consenting to. Be sure to fully describe any potential risk to the participant as well as to explain procedures to maintain privacy and confidentiality. A copy of the consent form is usually placed in the appendix of the protocol.

C. Variables/interventions

- **Variables**: Briefly list and describe the categories, topics, or fields of information you will collect and the types of information you will collect. Describe the consistency and quality of data obtained from multiple sources. Explain the process you will use to define the variables and how you will analyze them.
- **Study strategies, including questionnaires, laboratory instruments and analytic tests:** Describe the strategies you will use to obtain information, including laboratory techniques and instruments, and explain how you will use this information. Describe the attributes of these strategies as used in other studies, including the suitability, validity and reliability among the study population. Explain the sensitivity and specificity of the instruments among studies similar to the proposed study and whether there is any controversy about the methods being used in this protocol. Describe how you will deal with and document changes in study strategies.
- **Intervention or treatment:** Describe in detail the types of intervention or treatment you will test, including dose, administration schedule, etc.
- **Results and clinical or epidemiologic differences:** List the anticipated results from the exposure or intervention of interest to the study (i.e., results) and the clinical or epidemiologic differences in the result measurements that are important to detect.
- **Training of all study personnel:** Describe the type of training to provide to study personnel, such as: interviewing techniques, data collection/entry/processing methods, or informed consent.

D. Analysis and Data Management

- **Data analysis plan, including statistical methodology:** Describe sampling methods; procedures for the collection of information, test procedures and relevant statistics (i.e., variance, confidence intervals, and power based on the study data); the methods should include sufficient detail in order to be reproducible. This includes the calculation of relevant quantitative measures of tests and instruments, such as sensitivity and specificity, as well as appropriate coding/analysis of qualitative data.
- **Data collection:** Describe the data collection procedures, processes, and documentation. Also include the methods used to maximize response rates.
- **Information management and analysis software:** Provide the names and the rationale for selecting software packages and programming languages for the input, management, and analysis of the data used for the project.
- **Data entry, editing and management, including the handling of data collection forms, different versions of data, and the storage and disposal of data:** Describe the general procedures for handling collected data. In the description, include the process for data entry and editing. Describe how the study materials, including the questionnaires, statistical analysis, notebook entries, computer programs and other electronic information systems (whether used to publish or not) will be kept available to allow future access for analysis and revision while protecting privacy and confidentiality. Document the operating procedures for management of and access to different versions of the data sets. Specify to whom the data belongs and the access rights and restrictions of all primary and secondary data analysis and publications. Document the related procedures regarding confidentiality of the data, including how confidentiality will be maintained during transfer, use and storage of data and the names or positions of those responsible for the technical and administrative management. Document the final disposal of the records, data, computer archives and samples, including the location of any relevant information to be stored. Records should be stored in compliance with agency directives.
- **Quality assurance and control:** Describe the steps taken to ensure there are no unforeseen consequences that can affect the quality of the data. Such measures may include methods for entering all data exactly

as it is received; ensuring logical consistency among all parts of a record, as well as ensuring that the handling or transformation of the data (i.e. an audio tape transcribed into text) does not produce undesired changes; and the statistical verification of calculations are performed as proposed in the analysis plan. Describe the current quality control procedures for the data to ensure that the information is appropriate; is collected with the same depth, breadth and specificity; continues to be consistent within and among personnel over time; and achieves acceptable attribute levels such as validity, reliability, repeatability, sensitivity, and specificity.

- **Bias in the collection, measurement and analysis of data:** Describe the types of bias that may occur during the collection, measurement, or analysis phases of the data; and the steps which should be taken to avoid, minimize or account for the presence of these biases. Include factors in the study population or study personnel that could bias the results, as well as the steps taken to ensure that self-reported or observed data are valid. Include any randomization or blinding procedures used to eliminate or minimize bias by the investigator, other study personnel or study participants (e.g., participant selection, treatment group assignment, treatment provided or received).
- **Intermediate reviews and analyses:** Describe how the progress will be tracked and how the study will be evaluated prior to assessing the final results.
- **Study limitations:** Explain the factors which may reduce the internal or external (generalizable) validity of the study results. Discuss possible weaknesses or criticisms of the study, including alternative methods that could have been used.

E. Management of adverse or unexpected events

- **Responding to new or unexpected findings and changes in the study environment:** Describe the procedures for identifying and managing new or unexpected findings, and responding to changes in the study environment.
- **Identification, management, and reporting of adverse events:** Describe the types of adverse events that may arise and how study personnel will be trained to react. Describe the methods used to track adverse reactions and their possible implications on the study.

- **Emergency care:** Explain the steps to be taken in case an emergency develops during the study in any of the participants taking part in the investigation.

F. Dissemination, notification, and report of results

- **Participant notification regarding individual results:** Explain the process used to notify participants about their results. Include the circumstances that would drive the dissemination of urgent results and whether or not counselors will be used. Explain what procedures will be undertaken to address the participant's health condition(s) if these results are abnormal.
- **Participant notification regarding study conclusions:** Explain if participants will be offered the option to receive general study findings and how this will be done.
- **Expected products or inventions resulting from the study and their use:** List the products, including inventions, derived from the study and how they will be used.
- **Dissemination of the results to the public:** Define the channels of effective communication and the best ways to disseminate the project information and results to specific audiences.

