

# American University of Armenia Department of Public Health

Cross-sectional Survey on Hypertension Prevalence, Frequency of Risk Factors and Compliance Practices in Armenia.

(Research Grant Proposal)

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#### **Executive summary**

Hypertension is one of the major public health problems in the world. It is one of the major risk factors for cardiovascular mortality. Because of hypertension's central role in coronary heart disease and stroke, one of the biggest challenges facing public health authorities and medical practitioners is the control of hypertension worldwide.

According to data of Armenian Republican Health Information Analytic Center (RHIAC) in 1999 there were 1166 people per 100,000 population who suffer from hypertension. The incidence rate of hypertension has grown constantly since 1985.

To assess the hypertension prevalence in Armenia and to obtain precise information about compliance with hypertension treatment and the frequency of various hypertension risk factors, a survey of the Armenian population is recommended. The design of the study is cross-sectional observational survey. The main tool to conduct this quantitative study is a personal interview with the study population using a questionnaire and measuring blood pressure.

Respondents will be selected using multistage cluster sampling (probability proportional to size).

One thousand seventy five men and women aged 19 and above from Yerevan, Armavir and Aragatsotn will participate in the survey.

Statistical analysis will be done using STATA statistical package. The prevalence of diagnosed hypertensives, of those with elevated blood pressure and the prevalence of hypertensives that comply with treatment will be calculated. Also 2x2 tables and logistic regression model will be used to compare risk factors to hypertension, and to evaluate interaction between variables.

The overall duration of the study is six months. The overall estimated budget is approximately nineteen thousand (\$19,104).

#### **Background information**

Hypertension is one of the major public health problems in the world. According to the World Health Organization (WHO), hypertension is "a disorder characterized by high blood pressure which includes systolic blood pressure higher than 140mm/Hg and diastolic blood pressure over 90mm/Hg" [1]. To diagnose hypertension, these numbers should be validated by three measurements of blood pressure over a period of three months [1,2]. On average, people with uncontrolled high blood pressure are: seven times more likely to have a stroke, six times more likely to develop congestive heart failure, and three times more likely to have a heart attack [3].

Based on data provided by the Centers for Disease Control and Prevention, and the National Center for Health Statistics, as many as 50 million Americans have high blood pressure (HBP). Among people aged 65 years and older, about 40 percent of whites and 50 percent of blacks have HBP. Blood pressure increases with age, but the onset of hypertension most often occurs during the third, fourth, and fifth decades of life [4]. HBP was listed on death certificates as the primary cause of death of 42,565 Americans in 1997. HBP was listed as a primary or contributing cause of death in about 210,000 of the more than 2,000,000 U.S. deaths that year [5].

The costs of hypertension are alarming. It was estimated to be \$30 billion in the United States (US) in 1997 alone. Drug treatment covers nearly a third or \$7 billion of the \$22 billion in direct costs, which also includes the cost for hospitalizations and doctor visits [6].

The authors of the article "State of the art and perspectives in hypertension"[7], reported that as a whole 1/2 of hypertensives remain undiagnosed; 1/4 are not treated despite awareness of hypertension; 1/8 know they have hypertension but are not satisfactory treated;

and only the last 1/8 of patients are diagnosed and treated with sufficient blood pressure control. This fact was confirmed by other studies [8,9].

The WHO provides information that cardiovascular disease is rapidly becoming an important factor in developing countries and in the newly independent states of the former Soviet Union. It is projected that death and disability from coronary heart disease and cerebrovascular disease are now increasing so quickly in these parts of the world that they will rank as first and fourth, respectively, among the causes of the global burden of disease by 2020. Because of hypertension's central role in coronary heart disease and stroke, one of the biggest challenges facing public health authorities and medical practitioners is the control of hypertension [8].

A number of epidemiological studies have identified risk factors that increase the likelihood of developing hypertension [1]. However, the association with these risk factors does not necessarily imply an etiologic role [1]. Those risk factors are family history of hypertension and cardiovascular diseases, family and personal history of hyperlipidemia, family and personal history of diabetes mellitus, high salt (sodium chloride) intake, obesity, smoking, excessive alcohol intake, and lack of physical activity. A family history of hypertension, namely having hypertensives among first-order adult relatives (parents and siblings) is one of the strongest risk factors for developing hypertension [1]. Family and personal history of hiperlipidemia and obesity are also strongly associated with developing hypertension. The proportion of hypertension attributable to obesity has been estimated to be 30-65 percent in Western populations. Multivariate regression analysis of hypertension data indicates a rise of 2-3 mm Hg systolic blood pressure and 1-3 mm Hg diastolic blood pressure for each 10 kg increase in weight [1,10]. A number of experimental and observational studies show that the intake of

sodium chloride, in excess of physiological requirements, is associated with high blood pressure. The results of the interpopulation study "Intersalt" revealed that "a 100 mmol/day lower intake of sodium chloride over a lifetime would result in a 9 mm Hg smaller rise in systolic pressure from 25 to 55 years of age" [11].

Alcohol consumption has also been related to high blood pressure. "Two or more drinks consumed per day increases systolic blood pressure by 1.0 mm Hg and diastolic blood pressure by 0.5 mm Hg per alcoholic drink" [12]. Individuals with sedentary life style (no activity or any physical activity for less than 20 minutes or less than three times per week) have a 20-50 percent increased risk of developing hypertension when compared with more active people [13]. The National Institutes of Health in the US recommend adults to have at least 30 minutes of moderate activity most days of the week to promote cardiovascular fitness.

Moderate activities include walking, gardening, yard working, moderate-to-heavy house working, dancing, or home exercising [14]. The association between the aforementioned risk factors and hypertension is supported by many other studies conducted in the world [15, 16, 17, 18, 19, 20, and 21].

