

**AMERICAN UNIVERSITY OF ARMENIA
DEPARTMENT OF PUBLIC HEALTH**

**THE INVESTIGATION OF DETERMINANTS
OF DRUG COMPLIANCE AMONG
HYPERTENSIVE PATIENTS
IN YEREVAN, ARMENIA**

**MASTER IN PUBLIC HEALTH
A THESIS PROJECT**

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Yerevan 1999

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Abbreviations.

HYP - hypertension.

ISH - isolated hypertension.

SBP - systolic blood pressure.

DBP - diastolic blood pressure.

CVD - cardiovascular disease.

CHD - coronary heart disease.

CHF - congestive heart failure.

MI - myocardial infarction.

GP - general practitioner.

WHO - World Health Organization.

MOH - Ministry of Health.

NGO - non-governmental organization.

SRS - stratified random sample.

CI - confidence interval.

Definitions.

Isolated Hypertension - systolic blood pressure >160 mm Hg with diastolic BP < 90 mm Hg. Current treatment with antihypertensive drugs is also used as a criterion for the presence of hypertension.

Awareness to hypertension - is the recognition by the patients that they have high BP by the above definitions.

Treatment - is defined as the use of anti-hypertensive drugs at the time of the interview .

Control of hypertension is defined as BP 140/90 or 160/90 mm Hg while taking anti-hypertensive drugs.

Compliance - adherence to a prescribed therapeutic or preventive regimen.

Health outcome - any medically or epidemiologically defined characteristic of a patient or health problem in a population that results from health promotion or care provided or required as measured at one point in time.

Health promotion - any planned combination of educational, political, regulatory, and organizational supports for actions and conditions of living conducive to the health of individuals, groups, communities.

Health directed behavior - the conscious pursuit of actions for the protection or improvement of health.

Health education - any planned combination of learning experiences designed to enable, predispose and reinforce voluntary behavior conducive to health in individuals, groups, or communities.

Health status - the state of health of a person or a population, assessed by reference to general morbidity, morbidity from particular diseases, impairments, anthropomorphic measurements, and mortality, and indicators of functional status and quality of life.

I. Executive Summary.

Hypertension is a highly prevalent risk factor for cardiovascular diseases, which are still the major "killers" in Western countries. Hypertension leads to atherosclerotic cardiovascular disease, which includes the coronary heart disease, particularly, myocardial infarction and stroke. Ongoing control and life-long therapy are extremely important for prevention of adverse outcomes of hypertension. The mortality from cardiovascular diseases due to hypertension accounts for almost 50% of all deaths in US.[2]. Eighteen years follow up data on subjects from the Framingham Heart Study show that hypertension preceded the development of coronary heart failure in 91% of CHF cases. Data further indicate that uncontrolled hypertension increases the risk of congestive heart failure twofold among men and threefold among women, and that the risk of CHF increases with the severity of hypertension.[19]. Data from clinical trials, conducted in USA and in the other countries show that control of high blood pressure can reduce the incidence of CHF and stroke by as much as 55%.[18]. As a result of awareness, treatment and control the mortality from cardiovascular diseases due to hypertension declined in past years in US.[7].

Conversely, in Armenia the mortality from cardiovascular diseases caused by uncontrolled hypertension is still high and consist 52.3% of all causes of deaths.[17]. According to data of MOH the mortality from cardiovascular diseases have trends to increase: from 339 per 100,000 in 1995year to 354 per 100.000 in 1998y.

The aim of proposed study is to identify the determinants that influence on appropriate drug compliance of hypertensive patients in Yerevan. This project proposes to conduct the survey among hypertensive patients in Yerevan during the March of 2000y in order to assess the real situation with drug compliance among them.

A preliminarily qualitative research was conducted during the August - September 1999y for determining the main behavioral and environmental factors and for better understanding the contribution of each factor or the association of the factors on patients drug compliance. Inclusion criteria were following: Yerevan residents, both male and female older than 45years, enrolled in the local polyclinics as hypertensives. There were conducted 21 K informant in depth interviews, using a developed at baseline and slightly modified after pretesting Field Guide. Qualitative stage was important and useful for generate ideas and in depth understanding the behavioral patterns that lead to drug compliance among hypertensives. On the base of gathered information was developed the questionnaire for proposed "stage 2" - survey. The questionnaire also was pretested and 3 versions were examined The further quantitative research proposed to test the hypotheses developed from qualitative part . The results of the survey will provide health policy makers with additional precise information about drug compliance, will give the recommendations to improving existing drug compliance practices by financial support based on real estimation of necessary expenditures and will guide in a developing a comprehensive antihypertensive program in Armenia.

II. Background

Hypertension is an important public health problem all around the world. The World Health Organization (WHO) views hypertension as a global problem not only in wealthy countries, where cardiovascular diseases are already the main cause of deaths, but also for poorer countries still saddled with the burden of basic health problems such as malnutrition, infectious and parasitic diseases.

Hypertension is predicted to become an ever more common condition in such countries as they follow the path of industrialization and urbanization charted by today's world nations decades ago.[1].

1). According to data-National Health and Nutrition Examination Survey III (NHANES 1988-1991) in US in 1991 nearly 50 million people had elevated BP.[2].

2). The mortality from hypertension complications accounts for almost 50% of all deaths.

3). Uncontrolled hypertension is the cause of the largest days of disability. Hypertension and its complications have a crucial impact on the economic of each country.