  Examples of ways to disseminate results of the study include:

  - Progress reports
  - Final report
  - Publications
  - Seminars, workshops, and conferences
  - Discussions with policymakers and program managers

Questions to consider when discussing dissemination of study results include:

- What specific parts of the research or data will be covered?
- At what stage in the study will the results be written, and by whom?
- How much time will be required to prepare the materials?
- Who will receive these materials?

Also include a short description of how you plan to communicate your results to your *partners*.

- What audiences need to know about your findings?
- How will you accomplish this?

Practice Exercise #3

(estimated time: 50 minutes)

Instructions:

1. Complete this exercise individually or with a colleague.
2. Turn to **Appendix B** and read section **II: Procedures and Methods** and section **III. Sampling Procedure** of the Guatemala protocol.
   Note: Although this training explains that all information pertaining to study design, population, sample size, data collection, variables, data management, analysis, etc. should be included in section II, the Guatemala protocol uses two separate sections (II and III, as noted above).
3. Answer the questions below.
4. Ask a facilitator or mentor to review your work.

Questions:

1. How does the choice of study design address the research questions and objectives previously indicated?

2. In the Sampling Procedure Section / Sample Size of the protocol, the authors explain that they used a calculation sheet from WHO STEPS to calculate sample size. Is this method an adequate way to calculate sample size so that it answers the research questions and tests the hypothesis? Please explain.

3. What study instrument will be used? Does the protocol address the question of whether any controversy exists about the methods to be used? If so, what are they?

4. How effectively does the protocol describe the handling of **data entry, editing and management,** including the handling of data

Practice Exercise #3
(estimated time: 50 minutes)

collection forms, different versions of data, and the storage and disposal of data? Would you include any additional information in this section if you were conducting this NCD study?

5. How effectively does the protocol describe **quality assurance and control?** Would you include any additional information in this section if you were conducting this NCD study?

Activity

Complete skill assessment #3 in the activity workbook. Then continue reading in the participant workbook.

REFERENCES

List the bibliographic references used to create and define all aspects of the study. Important references that were not cited in the text may also be listed in the bibliography, including methodology sources.

APPENDICES

- **Data collection forms:** Include all forms and documents used to collect data or extract the data. Examples of these are questionnaires, medical records and other collection forms.
- **Suggested tables and figures:** Prove health tables and examples of data presentation and study results.

- **Other relevant documents:** Include any other complementary documentation, for example:
  - Informed consent form
  - Curriculum vitae of principal investigators
  - Information on institutional affiliation of researchers
  - Letters of endorsement for the study
  - Institutional review board and administrative approval documentation
  - Other information relating to the study

Practice Exercise #4

(estimated time: 10 minutes)

1. Complete this exercise individually or with a colleague.
2. Turn to the ANNEXES (i.e., Appendices) section of the Guatemala protocol. Note that all the appendices of the protocol are not included for this example.
3. List at least two other forms, tables, figures, and/or documents that you would include in the Annex section of this protocol.

Activity

Complete skill assessment #4 in the activity workbook.

Resources

For more information on topics found within this workbook:

Principles of Epidemiology in Public Health Practice
Third Edition
An Introduction to Applied Epidemiology and Biostatistics

http://www.cdc.gov/osels/scientific_edu/SS1978/SS1978.pdf

Sundaram, K.R., "Principles of Writing Research Protocol" *Kerala Journal of Ophthalmology*. (Vol. XXIV, 1, March 2012)
http://www.ksos.in/ksosjournal/journalsub/Journal_Article_27_471.pdf

Lipowski, Earlene E. "Developing Great Research Questions" *American Society of Health-System Pharmacists, Inc*. (Vol 65, September 2008)
http://www.ashpfoundation.org/MainMenuCategories/ResearchResourceCenter/FosteringYoungInvestigators/AJHPResearchFundamentalsSeries/Developinggreatresearchquestions.aspx

Singh, Sanjay et al. "Writing Research Protocol: Formulation of Health Research Protocol, a step by step description" *NTI Bulletin*, 2005.
http://www.scribd.com/doc/118320551/Writing-Research-Protocol-Formulation-of-health-research-protocol-a-step-by-step-description

Enarson, D. et al. "Research Methods for Promotion of Lung Health: A Guide to Protocol Development for Low Income Countries" *International Union Against Tuberculosis and Lung Disease*, 2001.
http://www.theunion.org/index.php/en/resources/technical-publications/research/item/166-research-methods-for-the-promotion-of-lung-health-a-guide-to-protocol-development-for-low-income-countries

"Developing a Protocol: A Guide for CDC Investigators"
http://www.maine.gov/dhhs/mecdc/irb/IRB%20intranet/protocolchecklist06.pdf

Appendices

Appendix A: Sample Proposal

Example – Study Proposal[3] to Assess Risk Factors for Chronic Disease – Jordan, 2004

"Assessing Risk Factors for Chronic Disease – Jordan, 2004"

MMWR, June 16, 2006. Vol 55/No. 23: 653-655 (A. Belbeisi, M Zindah, Jordan MOH; H Walke, B Jarrar, AH Mokdad, CDC)

Background:

In 2003, chronic diseases were the leading causes of mortality in Jordan; 38.2% of deaths were attributed to cardiovascular disease and 14.3% to cancer. In 2002, Jordan Ministry of Health (MOH), with assistance from CDC and the World Health Organization (WHO), established a behavioral risk factor surveillance program to monitor risk factors associated with chronic diseases (*1*).