One of the largest projects in the US related to hypertension was the National Health and Nutrition Examination Surveys (NHANES I, II, III, IV). These studies were conducted by the National Center for Heath Statistics, and the Centers for Disease Control and Prevention, during four separate periods of time: 1960-1962, 1971-1974, 1976-1980, and 1988-1991. Due to significant improvement in awareness, treatment and control of hypertension, the prevalence of the disease has declined since 1971. Age-adjusted prevalence rates have declined from 36.3% to 20.4% (I-III). Age-adjusted mean systolic pressure declined from 134 mm Hg at NHANES I to 119 mm Hg at NHANES III. During the interval between the

NHANES II and III, the threshold for defining hypertension changed from 160/95 to 140/90 mm Hg. Despite this favorable trend, many people with hypertension are unaware of their condition, and many more are untreated or inadequately treated [22, 23]. Current management of the disease is characterized by underdiagnosis, misdiagnosis, undertreatment, overtreatment and misuse of medications. As a result, 75 percent of the estimated hypertensives increase their risk for vascular complications [9].

In order to avoid possible complications, hypertension should be under strict control and monitoring. Even after diagnosis and adequate control and treatment, the risk for coronary heart disease and renal disease continues to be elevated. Thus, early treatment of elevated blood pressure may reduce the incidence of clinical manifestations of hypertension and decrease long-term consequences of the disease [24].

Despite decades of attention to fight noncompliance with treatment of hypertension, the problem remains a significant factor in the control of blood pressure [25, 26]. There are several reasons for not complying with treatment and low utilization of health services. In addition to drug side effects and costs, the most common reason that the treatment fails is the poor patient-physician relationship. Recent studies suggest that improving the effectiveness of provider-patient contacts would improve the treatment of hypertension [27].

According to 1999 data from the Armenian Republican Health Information Analytic Center (RHIAC), there were 1,164 people per 100,000 population who suffer from hypertension. The incidence rates of hypertension and patients mortality have consistently grown since 1985. Mortality from HBP in 1985 was 52.8 per 100,000 population, while in 1999 it was 75.4 per 100,000 population [28]. Stroke is one of the severe complications of

hypertension. According to RHIAC, in 1998 mortality due to stroke was 85.17 per 100,000 [28].

The problem with these figures is they were calculated using unreliable population data. The official population of the country is still reported to be 3.5 million people. However, there has been large migration of the population of Armenia during the last years and according to non-official sources, it may be less than 2 million people. Moreover, the data provided by RHIAC are based on cases registered upon referral for specialized medical care. Taking into account poor socioeconomic conditions of a large proportion of the population, and the negative attitude towards primary health care, it can be assumed that there are many people who do not access appropriate care. Also, due to lack of knowledge of the importance of hypertension, Armenians may not seek care for the problem. The estimation of the real prevalence of hypertension among Armenians is hindered also because during the first stages of hypertension, there are no symptoms. An individual can have HBP and still feel well. All these reasons indicate Armenians not know they have HBP and among those that know, many are self-treating the problem. Self treatment not only worsen the situation with hypertension, but could also increase the risk of developing serious complications such as stroke, heart attack, kidney diseases, and other serious complications. Taking into account already mentioned data, it can be assumed that the actual figures on hypertension prevalence in Armenia are likely to be appreciably higher. In effect, the prevalence is not really known. No large national studies have been undertaken.

# **Pilot Study**

To obtain preliminary data on the hypertension situation in Armenia and to test the study instrument (hypertension questionnaire), a small study was conducted among the adult population from several districts in Yerevan. The study included 50 people aged 19 years and older. The sampling methodology for the pilot study was convenience sampling, and one individual from every third apartment in a specific location was interviewed. The interview lasted approximately 10 minutes. An additional 10 minutes was needed to take the blood pressure measurement. The blood pressure reading was taken twice: before and after conducting the interview. As a result of the pilot, the questionnaire was minimally changed. Changes consisted of changing the sequence of questions and reorganizing some of the skipping patterns used in the original instrument.

The following groups of people were identified during the pilot study:

- 1) People with normal blood pressure (N=32): 64% (95% CI: 50.7% 77.3%)
- 2) People with diagnosed hypertension (N= 13): 26% (95% CI: 14%-38%)
- 3) People not previously diagnosed with hypertension, but with high blood pressure readings (N=5):10% (95% CI: 1.7% 18%)

Among those with diagnosed hypertension 61.5 percent (N=8) were complying with the prescribed treatment. Five or 38.5 percent of the hypertensives were not complying with treatment (95% CI: 12% - 65%). However, even among the eight people who reported that they were following their doctor's prescriptions, none had blood pressure less than 140/90 mm Hg.

Although these data are not representative and could not be generalizable to the whole population, it provided further justification to conduct a large-scale study.

# Specific Aims and Objectives of the Study

To date, no population-based studies have been conducted in Armenia regarding hypertension. To assess the situation of hypertension prevalence in Armenia, and to obtain precise information about compliance with hypertension treatment, a study is needed. The aims and objectives of the study proposed in this grant proposal are the following:

- To estimate the prevalence of hypertension in the adult population of Armenia
- To estimate the frequency of the hypertension risk factors
- To estimate compliance with treatment practices among diagnosed hypertensives and to find out the reasons for noncompliance.

#### Methods

The design of the study is a cross-sectional observational survey. This quantitative study will use a personal interview and measure blood pressures as an inseparable unit. This unit is the main task of interviewers. Interviewers, who are selected from senior students or interns of the Medical University, will be prepared during special two-day-training.