Justification:

Although many countries are improving their health infrastructure, chronic diseases continue to be a public health problem. In addition, the high cost of chronic disease treatment puts an additional strain on countries with developing economies. More global collaboration and partnerships in chronic disease prevention and control are needed; certain FETPs (e.g., in Egypt and China) have begun working to address the problem.

Previous studies have demonstrated that changes in lifestyle can prevent diabetes and obesity in selected groups of adults at high risk.

We are interested in the change in prevalence of chronic diseases between 2002 and 2004. The 2004 survey will contain additional questions on chronic disease risk factors, including diabetes, heart disease, seatbelt use, physical activity, oral health, eyesight, women's health, and screening.

Research Question: What is the current prevalence of behavioral risk factors in Jordan?

Objectives:

- To identify behavioral risk factors in Jordan associated with chronic diseases
- To develop a national plan to prevent and control chronic diseases in Jordan

Proposed Methods:

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[3] *For the purposes of this training, the MMWR article Assessing Risk Factors for Chronic Disease – Jordan 2004 was used to develop a sample proposal.*

Study population: Persons 18 years and older living in Jordan.

Study design: This is a descriptive study. We will conduct a cross-sectional survey about behavioral risk factors in Jordan.

Operational definitions: Overweight was classified as having a BMI of 25.0 -25.9; obesity was classified as having a BMI of >=30. Cigarette smoking = ever smoked >=100 cigarettes in lifetime and currently smoke every day or some days. Vigorous activity = activity resulting in heavy sweating and large increase in breathing or heart rate for 20 minutes.

Sampling procedure: The MOH will use sampling methodology comparable to that used in 2002. The sample will be based on the sampling frame provided by the Jordan Department of Statistics, used for quarterly, multistage, cross-sectional employment surveys. The study will be conducted among a nationally representative sample of adults aged >=18 years. In each household, one adult will be selected at random and interviewed in person.

Sample size: 3,334 adults will be interviewed for the survey.

Data collection: The survey will include questions on demographics, health status, health-care access, hypertension awareness, cholesterol awareness, diabetes, asthma, heart disease, tobacco use, seatbelt use, physical activity, nutrition, weight and height, oral health, eyesight, women's health, medical services, and screening.

In-person interviews will be conducted by MOH and Jordan FETP trained staff between October and December 2004.

Analysis plan: We will do a descriptive analysis of selected behavioral risk factors by sex and age group.

Expected benefit

These results will allow us to develop and implement a national plan to prevent and control chronic diseases

Proposed budget:

Item	Cost/month of study	Number of months of study	Year 01
Study Personnel			
Coordinator	$150 (US)	12	$1,800
Data manager	$ 75	9	$ 675
Interviewer	$ 30	6	$ 180
Supplies and Equipment			
Netbook	$150		$ 150
Travel			
Transport for Interviewer	$60	6	$ 360
Lodging in field	$40	4	$ 160
Miscellaneous cost			
Training (2 day for 8 people)	$125		$ 135
Total			$3,460

References

1. CDC. Prevalence of selected risk factors for chronic disease—Jordan, 2002. MMWR 2003;52:1042–4.

2.. Yach D, Hawkes C, Gould CL, Hofman KJ. The global burden of chronic diseases: overcoming impediments to prevention and control. JAMA 2004;291:2616–22.

Appendix B: Sample Protocol

Universidad del Valle de Guatemala
Center for Health Studies
Field Epidemiology Training Program (FETP)

Centers for Disease Control and Prevention (CDC)
Regional Office for Central America and Panama (CDC/CAP)

Study of prevalence and factors associated with tobacco consumption among adolescent students from middle level schools in Antigua Guatemala, Sacatepéquez, Guatemala, 2012

Protocol

Authors:

Seventh Cohort of the
Masters Degree Students of the Field Epidemiology Training Program (FETP)
Universidad del Valle de Guatemala

I. Introduction

A. Background / current knowledge about the research topic

Tobacco consumption is the highest preventable risk factor for a great number of chronic diseases expected to continue forming part of a great disease burden worldwide. It is estimated that deaths due to tobacco consumption will double from 5 million during 2005, to about 10 million in 2020, with 70% percent of this mortality occurring in developing countries [1] [2]. These figures exceed those reported of 1.8 million deaths attributed to HIV in 2009 [3].

Of the deaths attributed to tobacco consumption, 36.3% involve different types of cancer, 29.0% cardiovascular diseases and 23.3%, respiratory diseases [4]. Of the 1,100 million smokers in the world today, 90% began smoking before they were 19 years old. In Latin America, 3 out of 4 smokers started smoking between the ages of 14 and 17 years and most of them live in urban areas [5] [6].

Studies conducted in Argentina estimate that the economic losses due to the deaths caused by tobacco consumption are about US$525 million (approximately 0.18% of the GIP) translated to US$15 per capita [7]. Within the social elements that influence tobacco use, is the heavy focus on youth and young adult populations in tobacco advertising [8]. Presently, it is estimated that annual cigarette consumption per capita is 525. In countries like Guatemala and Peru, with low cigarette consumption rates, the annual consumption per capita is of 350 cigarettes, while in the higher consumption countries such as Cuba and Venezuela consumption rates are as high as 2,000 cigarettes[4]. [5].

According to the Global Youth Tobacco Survey (GYTS), the prevalence of tobacco consumption among middle-level students aged 13 to 15 years at a global level, is 17.3%, being higher in males (20.1%) than in females (14.3%). Forty percent of the young people had been exposed to tobacco smoke in their homes during the week prior to the study. Among the young, 54.2% of all students from all regions had been exposed to tobacco smoke in public places. Young Americans have the second highest rate of consumer susceptibility to start smoking during their teenage years (30.5%), followed by the Europeans (24.8%) [9] [10].

North and South America have the highest prevalence of tobacco consumption (22.2%) worldwide; 24.0% in males and 20.4% in females [9]. Chile is the Latin American country with the highest prevalence of tobacco use among middle-level students of 13 to 15 years (36.8-39.5%); followed by the countries of the Southern Cone and the Andean Area, the

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[4] *Assuming 20 cigarettes per pack, an annual consumption of 2,000 cigarettes is 100 packs per year.*

United States, Costa Rica, México and the Caribbean. In Central America, prevalence data is available for tobacco consumption among young people in Belize (18.3%), Costa Rica (14.5%), El Salvador (19.0%), Guatemala (16.6%), Honduras (20.4%), Nicaragua (25.1%) and Panamá (8.4%) [11] [10] [12].

Since tobacco consumption constitutes a public health problem, the World Health Organization (WHO), during the Convention for Tobacco Control (CTC), called on all countries to establish national surveillance and global control programs on tobacco consumption. As a result, the WHO, the Centers for Disease Control and Prevention (CDC), and the Canadian Public Health Association (CPHA), developed guidelines for the implementation of surveillance measures, prevention and control of tobacco use. These guidelines are primarily focused on reducing demand and supply, as well as on the development and strengthening of public policies above the interests of the tobacco industry [13]. One hundred and three member states (103) have committed themselves in the implementation of these programs, including Guatemala [14].

During the period 2008-2009, Guatemala approved a law on the " creation of tobacco smoke- free environments" and this law was implemented through Agreement No. 137-2009 [15] [16]. Furthermore, Global Youth Tobacco Surveys (GYTS) have been also conducted. The two most recent surveys were applied to students of first, second and third basic levels during 2006 and 2008 [17] [18]. As a result of these surveys, it was reported that 38.0% and 32.8% of the students had smoked cigarettes at least once, being higher among boys (39.1% and 39.2%) than girls (37.0% and 26.4%). Among these, 13.3% in 2006 and 11.4% in 2008 reported being current smokers. Between 18.3% and 14.8% of the non-smokers surveyed had thought about starting to smoke during the following year. Among the students, 19.4% and 11.7% reported that they usually smoked at home; 50.5% and 51.7% bought their cigarettes at stores and 85.0% and 80.9% of those buying cigarettes from stores were never denied a sale due to their age. In both surveys, it was found that one out of ten young people had been offered free cigarettes by employees of tobacco company at some time [17] [18].

With respect to exposure to secondhand smoke, 25.8% of the respondents during the 2006 survey and 23.1% during the 2008 survey reported that they had other family members and other persons who smoked in their presence in their homes. One fourth of these young people had a parent who smoked in their homes. In addition, 46.6% (in 2006) and 40,8% (in 2008), reported being surrounded by people who smoked outside their homes. Of the young people who reported being a current smoker at the time of each survey, 71.6% and 60.1% hoped to quit such practice; 64.8% and 72.1% had attempted to quit during the previous year and two thirds of them reported having received, at one time, some kind of support to quit. Among the surveyed, 88.5% in 2006

and 84.6% in 2008, thought that smoking should be prohibited in public places; 74.2% and 69.5% respectively, thought that tobacco smoke was harmful to their health [17] [18].

With respect to exposure to media advertisements, 75.2% and 76.6% reported having seen messages against tobacco use in communication channels in the last 30 days. Just over one half of the respondents (54.0% during both 2006 and 2008 surveys), mentioned that during the previous study year they had received school presentations about the adverse effects of tobacco consumption, but only one third had had class discussions about the reasons young people their age choose to smoke. Publicity in favor of cigarette consumption is greater than the efforts of prevention and control of tobacco; 81.2% of the respondents during both surveys, reported having seen messages/ advertisements/ billboards promoting the use of cigarettes in the last 30 days; 76.8% and 79.0% had seen messages in newspapers or magazines, and 10.4% and 9.5% (2006 and 2008), owned a personal object with the logotype of a cigarette brand at the moment of the interview [17] [18].

The present study will be conducted in the municipality of Antigua, Department of Suchitepéquez, Guatemala. The Department of Suchitepéquez is geographically divided into 26 municipalities and its capital is Antigua, Guatemala. Its territorial extension comprises 0,4% of the total country and contains 2.2 % of the total population of Guatemala. It is the second most densely populated department with 667 inhabitants per km². Its population in 2011 was estimated to be 315,864 (52.0% female and 39.0 % minors under 15 years of age) [19] [20].