The hypertension questionnaire, elaborated and designed for use in household interviews, is based on the specific objectives of the study. It includes sociodemographic questions, questions regarding hypertension risk factors, and compliance with treatment practices among those diagnosed with hypertension. The complete hypertension questionnaire is presented in Appendix D

Ideally, to confirm high blood pressure, several measurements of blood pressure are necessary. According to the Ministry of Health of Armenia, to diagnose hypertension, the elevated blood pressure should be validated by at least three measurements over a period of three months. Moreover, to confirm a diagnosis of hypertension, it is necessary to conduct a thorough physical and laboratory examination. However, considering the financial issues and time limitations, it is only planned to identify individuals with elevated blood pressure.

Participants with abnormal readings will be referred to their nearest policlinic for follow-up. In order to decrease the number of false-positives, the blood pressure will be measured twice over a period of 10 minutes: before and after the completion of interview. Both values should be recorded and the mean value used in the analysis.

It is important that measurement of blood pressure will be as precise as possible. The recommended procedure is a mercury sphygmomanometer using auscultatory method. The examination should take place in a quiet room. The blood pressure should be measured after

resting with no change in position for at least 5 minutes. The participant will be in a sitting position and the right arm will be used. The sleeve of shirts and blouses will be rolled up so that the upper right arm is bare for the placement of the blood pressure cuff. A cuff for adults must have a bladder 13-15 cm wide and 30-35 cm long to surround at least two thirds of the upper arm.

## Target population.

As it is impossible to interview all adults living in Armenia who meet the criteria, a sample of the target population must be chosen. Therefore, an efficient sampling technique must be chosen to select a sample, which will be representative of the whole adult population of Armenia.

To answer the research question, the survey will be conducted in all districts of Yerevan and in two selected marzes of Armenia. The two marzes are Armavir (low mountainous) and Aragatsotn (high mountainous). It is assumed that marzes in Armenia are similar to each other by the following characteristics: socioeconomic status of population, rate of migration, and the level and quality of medical care. Thus, results obtained from the study can be generalized to all marzes.

# Eligibility criteria for the selection of participants are the following:

- People aged 19 years and above
- Males and females
- People who agree to participate in the survey and sign the consent form.

People less than 19 years old and pregnant women will be excluded from the study. Also, people unwilling or unable to participate will be excluded from the study population.

#### Sample size and sampling methodology

There is no available information on the proportion of hypertension in the adult population of Armenia, but based on literature data the assumption is made that it is about 30 percent. In calculating the sample, the following methodology is used:

For 95% confidence interval type I error will be

$$\alpha = 0.05$$

Thus, 
$$Z_{\alpha} = 1.96$$
 (2-sided)

The following formula will be used:

$$\mathbf{n} = \mathbf{Z}^2 \mathbf{x} \, \mathbf{p} \, \mathbf{x} \, \mathbf{q} / \mathbf{d}^2,$$

where d is a tolerable error. We assume that d is 3%, so our sample size will be:

$$n = 1.96^2 \times 0.3 \times 0.7 / 0.03^2$$

$$n = 896$$

This formula is acceptable for simple random sampling or other unbiased sampling strategies.

However, in case of cluster sampling, we will have homogeneity within a cluster (individuals within a cluster are more likely to be similar than individuals among different clusters), which will produce design effect and increase sampling error. To offset this bias due to homogeneity within

clusters, it is suggested to increase the sample size by 20 percent. Thus, our sample size will be the following:

$$n = 896 + 896 \times 0.2 = 1,075$$

For respondent selection, multistage cluster sampling (probability proportional to size) will be used. Those 1,075 people are divided between Yerevan and selected marzes based upon population ratios. The accurate population size in Armenia is not available due to the absence of an updated census; however, according to the last census data, the population distributions in Yerevan and the two marzes are the following [29]:

Yerevan: 1, 247,200 people

Armavir: 322, 900 people

Aragatsotn: 167,800 people

Thus, the proportion of population in these sites can be computed as 7: 2: 1. The sample size of the study should be divided among these sites using the same proportion. Hence the final number of study population will be 753 people in Yerevan; 215 people in Armavir; and 108 people in Aragatsotn.

Although population lists, such as administrative rosters are not unavailable, the registries of patients in adult policlinics will be used for the selection of the first elements of clusters. However, due to many shortcomings in the registries of patients in adult polyclinics, it will be more appropriate to choose as the sampling frame children polyclinics. Registries in children policlinics are more accurate and contain relatively available sources of information. Assumptions for choosing children policlinics are that age distribution of population is approximately the same in each area served the by policlinics. These data will be more representative for the general population. Thus, the following sampling design will be used:

- Identification of children policlinics in Yerevan and the two marzes
- Enumeration of number of children served by each district of the policlinics.
- Identification of number of clusters that have to be taken from each district.

Taking into consideration the sample size required for this study (1,075) and the common number of the surveys per each cluster (~7), the total number of clusters is calculated as:

#### 1,075 / 7 = 154 clusters

Taking into consideration the probability proportional to size cluster sampling, the total number of clusters in Yerevan, Armavir and Aragatsotn will be 108, 31, and 15 respectively.

- Identification of sampling intervals for selecting the appropriate number of clusters from each district using simple random sampling method. This will be done by dividing the total number of children served by the policlinics in the sites to the number of clusters.
- Random selection of addresses, which will serve as starting points of households in each cluster. This step also will be done using simple random sampling of the medical records of each policlinic.
- Completion of the determined number of interviews in each cluster.

The complete interview guide and information on sampling instructions for interviewers is provided in training materials (Appendix A)

#### **Study Limitations**

The validity and reliability of the study could be affected by several limitations.

- The most important study limitation is that blood pressure measures were taken only on one occasion, which limits both the definitions of hypertension and increases the number of false positive persons. Thus, the survey will find out only those who have elevated at the moment of measurement blood pressure, except in those participants, who are already diagnosed with hypertension.
- Interviewer bias could happen because of different skills of the interviewers regardless of training.
- Some questions in hypertension questionnaire may introduce a recall bias, and there is no
  way to prove responses given by the participants. Examples are questions regarding diet,
  smoking, alcohol consumption, and physical activity.
- The assumption that the population in Yerevan and the two marzes is homogeneous needs
  to be validated. There could be BP differences between rural and city dwellers, between
  those at lower and higher altitudes, etc.