The population density in the municipality of Antigua, Guatemala is of 580 inhabitants per km^2. In this municipality the first cause of health consultations among adolescents from 10 to 19 years is due to infectious and parasitic diseases, followed by circulatory diseases. At the hospital level, among the first admittance cases are trauma and the leading cause of mortality is due to tumors and other external causes.

In 2011, public schools in Antigua, Guatemala enrolled 552 students of the secondary level (first, second and third basic levels). Of these, 50% were female; 56.6% aged 12 to 16 years and the rest aged 17 to 20 or more years of age; 25% of these students attended the morning educational schedule, 13% the afternoon educational schedule and 62 the evening educational schedule (data provided by MINEDUC, 2011).

B. Study justification

The characteristics of Antigua, where an environment of bars, restaurants and nightlife activities are part of its attraction to meet the demands of tourism, may promote among young people an atmosphere of alcohol and tobacco consumption. Despite the existence of the national decree to promote smoke-free environments [15] [16], it is difficult to control and in particular, the sale of cigarettes to minors and their exposure to secondhand smoke. According to previous surveys on tobacco consumption among adolescents of Guatemala City and Chimaltenango, it was found that approximately 14 of every 100 students of these cities between 13 and 15 years of age are smokers [21] [22], and 16 of every 100 students at the national level [17] [18]. At present, the level of tobacco consumption among middle level students of Antigua, Guatemala is not known; neither are the factors that may be associated with this practice. Taking into consideration the particular characteristics of Antigua, Guatemala and that it is geographically located between two of the cities where previous surveys on tobacco consumption were conducted, we may assume that the prevalence of tobacco consumption among young people is equal to or greater than that found in during the previous studies.

This research will provide updated information on the indicators that were measured during the previous studies. This will allow us to set the prevalence trend of tobacco use among students of the middle level of Antigua Guatemala and will provide strategic information for a better comprehension of the problem, providing additional guidelines for decision-making to reduce tobacco consumption in this population.

C. Anticipated uses of the results of the study

The results of this study are expected to be used by the health authorities to prepare health educational campaigns specifically designed to prevent the use of tobacco particularly aimed to students of the middle level educational system in Antigua Guatemala.

A report on the findings of the study will be presented to the Ministry of Education to be incorporated into the contents of the curriculum for middle level school programs.

Religious leaders, parents, NGOs, and other pertinent institutions will be contacted to help promote efforts to control de use of tobacco among middle level students against smoking, parents' awareness avoid smoking in their homes and prevent more young people from acquiring this harmful habit.

D. Study design and locality

Based on the above, a cross-sectional survey is being planned to allow updated knowledge on the prevalence of tobacco consumption among middle level students of the city of Antigua Guatemala and the identification of factors associated with smoking, in order to recommend measures addressed at controlling and preventing the use of tobacco by these young people.

E. Objectives

1. General objective

Estimate the prevalence of tobacco use and its associated factors among students of the middle level that includes the first, second and third basic grades, that are presently attending a private or public educational center during the morning or afternoon educational schedules in Antigua Guatemala, Sacatepéquez.

2. Specific objectives

- Estimate the life prevalence and the current prevalence of tobacco consumption.
- Determine the intention to smoke, the access to tobacco, and the exposure to passive smoking among these students.
- Identify other risk factors associate to the use of tobacco.

F. Hypothesis or research questions

Null Hypothesis (Ho): That the current prevalence of tobacco consumption among students of the middle level in Antigua Guatemala is equal or lower than the prevalence of tobacco consumption among students of the middle level at the national level.

Alternative hypothesis (Ha): That the current prevalence of tobacco consumption among students of the middle level in Antigua Guatemala is higher than the prevalence of tobacco consumption among students of the middle level at the national level.

G. Viability and feasibility of the investigation

Human and financial resources are available as well as technical assistance on the part of Universidad del Valle de Guatemala (UVG) for the execution of this study. Consultations conducted with health and educational authorities have been positive and the collection of data has been coordinated for the month of March, 2012.

This study forms part of the training activities of the Field Epidemiology Training Program for Central America, the Caribbean and Panama (CFETP). The survey to be conducted will be using the international indicators of tobacco consumption among middle level students and instruments that have been already validated during previous.

II. PROCEDURES AND METHODS

A. Study design.

A cross-sectional epidemiological survey will be conducted.

B. Study population.

Middle-level students in Antigua Guatemala from first to third basic grades enrolled in urban, public and private schools, attending the morning and afternoon educational schedules

C. Case definitions.

- Smoker: A smoker is defined as an adolescent that has smoked cigarettes in the last month (any amount); A **Daily smoker**: The student that smokes one or more cigarettes a day; an **Occasional smoker**: The student that smokes less than one cigarette per week.

- **Nonsmoker**: A student that has not consumed any cigarettes within the last month [23].

D. Inclusion criteria.

Students of the middle level, of any age, that in 2012 enrolled in the first, second or third basic education grades from a selected public or private school in Antigua Guatemala, attending the morning or the afternoon study schedule and that have the permission of one or both parents or legal representative to participate in the study as well as having agreed and signed the assent form to voluntarily participate; attending classes on the day when the survey takes place.