#### **Study Strengths**

The sampling design (probability proportional to size) and procedure (random selection of households), and the sample size, which was adjusted considering the design effect, contribute to the generalizability of the findings. Other strengths include the possibility of identifying people with undiagnosed hypertension and referring them for early treatment. Moreover, the results of the study can be helpful for the future development of a comprehensive strategy to prevent and control hypertension and decrease the burden of cardiovascular diseases in Armenia.

#### **Data analysis**

The statistical analysis of the data will be done using STATA statistical package. There will be three different groups of people after the completion of the survey. The first group includes those with diagnosed hypertension. The second group is those who do not have diagnosed hypertension, but whose blood pressure was elevated during the test. And the third group involves people who do not have elevated blood pressure or the diagnosis of hypertension. In these groups the following statistical analysis will be done:

- Overall prevalence of the hypertension in the population (p), with 95% confidence interval
- Prevalence of diagnosed hypertension (p), with 95% confidence interval (CI)
- Prevalence of elevated blood pressure (p) without diagnosed hypertension, with 95% confidence interval (CI)
- Among those with diagnosed hypertension, prevalence of compliance with treatment (p),
   with 95% confidence interval (CI)
- Prevalence of hypertension risk factors in the population (p) with 95% confidence interval
   (CI)

Having hypertension and elevated blood pressure coded as a binary variable propose using 2x2 tables to compare all risk factors included in questionnaire to hypertension (smoking and hypertension, alcohol drinking and hypertension, low level of physical activity and hypertension and so forth). It is also possible for all these risk factors to do Z-tests comparing the difference of two proportions. Another possibility is to do logistic regression. The dependent variable (outcome) will be a binary hypertension variable, and the independent variables (predictors) will be risk factors coded as 0 or 1.

#### **Human subject and ethical considerations**

The proposal was submitted to the Departmental Review Board/Committee on Human Research of the American University of Armenia and obtained approval. The proposed study possesses minimal risk for participants. Although the topic of the proposed survey is not very sensitive nor does not lead to financial or job loss, there are some inconveniences connected to the interview. Asking to remove other members of the family in order to conduct face-to-face interviews in a separate room could create some minor disturbances. The measurement of blood pressure could also create some minor annoyances and unwillingness to participate in the study. Additional discomfort may be created for those who learn for the first time that they might have HPB. To address these ethical issues, written consent form will be provided to participants prior to the interview. It will include a description of the nature of the research, the risks and benefits of being included in the research, and that the participation is voluntary. A unique identifier on the cover page of the questionnaire will ensure the confidentiality of the participant, and the information provided. Only the study investigators will have access to the names and identification numbers of the participants.

#### **Time Frame for the Project**

Before beginning the study, the personnel will be hired. Overall, there are 1,075 interviews to be conducted. The time needed to conduct an interview is about 10 minutes. Additional 5-10 minutes will require blood pressure measurement. Thus, the whole procedure requires no more than 15-20 minutes. An interviewer will be able to conduct about 10 interviews per day. As 10 interviewers will be hired for the project, and they complete about 100 interviews per day, data collection will be completed in a period of about 15 days. Data entry and analysis will begin after completion of all interviews and will last two months. The overall duration of the study is six months. The complete time frame is attached in Appendix B.

#### Budget

The overall estimated budget is approximately nineteen thousand (\$19,104). Direct costs comprise \$18,194. The budget is comprised of salaries, which together with taxes are about 66 percent of total expenditures; cost of capital assets, which is about 15 percent (\$2,800) of total expenditures; and operating costs, which are about 13 percent (\$2,550) of total expenditures. The remaining 1.6 percent (\$306) covers the cost of interviewer training and the cost of copying. Five percent of the direct costs are provided for unexpected needs. The estimated expenditures for implementing the proposed study are presented in the budget [Appendix C].

#### **Personnel Responsibilities**

- Program Coordinator is responsible for the whole study, for administration and study
  management. He/she will also be responsible for data analysis and preparation and
  submission of the final report.
- Project Assistant is in charge of training the interviewers, administration and monitoring of interviewer's activities, for data coding, editing and entry into computerized software, and data analysis.
- Data entry/analyst will do double data entry.
- Accountant is responsible for accounts preparation, bookkeeping, and preparation of financial statements and analysis.
- Interviewers will complete questionnaires and measure blood pressures. The interviewers will be senior students, or interns of Medical University at the respondents' home.

It is possible that during the procedure of blood pressure measurements previously undiagnosed participant will be discovered to have high blood pressure. In that case interviewers will refer the respondent to a physician for appropriate treatment. In the case of dangerously high blood pressure, an emergency call will be made to avoid possible complications of high blood pressure. Such a call will be initiated only after obtaining permission from the respondent.

#### **Project Feasibility**

The proposed project is feasible.

<u>Technical considerations.</u> The survey will be conducted by the trained team, including public health specialists, trained interviewers, statisticians and analysts, who have the experience conducting such studies.

<u>Logistical considerations.</u> Overall, the implementation of the project, data analysis and evaluation will require 6 months.

Financial considerations. The proposed project is not very expensive. However, its accomplishment depends on the health policy makers of the Ministry of Health and a donor NGO's financial support. Considering the importance of the problem of hypertension, it is anticipated that there are organizations which will be interested in the conduction of the survey. Administrative considerations. Having a public health specialist as a project manager will support and simplify the conduction of the project. The head of the project should have both good managerial and administrative skills and work experience.

<u>Political considerations.</u> Considering the importance of the problem and the hypertension burden of mortality and morbidity from cardiovascular diseases in Armenia, health policy makers of the Ministry of Heath should be interested in and contribute to the project.

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#### **Training materials**

#### 1. Project overview

The Public Health Department of the American University of Armenia is conducting the project on hypertension. This project designed in the framework of the quantitative research methods. The study will be conducted by graduate student of Master of Public Health Program at the American University of Armenia and specially trained interviewers.

The research question for the study is the following: what is the prevalence of hypertension, the frequency of various hypertension risk factors in general adult population of Armenia, and the compliance practices among already diagnosed hypertensives?

The study objectives are as follows:

- To estimate the prevalence of hypertension in the adult population of Armenia
- To estimate the frequency of the hypertension risk factors
- To estimate the compliance to treatment practices among diagnosed hypertensives and to find out the reasons for noncompliance.

#### 2. Review of the entire process

The design of the study is a cross-sectional observational survey with estimated 1,075 participants, who should from general adult population aged 19 years old and above. The data collection activities are expected to begin in May 2002 and be accomplished within 15 days. It is expected that the survey conduction will be done by 10 specially trained interviewers (senior students and interns of the Medical University). Each interview will last 10 minutes. An additional 10 minutes will be needed for blood pressure measurement. It is projected that each interviewer will complete 15 clusters. The survey will be conducted in Yerevan and the two marzes of Armenia (Armavir and Aragatsotn). Transportation will be provided by the program manager. Each interviewer will be provided with the necessary supplies: questionnaire forms, consent forms, survey administration guides, and so forth.

#### 3. Sampling instructions

**Starting.** For each cluster the interviewers should have an address of the randomly selected starting point. This address should be found first. After the address is found an interviewer has to skip this household and go to the third apartment/private house to the right/up counting from the starting point (excluding business addresses). Subsequent selection of household will depend on whether a completed survey was obtained from the previous household. In case if the interview is completed, the interviewer after living the house must toss a coin to chose the following direction (tail – right/up, head – left/down), and move 3 households in the chosen direction. In case when the interview is unsuccessful (nobody at home, not open the door, or not eligible for our study), a coin toss is done like in the previous case also to choose the subsequent direction.

# Note: the direction of movement is chosen only once for each cluster.

After the direction is chosen, the interviewer moves to next door. If there is more than one eligible person, namely, an adult who meet inclusion criteria, the household number and table "Selection of the individual respondent" have to be used to determine randomly who must be interviewed.

Basic concepts: if in the prior household a survey was completed move 3 units; if incomplete or there were no response move 1 unit.

<u>Cannot find start address:</u> If at the beginning of the survey you cannot find your starting point (address is not correct, no such address exist, etc), you should define new starting point yourself. This starting point should be on the same street as the address not found. You should pick the address, which is geographically closest to the one that you were not able to find. Record why you were not able to find the address, the time spent on the new address searching. After the new address is defined, start the same process is mentioned above. **Note:** this is the last option. Always try to find the previously chosen starting point.

<u>If an eligible respondent lives in the household:</u> Start the selection of the respondent within household. If there are more than 1 respondent in the household, use the table "Selection of the individual respondent" to make a random choice. For each of the adults aged 19 years old and above (born before May 1982) gather the information as indicated in the table. Interview the respondent.

- a. If you complete the interview, move 3 units.
- b. If the interview is incomplete, or the selected respondent refuses to participate, or is later determined to have been ineligible:
  - i. Select another eligible respondent from the household
  - ii. If no eligible respondent remains in the household, consider the household as a non-respondent and move 1 unit to the next household.

#### 4. Survey administration.

a) Script of an interviewer's introduction to the household.

Good morning/day, I am from the Public Health Department of the American University of Armenia. We are conducting a study on hypertension.

If a respondent opens the door/you enter and continue. If refuses first try to address specific objections; if unsuccessful, leave the household.

1. Sorry for troubling you. Our study focuses on adults aged 19 years old and above. Do you have family members in the household fitting that age group.

Possible answers: Yes

No - Apologize and thank the person you are talking with. Leave the household.

Don't know - Ask once again, if the answer is the same or "No", apologize and thank the person you are talking with. Leave the household.

2. If there is only one respondent start interviewing. If there are two or more people fitting the given criteria go ahead and fill the "Selection of respondent" page.

After respondent is selected, continue.

3. Is he/she at home?

Possible answers: Yes

No - Select another respondent from the same household and continue. If no one in the selected respondents is at home

apologize and thank the person you are talking with. Leave the household.

### 4. Can I talk to him/her/you?

Possible answers: Yes

No – Try to find out the reasons for the refusal. Try to convince a person to participate, based on what you know about the survey – talk about the confidentiality issues, say that it will be interesting experience for him/her and that his/her answers will be really valuable for the study, etc. NOTE: Don't be too persistent. If a person still refuses, try to contact another family member, if there are no other eligible people - apologize and leave the household.

#### 5. Present the introductory statement.

We would be very thankful if you participate in our survey and answer some questions that we are going to ask. Any personal information that you'll provide will be anonymous and will not cause any harm to you. Your participation is very important and valuable for us and hopefully it will help to evaluate the current situation with hypertension, to identify and effectively manage the individuals with hypertension, and to prevent the complications associated with high blood pressure. The interview and blood pressure measurement will not take more than 20 minutes. Thank you in advance.

#### 6. Can we start?

Possible answers: Yes

No – Try to find out the reasons for the refusal. Try to convince a person to participate, based on what you know about the survey – talk about the confidentiality issues, say that it will be interesting experience and that their answers will be really valuable for the study, etc. NOTE: Don't be too persistent. If the person still refuses- apologize and leave the household.

Do not forget to stress value of early discovery of hypertension.