E. Exclusion criteria.
Students that do not belong to the first, second or third basic education grades during 2012; that do not belong to the classes selected during the sampling; that do not have the informed consent of their parents or legal representative; that have not agreed to participate and/or are absent on the day when the survey takes place.

F. Execution period.
The activities to be developed, in accordance with de Gantt diagram, is available in Annex A; the communication process that will be underway during the investigation between the different actors, is available in Annex B.

III. SAMPLING PROCEDURE

A. Sample selection
The primary sampling unit: includes the educational establishments for middle level education (first to third basic grades) in the city of Antigua Guatemala.

1) Selection of schools

Two characteristics will be identified within the educational establishments that could be better correlated with the resulting variable of this study: cigarette smoking. The selected variables include: type of establishment (public private) and type of study schedule (morning or afternoon) will be the ones taken into account as strata for selection of educational institutions.

Once these two strata have been identified, the educational establishments will be divided into levels. In other words, the establishments will be classified in accordance to their size and then a simple random selection will be conducted for each level in every stratum. For example, establishments with less than 100 students will belong to level 1; from 101 to 300 students, level 2; etc.

Three levels will suffice.
The levels must contain a similar number of students notwithstanding their differences in the number of establishments. Therefore, there must be few establishments at the level of the bigger establishments a many more establishments at the level of the smaller establishments.

In the strata defined by the variables identified in item (1), and the levels of size defined as described on item (2), the same number of establishments will be selected for the sample.

For each level, at least 2 establishments should be selected.
Advantage: More control over the selection of the establishments.

2). Selection of students

We will proceed to select, at random, one of the three grades that belong to the middle level. When arriving to an establishment, a section will be randomly selected in case there is more than one. The questionnaire will be administered to all those students having voluntarily assented to participate and whose parents have consented.

B. Sample size

The total sample of students for the survey will be of 800, including males and females. The size of the same was estimated through the calculation sheet entitled STEPS of WHO (available at http://www.who.int/chp/steps/resources) in accordance with the following parameters (Table 1):

Table 1. The parameters defined for the calculation of the sample size of students in the middle level in Antigua Guatemala, Sacatepéquez, 2012

Sampling parameter	Value	Description of parameter
Measure of the confidence level (*z*)	1.96	Describe the level of uncertainty in the prevalence (level of confidence 95%)
Error margin (*me*)	0.05	The smaller the margin of error, the bigger the size of the sample needed
Basal level of indicator (*p*)	0.14	The estimated prevalence from the risk factors of the target population
Effect of the design (*ef*)	1.5	Describes the loss of efficacy of the sampling due to the use of complex sampling design
Expected response rate (*r*)	0.70	Expected response rate.
Number of estimates (*es*)	2	The number of groups, by sex, for which the estimates were calculated.

Step 1: Initial calculations

$$n0 = \frac{z^2 * (p * (1- p))}{m^2}$$

$$= \frac{3{,}8416 \text{ x } (0.14 * (1-0.14))}{0.05 * 0.05} = 185$$

Step 2: Adjustment for the effect of the design and the number of estimates for sex

$$n1 = n0 * ef * es$$

$$= 185.0 * 1.5 * 2 = 555$$

Step 3: Adjustment for the expected rate of response

$$n = n1 / t$$

$$= 555.0 / 0.7 = 793 \approx \mathbf{800}$$ (final size of the sample)

C. Data collection

The standardized WHO Global Youth Tobacco questionnaire [10] will be adapted to collect data on tobacco consumption and risk factors. The data will be collected by FETP students simultaneously within all selected schools. The questionnaires will be self-

administered. A database will be created in EpiInfo 3.5.3 and the FETP students will be responsible for entering the data. A revision will be made of at least 10% of the questionnaires for quality control.

D. Questionnaire

A first draft of the questionnaire was created and a pilot test conducted in the field among students of the middle level. The observations made by the researchers, the students, and the results obtained during the pilot testing, provided the grounds for adjustments in the vocabulary used and the final format **(Annex C)** in order to improve the information flow and the comprehension of the questions. As well, the timing required was recorded by the FETP students for completion of the questionnaire resulting in a maximum of 35 minutes.

E. Operational variables

Table 2. Demographic variables on tobacco consumption, survey of middle level students of public and private schools in Antigua Guatemala, Sacatepéquez, 2012. ***(For the purposes of this training, only a portion of the table is represented below.)***

No.	Variable	Concept	Type	Value
1	Code assigned to the survey	Identification code for the records	Numeric	1,2,3,…etc.
2	Code of the interviewer facilitating the survey	Identification code for the interviewer	Alphanumeric	JA, BH, MM, 1,2,3,…etc.
3	Name of the educational center	Identification of the educational center where the respondent attends	Categorical	1.La Salle 2.El INEV 3.INSOL 4.Santiago
4	Type of educational center	Administrative sector to which it belongs	Categorical	1. Private 2. Public
5	Educational schedule	Schedule of assistance to educational center	Categorical	1.AM 2.PM
6	Date of Interview	Date interview was conducted	Time	Calendar date (Format day, month, year)
7	Parents informed consent	Extension of consent of parents interviewed for responding this questionnaire	Categorical	1, yes 0. no
8	Student informed assent	Acceptance of student to participate in the study	Categorical	1, yes 0. no

No.	Variable	Concept	Type	Value
9	Eligibility	Enrollment of interviewed for study participation	Categorical	1, yes 0. no
10	Age in years	Time as of date of birth	Integer	0,1,2,3…etc.

F. Enrollment

Prior to the coordination with educational authorities of Antigua, Guatemala, we will proceed to explain to the parents and students the objectives, methodology to be followed and the confidentiality of the study. The days when the questionnaire is applied, the participating students will be asked to remain in their classrooms while the non-participants that were not enrolled due to lack of consent from their parents or tutors or because they expressed unwillingness to participate, will be sent to a conference room or another room previously designated for this purpose through the coordination with respective authorities.

G. Consent process

An informed consent provided by one of the parents or the legal representative of the potential participant will be requested, as well as the informed assent from the participating student **(Annex D)**. The study protocol will be submitted to the Ethics Committee of the Universidad del Valle de Guatemala for approval and to ensure ethical treatment of the subjects under study. The informed consent and assent will contain the title of the study, introductory explanations about the investigation, its objectives, approximate number of participants and duration. The name of the sponsors will also be mentioned and the procedures to be used will be described as well as the participants' expectations, risks, benefits, rights and the confidentiality policy of the documentation collected. Finally, the signed informed consent forms from the parents/legal representative allowing their children participation along with the assent forms, will also be signed and dated by the interviewer.

Data management and analysis

1). Data analysis plan and statistical methodology

The database will contain two sections, each with different variables distributed as follows: section I (demographic data) 6 variables; section II (tobacco consumption) 38 variables. These variables will be analyzed and weighed in accordance to their indicators (the will be weights calculated at the moment of the selection of the sample) for non-response and different selection probabilities by school, grade, class, and sex.

The weighing of the variables will be calculated according to the following formula:

$W = W1 * W2 * F1 * F2 * F3$

Where:

W1 = the inverse of probability of school selection
W2 = the inverse of probability of selecting the classroom within the school.
F1= adjustment factor for the non-response level of a school, calculated by category of school size (small, medium, large).
F2= adjustment factor for level of non-response calculated at the classroom for each school.
F3= adjustment factor of non-response at student level calculated at the classroom for each school.

The re-coding of categories will be conducted as well as the creation of a dictionary of variables with their operation definitions. Each variable will be assigned the form in which the information will be collected during the survey. Table 3, below, details the statistical analysis that will be conducted for each variable.

Table 3. Statistical analysis of sociodemographic variables about tobacco use among adolescents, studying at the middle level in Antigua Guatemala, Sacatepéquez.

Analysis	**Variables**
Tobacco consumption	
Simple proportions stratified by sex, smokers, and non-smokers.	Sociodemographic variables: age, grade, municipality of residence, civil status, cohabitation, ethnic group. Variables about cigarette smoking: smoking at home, friends who smoke, intention to smoke, perception about smoking (more friends, attractiveness, harmful to health, prohibition) exposure to secondhand tobacco smoke (in public places, at home), days in which one smokes, access to cigarettes (given, bought), reasons for smoking, consumption other types of tobacco, cigarette dependence, intention to quit the habit (at present, in the last 12 months), received support or counseling to quit smoking, relationship between smoking and drinking alcohol, preventive education.
Median and inter-quartile ranges	Age, monthly income, age of onset of smoking habit, number of days of cigarette smoking in the last 30 days, number of cigarettes smoked daily.
Ratio	Male: female, smokers: non-smokers, dependency: non-dependent
Chi Square Test	To compare statistically significant differences between proportions
Wilcoxon Test for ranges	To compare statistically significant differences between medians
ANOVA (continuous variable by levels of one categorical continuous variable)	To calculate the median rate of the first cigarette, grade (people smoking at home), by age and income for tobacco use.
T-Test (Evaluate the media of a continuous variable)	To calculate the medians of continuous variables; age of onset, # of cigarettes in the last 30 days, start of consumption
Pearson's correlation (relation between two continuous variables)	Correlation between age of onset versus number of cigarettes smoked in the last 30 days Publicity vs. Tobacco use

The prepared analysis plan will be detailed and the output tables **(Annex E**) with non-adjusted data and weighed for each type of analysis and variable.

2). Information management and software for data analysis

Questionnaires will be grouped by grades and sections to facilitate data entry. The questionnaire information will be entered into a database created with free EpiInfo software version 2001 for Windows. This program will be used to calculate simple averages and frequencies taken into account within the sampling design, knowing the stratum of the data, the sample of primary units and the final weight of the sample, as well as estimating the weighed prevalence and standard errors (SE) of the estimates, the confidence intervals (CI) of 95% and the statistical analysis to determine if significant statistical differences exist ($p<0.05$).

3). Data entry, editing and management

A double entry of 10% of the data will be done to ensure the quality of digitalization. The 800 completed questionnaires will be entered by FETP students. Once this process is completed, the data base from the different technicians entering the information will be joined into one single database. This virgin database will be copied for security purposes. Once the database has been cleaned, a second copy will be made to ensure its security. The principal investigators will be custodians of safety of the databases and their copies.