- 7. It is preferable that you and respondent are alone in a room. If someone else is present/wants to be present, explain gracefully that the specifics of the interview requires that the third person should not interrupt the interview or express his/her own ideas in order to avoid influencing the respondent's answers.
- 8. Now it is necessary to provide a participant with the consent form. The interviewer should read it and sign in. If he/she has questions answer them. After getting the respondent agreement to participate in the study go ahead, check the blood pressure, and start the interview.

#### b) Interview tips

The interviewers should pay attention to their style of communication with the potential and actual respondents and to the style of the survey administration.

The interviewer should:

- 1. Use the introductory statement as an opportunity to gain the rapport with a respondent. It is better not to read the statement, but say it in the conversational manner, to avoid tension and formal tone.
- 2. Not be intrusive/ too persistent in his/her attempt to recruit the respondent.
- 3. Provide respect to person being interviewed/members of the household
- 4. Convey that respondent's knowledge, experience and attitude are important
- 5. Listen and record without passing verbal/nonverbal judgment
- 6. Show no favor, discontent, shock, anger
- 7. Not be afraid to interrupt gracefully when the respondent starts talking too much, goes into details, or deviate from the topic/question.

#### c) How to deal with ongoing "flows"

**Question Refusal**: it is possible that during the interview a respondent will refuse to answer certain questions or even refuse to continue the interview. In the first case, it is necessary to ask about the reasons for refusal, record it, and continue with the next question. In the second case, it is necessary to ask about the reasons for discontinuing and then try to convince the respondent to continue. *NOTE*: Have just one attempt, don't be too persistent. If a respondent still refuses, apologize and quit the surveying. Try to interview another person from the same household.

**Probing:** Sometimes respondents may not fully understand or misunderstand the content of the question, in that case the interviewer should repeat that question and if it does not help much to clarify that question using appropriate probes. It is important that the probes should be maximally close to the initial question and address the same domain without any interpretation.

**Ineligible Respondent**: if you discover during the interview that a respondent is ineligible or misunderstood in the beginning the relevant eligibility criteria, stop the interview. Go back and try to clarify this issue once again emphasizing eligibility criteria. If it becomes apparent that he/she is ineligible quit the interview, explain gracefully that a respondent doesn't fit the defined criteria and try to contact another person from the same household. If there is no any appropriate person, thank the respondent and leave the household.

**Incorrect Administration/Skipping**: it is possible that while administering the survey you make wrong skip. In this case you should find out where the right flow of the questions was distorted – for that, go back from the current question and check the previous questions/answers. Find the point and proceed from this. Explain the respondent that you found a minor mistake and

want to correct it, ask him/her to help you and, if necessary, to answer certain questions second time.

**Recording answers:** It should be done carefully in a readable handwriting and if jotting is used it should be easily understandable.

#### **Oversight/Authority**

It is necessary to warn the interviewers about the possible oversight of the field activities by the members of the executive committee. They should know that the procedure of spot-checking is one of the components of the survey administration and does not pursue the aim of revealing their mistakes and subsequent panelizing.

#### d) What defines completed Survey

# 1. Does that mean that a person can refuse to answer one third of the questions, regardless of the question?

Do not leave the household until the survey is completed. The survey can be considered completed if:

- 1. If at least 2/3 of the questionnaire is covered (do not consider selective refusals to certain questions as omissions)
- 2. The information on the respondents' selection is recorded/completed
- 3. The "Journal form" is filled correctly
- 4. Time interview started/ended is recorded
- 5. Consent form is signed by the participant

#### 5. Blood pressure measurement guide

- 1. It is important that measurement of blood pressure will be as precise as possible.
- 2. The examination should take place in a quiet room.
- 3. The blood pressure should be measured twice over a period of 10 minutes, before and after the completion of the interview.
- 4. It should be measured after resting with no change in position for at least 5 minutes.
- 5. The patient should be in a sitting position and the right arm will be used.
- 6. When seated the person's arm should be allowed to rest on a desk so that the antecubital fossa is level with the heart. The person must be always in an upright position and feel comfortable.
- 7. The sleeve of shirts and blouses should be rolled up so that the upper right arm is bare for the placement of the blood pressure cuff.
- 8. A cuff for adults must have a bladder 13-15 cm wide and 30-35 cm long to surround at least two thirds of the upper arm.

#### 6. Logistics

#### a) Interviewer Checklist:

It 1	s required to have the list of the following items checked before leaving for
Int	erviews.
	Blood pressure measurement instrument
	Sampling Guide
	Survey Administration Guide
	Blank Surveys
	Consent Forms
	Journal Forms
	Writing Implements (pens)
	Note taking paper
	Contact Information (phone numbers of the program manager and/or program
	assistant)
	b) Languages used

All interviews are expected to be conducted in Armenian.

#### c) Conclusions

It is imperative for the success of any survey that the sampling strategies/respondent selection is performed in unbiased and systematic manner. It is necessary also that the questions in the survey are asked precisely and uniformly and the answers of respondents are registered accurately and correctly. Thus, the interviewer's adherence to the survey rules and instructions and their ability to feel responsible for their performance is important, since they are the performers of the most essential part of the study – information gathering.

# e) Selection of Respondents

1. To obtain the number of adults aged 19 and more (born before May 1982) live in the
apartment/house? persons
2. To receive the following information for each adult in the apartment/ house. Order and
sequence of registering information is presented in the table (see table 1).

Table 1. LIST FROM OLDEST TO YOUNGEST

Line	First name	Age
1		
2		
3		
4		
5		
6		

After the information is registered in the above table, randomly one from the list must be selected using below presented table and interviewed.

Table 2. SELECTION OF INDIVIDUAL RESPONDENT

	LAST DIGIT OF THE VISIT NUMBER IN THE CLUSTER									
# of Eligible Respondents	0	1	2	3	4	5	6	7	8	9
2	1	2	1	2	1	2	1	2	1	2
3	3	1	2	3	1	2	3	1	2	3
4	3	4	1	2	3	4	1	2	3	4
5	1	2	3	4	5	1	2	3	4	5
6	6	1	2	3	4	5	6	1	2	3

#### JOURNAL FORM

Date:														
City														
Interviewer's nai	ne													
Cluster num Starting add Shared clust Direction:	ress:	Yes Right	t	No Left										
Visit number	1	2	3	4	5	6	7	8	9	10	11	12	13	14
#Of eligible respondents														
Result														
Amount of shift to this attempt														
Visit number	15	16	17	18	19	20	21	22	23	24	25	26	27	28
# Of eligible respondents														
Result														
Amount of shift to this attempt														

#### RESULT CODES

- 1. Completed interview
- 2. No eligible respondent at home
- 3. Nobody at home
- 4. Selected respondent (from baseline) not at home
- 5. Total refusal
- 6. Refusal by selected respondent
- 7. Unoccupied house
- 8. Respondent incompetent\_\_\_\_\_
- 9. Other \_\_\_\_\_
- 10. Incomplete interview

# Appendix B

## **Time Frame**

Activities Planning for 2002	March	April	May	June	July	August
Staff hiring	~					
Office rent, supplies, equipment, preparation of materials, etc.	~	~				
Training of the interviewers			~			
Interview conduction			~			
Data editing, coding and data entry into computer				•	~	
Data analysis						<b>&gt;</b>
Report preparation						<b>&gt;</b>

## Appendix C

# Budget

	\$	Duration	Total
Personnel salaries (Net)	Salary/month		
Program coordinator	\$500	6 months	\$ 3,000
Program assistant	Salary/month \$400	6 month	\$2,400
Accountant	Salary/week \$70	1 week	\$70
Interviewer	\$2 / interview in Yerevan, \$4 / interview in marzes	753 interviews in Yerevan, 323 interviews in marzes	\$2,800
Data entry/analyst	Salary/month \$300	1 month	\$300
Driver	Salary/15 days \$150	3 drivers	\$450
Subtotal			\$9,020
Salary taxes 20% income tax 4% pension tax/employee 15% pension tax/employer Subtotal			\$1,804 \$361 \$1,353 <b>\$3,518</b>
Training of the interviewers			
Training materials	\$30		\$30
Food cost	Cost/person/day \$5	10 persons@2 days	\$100
Subtotal			\$130
Copying	0.16/copy	1,075 copies	\$176
Subtotal			\$176
Capital assets			
Personal Computer	\$800/computer	2 computers	\$1600
Printer	\$400/printer	1 printer	\$400
Copier	\$600/copier	1 copier	\$600
Sphygmomanometers	\$20/instrument	10	\$200
Subtotal			\$2,800
<b>Operating costs</b>			
Office rent for 6 months	\$100/ month	6 month	\$600

Office supply for 6 months	\$100 /month	6 month	\$600
Communication and Electricity	\$50/month	6 month	\$300
Transportation: car rental & maintenance	Cost/month \$200	3car @1 month	\$600
Fuel cost	Cost/car/month \$150	3 car @1 month	\$450
Subtotal			\$2,550
Total direct cost			\$18,19
			4
Unexpected needs	5% of total direct cost		\$910
<b>Total cost of the project</b>			\$19,10
			4

#### **Consent Protocol**

The Public Health Department of the American University of Armenia is conducting a survey of the Armenian population 1) to assess the prevalence of hypertension and associated risk factors in the community, and 2) to obtain information about compliance with advice and treatment among patients with diagnosed hypertension. Men and women age 19 and over can participate in the study. The study protocol includes the conduction of interview using the questionnaire, and the measurement of blood pressure. The interview will take place only once and last 15-20 minutes. The study will be conducted by graduate student of Master of Public Health Program at the American University of Armenia and specially trained interviewers. The investigator may stop the procedure if necessary. We appreciate your participation in this study. The information given by you will be very useful and valuable for this research.

### Explanation of Research Project

#### RISKS/DISCOMFORTS:

There is no known risk for the participants of the study. There is some discomfort associated with blood pressure measurement. Otherwise the study poses the same risk and inconvenience as encountered in your daily life.

#### BENEFITS:

You will directly benefit from the participation in this study: it will tell you if you have to be concerned about your blood pressure, and increase your awareness of your health status. Moreover, the information provided by you might help to evaluate the current situation with hypertension in Armenia, to identify and effectively manage the individuals with hypertension, and to prevent the complications associated with high blood pressure.

#### **CONFIDENTIALITY:**

All information received will be kept confidential and will be used only for research purposes. Only identifying codes will be noted on the questionnaires. Your name, address, or any other identifying data will confidential. Your responses will be available only for the Public Health Department of the American University of Armenia.

#### PERSONAL DECISION

Your participation in study is completely voluntary. You have the right to stop the interview any time you want. You are free not to answer any question you consider inappropriate. Your refusal to participate in the study or your decision to withdraw from at any time will not influence your job.

#### WHOM TO CONTACT:

You could ask the person in charge (interviewer) any questions you may have about this research, now or in the future. At your request, the researchers will tell you anything you want to know, and provide you with any information they obtain from the research. The results of the study will be made public and available at the Reference Library of the Center for Health Services Research at the American University of Armenia.

If you want to talk to anyone about this research you should call the person in charge of the study, [Michael Thompson] at [phone number: (374 1) 51 25 60 /e-mail: mthompso@aua.am].