4). Assuring quality control

Inconsistencies found due to double entries of data will be corrected consulting the corresponding questionnaires until a clean database is obtained. The validity of the data will be reviewed according to the logical sequence of the questions. For this purpose, simple frequencies will be calculated for all variables, allowing the detection of inconsistencies and incomplete information. Any inconsistencies found will be discussed with the principal investigators to determine the actions to be taken and the modifications will be made by one single data manager. This will complete the process of data cleaning.

5). Potential biases in the collection, measuring and analysis

The random stratified sampling used is efficient enough to avoid biases but requires de use of weights for analysis or weighing factors to obtain estimates. The variation in the weighing factors should reflect the variation in the probability of selection of grade between the different educational centers.

6). Limitations of the study

Because the survey is limited to students of the middle level in Antigua Guatemala, it will not be representative of all the young people of Municipality of Sacatepéquez. Although the majority of young people attend schools, it only includes young people attending the day educational schedules selected for the survey and questionnaire.

The national and political environment has been taken into consideration with respect to the continued labor unrest and the protests from the teachers. The possibility of suspensions of classes due to these activities may affect the collection of data at certain moments.

Another limiting factor is the sub-notification on the part of the students at the moment of completing the survey, particularly for those who consume the greatest amounts of tobacco due to their lack of confidence on the possible uses that investigating team might give to such personal information.

7). Management of adverse or unexpected events

Five major risks were identified for the conduction of this study defined as critical points and response actions **(Annex F).** This identification will allow a rapid response and the successful completion of the study.

8). Dissemination, notification and report of results

No individual notification of the results will be done since the survey will be anonymous, however, the final results will be notified. The most important conclusions and findings will be made known through a report addressed to the directors of the educational centers, health personnel and student representatives. As well, at least one oral presentation of the main results will be made for both the educational and the health authorities.

9). Expected products and use of study results

The results will be used to make recommendations that will allow the development of strategic prevention plans and interventions for students of the medium educational level pertaining to this age group. Such recommendations will be useful to the health institutions that work in coordination with the educational sectors, churches and parents'

associations, representatives of communications media and representatives of legislative committees.

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Vi. Annexes ***(For this training, all of the appendices have not been included.)***

Questionnaire for the study on prevalence and associated factors of tobacco consumption among middle level students in Antigua Guatemala, Sacatepéquez, Guatemala, 2012

Universidad del Valle de Guatemala
Center for Health Studies
Field Epidemiology Training Program
UVG Collaboration/U.S. Centers for Disease Control and Prevention

Prevalence and associated factors of tobacco consumption among adolescent students of the middle level in schools of Antigua Guatemala, Sacatepéquez, Guatemala
2012

CHECKLIST FOR INTERVIEW
To be completed by interviewer

H001 Code assigned to the survey: |___|___|___|___|___|

H002 Code assigned to the interviewer: **|**___**|**___**|**___**|**___**|**___**|**

H003 Name of the educational center:

1. La Salle ___|___|
2. El INEV ___|___|
3. INSOL ___|___|
4. Santiago ___|___|

H004 The educational center is:

1. Private ___|___|
2. Public ___|___|

H005 Educational schedule:

1. AM___|___|
2. PM___|___|

H006 Date of interview: _____/_____/_____ dd/mm/yyyy

H007 Parents' informed consent No-0 Yes-1

H008 Students' informed assent No-0 Yes-1

H009 Is the participant eligible for the study? No-0 Yes-1

INTRODUCTION:

Good morning/good afternoon, my name is_____, I work at the Field Epidemiology Training Program of the Universidad del Valle de Guatemala. We are conducting a study related to the use of tobacco among adolescents from educational centers of the city of Antigua Guatemala. This study will help us to better unsterdand the factors promoting this habit among students and will provide recommendations for additional health programs. Your answers will be treated as confidential information and will be used only for the purposes of this study; therefore, your total honesty in your replies will be extremely valuable to our purposes. This survey contains 44 questions and takes around 30 minutes to complete. We appreciate your time and responses. Do you agree to participate?

INSTRUCTIONS:

Please read very carefuly each question before you answer it.

Select the answer that best describes what you believe or feel is the right one.

Select only one answer for each question.

When selecting your answer, please draw a circle around the number located at the right side of the answer.

If you want to change your answer, you can erase the circle making sure not to leave marks.

Please remember that each question must have only one answer.

Example:

P102	What is your sex ?	Male O Female 2

REMEMBER THAT YOUR ANSWERS WILL BE CONSIDERED CONFIDENTIAL

THE FOLLOWING 6 QUESTIONS HAVE TO DO WITH GENERAL INFORMATION ABOUT YOU

P101	How old are you?	Age in years |___|___|
P102	What is your sex?	Male 1 Female 2
P103	In what department/municipality do you live?	Guatemala 1 Chimaltenango 2 Escuintla 3 Sacatepéquez 4 Other 88 I do not want to anwer 99
P104	At present, what is your civil status?	Single 1 Married/ united 2 Other 88 I do not want to anwer 99
P105	In a month, how much money do you have available for spending?	I do not have any money to spend 1 Amount in quetzales |___|___|___|___|___| I do not want to anwer 99
P106	To what ethnic group do you belong?	Garífuna 1 Mayan 2 Xinca 3 Mestizo or Ladino 4 Other: Specify_____ 88 I do not want to anwer 99

(For this training,not all of the questions have been included.)