If you want to talk to anyone about the research study because you feel you have not been treated fairly or think you have been hurt by joining the study you should contact the Public Health Department, American University of Armenia at (374 1) 51 25 12.

you agree to be in this study, please sign your name below.	
gnature of Participant	
gnature of Investigator	

### Appendix D

### HYPERTENSION SURVEY

	ID NUMBER:
	DATA: M M D D Y Y
INTERVIER'S NAME:	

### \*The coding for ID number:

Digit 1	Code of Site
Digit 2-3	Cluster number
Digit 4-5	Visit number (number of attended household/person in a cluster)  Note: Use Journal form for writing this number
Digit 6-7	Code of interviewer

Ti	me	interview started:
Ba	ickg	ground
1.	Da	ate of birth (day/month/year)
2.	Na	ationality 9 (do you mean ethnicity or
	cit	tizenship?)
3.	Ge	ender
	1.	Male
	2.	Female
4.	M	arital status
	1.	Married
	2.	Single
	3.	Divorced
	4.	Widowed
5.	En	mployment status (Check all that apply)
	1.	Employed
	2.	Not employed
	3.	Retired
	4.	Disabled
	5.	Student
6.	W	hat is the level of education you received?
	1.	Incomplete secondary (8 years)
	2.	Complete secondary (10 years)
	3.	Professional technical
	4.	Student/Incomplete University
	5.	University
7.	Ha	as your blood pressure ever been measured?
	1.	Yes
	2.	No <b>→ IF ANSWER IS NO, GO TO QUESTION 24</b>

8. When was the last time your blood pressure was taken?
9. What was your blood pressure (top and bottom numbers of blood pressure) the last time
doctor measured it?
10. Do you regularly check your blood pressure outside of your doctor's office?
1. Yes
2. No — FANSWER IS NO, GO TO QUESTION # 12
11. How often do you measure it?
1. Once a day
2. Twice a day
3. Once-twice a week
4. Once a month
5. Other (please,
specify)
12. Have you ever been told by doctor that you have high blood pressure?
1. Yes
2. No   IF ANSWER IS NO, GO TO QUESTION 24
13. When were you first told by a doctor that your blood pressure was higher than it should
1. Less than 12 months ago
2. 1-3 years ago
3. 3-10 years ago
4. Over 10 years ago
5. Other (specify)
14. Has your doctor told you what your ideal blood pressure number should be?
1. Yes
2. No
3. Don't know/remember

15. Ho	ow often do you visit your doctor?
1.	Once a week
2.	Once a month
3.	Once in three month
4.	Other (specify)
16. Di	d your doctor prescribe any blood pressure medicines?
1.	Yes
2.	No —————IF ANSWER IS NO, GO TO QUESTION # 22
17. Di	d your doctor make any explanations of how the prescribed medicine works?
1.	Yes
2.	No
3.	Don't know/remember
18. Di	d you get a clear and understandable explanation about how to take your blood pressure
medic	ine (time of day and dosage)?
1.	Yes
2.	No
3.	Don't know/remember
19. Pl	ease list the names of any PRESCRIPTION blood pressure medicines you are currently
taking	
20. Do	you follow the doctor' prescriptions?
1.	Yes IF ANSWER IS YES, GO TO QUESTION 22
2.	No

21. If	you do not take blood pressure medicine now, why did you stop taking it?		
1.	I didn't like side effects of the medicine		
2.	I didn't like taking medicines or pills all the time		
3.	The medicine cost too much		
4.	The medicines do not help		
5.	My doctor told me I could stop		
6.	Someone told me not to take those medicine		
7.	Other (please, specify)		
22. Please list the names of any NON-PRESCRIPTION blood pressure medicines yo			
currer	ntly taking		
23. H	ow did you receive information about those NON-PRESCRIPTION medicines?		
1.	From another familiar doctor		
2.	From friends/neighbors		
3.	From newspapers/journals		
4.	From TV advertisements		
5.	Other (please, specify)		
24. Pl	ease list any herbal supplements/teas or vitamin/mineral supplements you take for your		
blood	pressure		
25. H	ow would you rate your consumption of fatty foods?		
1.	I avoid animal fats and foods prepared in fats and oils		
2.	I do not pay attention to the amount of fats and oils in my food		
3.	I use a lot of fats		

26. Hov	w would you rate your consumption of salt?
1.	I avoid foods rich in salt
2.	I do not pay attention to the amount of salt in my food
3.	I eat a lot of salt
27. Do	you smoke know?
1.	Yes
2.	No <b>→ IF ANSWER IS NO, GO TO QUESTION #30</b>
28. Ho	w many years have you smoked?
29. Ho	w many cigarettes do you usually smoke a day?
30. Do	es anybody from your family or work place smoke in your presence?
1.	Yes
2.	No
3.	Don't know/remember
31. Dur	ring the past 12 months, how often did you usually get physical exercise (such as
walking	g, gardening, exercising, swimming, tennis)?
1.	Every day
2.	3 to 6 times a week
3.	Less than 3 times a week
4.	Never GO TO QUESTION 33
32. On	the days that you exercised, haw many total minutes did you usually spend exercising?
1.	Less than 15 minutes
2.	15-30 minutes
3.	30 minutes or more
33. Dur	ring the last 12 months how often have you had a drink containing alcohol?
1.	Every day
2.	1-3 times a week
3.	Once a month or less
4.	Not at all ———— GO TO QUESTION 35
34. On	the day when you had a drink of alcohol, how many drinks usually do you had (1 drink
= 340g	of beer, or 115g of wine, or 30g of vodka)?

1.	One drink
2.	Two drink
3.	Three or more drink
35. Ha	ave you ever been diagnosed with diabetes mellitus?
1.	Yes
2.	No
36. Ha	ave anybody of your family members had high blood pressure? (Check all that apply)
1.	Father
2.	Mother
3.	Brother
4.	Sister
5.	Nobody
37. W	That is your height?
38. W	That is your weight?
	Thank you very much for your participation
	interview ended: ewer of the questionnaire
	entry operator # 1
	entry operator # 2