The mortality from cardiovascular diseases and disability days from uncontrolled hypertension are the problems in Armenia as well. According to data Ministry of Health of Armenia, the mortality rate from a cardiovascular diseases have increased over time from 339 per 100,000 in 1995 to 354 per 100,000 in 1998. The morbidity rate of hypertension has increased too: from 105 per 100,000 in 1997 to 114 per 100,000 in 1998. Data of City Health Department indicate that in 1998 year 15060 hypertensive patients (Isolated Hypertension) were enrolled in the 29 polyclinics of Yerevan, combination hypertension with myocardial infarction - 8919 patients.

Control of hypertension at high degree depends on appropriate treatment, includes efficient anti-hypertensive drugs. Taking into account the high morbidity rate of hypertension and increasing mortality rate from cardiovascular diseases in Armenia it could be concluded that the hypertensives in Armenia do not receive such treatment. The burden of cardiovascular disease also has increased in the Eastern Europe and Russia in recent years.[15].

The WHO runs in 1996 a hypertension project known as MONICA designed to monitor the determinants of cardiovascular disease worldwide. MONICA reveals that the hypertension treatment rates worldwide did not reach 50%. The rate for men was much worse (only 5 centers had 50% treatment rate for men), than in women (20 centers had 50% treatment rate for women). This important study made clear that complete diagnosis and successful treatment of hypertension under optimal conditions would prevent about 70% of the excess coronary heart disease deaths caused by high BP.[1].

The most studies shows that the burden of diseases due to hypertension has decreased over time because of improved treatment of hypertension, which will lower both prevalence of hypertension and the associated relative risk. The fact that the estimated rate ratios associated with hypertension are similar in studies carried out in the U.S. and elsewhere suggests that these results may be similar for other populations.[4].

It is known now from large randomized trials such as Systolic Hypertension in the Elderly Program (SHEP), the European Working Party on Hypertension in Elderly (EWPHE) and more recent SYST-EUR trial, that the treatment of hypertensives gives greater absolute benefits, than the treatment of any other group of patients, with large reduction in both strokes and coronary events.[16].

Studies show that the only measurable aspect of treatment is associated with BP control is the amount of antihypertensives drugs obtained. More days of medication means better control BP. There was not, however, correlation between physician's visits and anti-hypertensive drug days. The patients, who saw their doctors most often did not receive more medications.[7].

One of the major problems in control of CVD is long-term adherence to drug treatment of hypertensives.[5]. Patient's drug compliance include those, who should, but who are not receiving medical care and those, who are misusing their prescribed medicines or recommended preventive treatment and self-care practices. [6].

As an asymptomatic chronic illness, hypertension does not pose a problem of diagnosis or cure, but rather the challenge of daily vigilance and ongoing commitment to treatment.[7].

Studies on random samples of clinic patients showed that only 55% of patients comply with physician's' prescription and advice (Davis, 1968).[18]. NHANES III revealed that despite increased awareness the prevalence of high BP is still too high, especially for elder people (50% of women and 51.1 % of men ages 60 to 74 years old have high BP). Data show that only 19% of women and 16% of men in these studies had controlled BP below 140/90 mm Hg . That level of BP control confirms the need of additional measures to convince clinicians and patients in importance of treatment high BP and maintaining long- term control of the condition. [20].

Some years ago physicians were cautious in advising treatment for isolated hypertension (ISH), believing, erroneously, that lowering BP might compromise coronary and cerebral flow and precipitate myocardial infarction and stroke. Now it is proven that recommended therapy, which includes diuretics, CA-channel blockers, alpha- and beta-blockers are being particularly effective in elderly patients by increasing aortic compliance and helps to control the heart failure.[16].

The knowledge about hypertension is concerning the ways to prevent and control high BP. A knowledge alone does not always cause behavioral and organizational changes, but the positive association were demonstrated in countless studies. In order to examine long-term effects of a health education program on appointment keeping behavior, BP control and hypertension related mortality rate in USA in 1983 was conducted a cohort study of 400 hypertensive outpatients with various educational experience. The five-year analyses demonstrated a positive effect of the educational program on compliance with medical treatment and BP control - the proportion of individuals reporting high compliance after interventions (score of 4 on 4-item scale) with their antihypertensive drugs regimen, comparing 40 % at baseline, increased to 53%. The results of this study provide

evidence that encouraged the health practitioners to utilize such educational program in a long-term management and control of high BP. [3].

In Japan, where the stroke is the leading cardiovascular disease and BP is the major contributor to the risk of stroke, the reducing BP through pharmacological and other means, as it was supposed, can reduce that risk. Since 1983y, each Japanese municipality had provided public screening and education about hypertension to all residents over 40 years old. The 1.5 year randomized trial compared the results of intensive and non-intensive classes on maintenance and control BP. The trial reinforced the value of education as part of screening program, as well as the value of pharmacological and non-pharmacological measures in reducing hypertension.[8].

The many reasons that the treatment fails, including drug side effects and cost, the mostly commonly cited reason is focused on the relationship between patient and physician. The WHO, European Collaborative Trial in the Multifactorial Prevention of CHD (WHO, 1989) shows that face-to-face counselling of high risk group men had a greater impact on risk factor modification, compared with the mass media approach, adopted for the lower-risk group during the trial. [5].

The physicians can provide reinforcement of patients compliance by ensuring that the patient's expectations are realistic, side effects of medicines should be anticipated. The misperceiving of treatment by patient should be corrected, before the patients giving it up. In the Belgian trial (1989) hypertensive patients had to be treated by general practitioner following recommendations from the physicians attached to the trial. After 2 years there was a decrease of 4.4% in SBP in the control group comparing with the decrease of 13.21% in the intervention group (De Backer et al, 1979)[5].

Even primary care physicians have difficulties in devoting much time and attention to efforts to educate their patients about risk factors and importance of treatment. Recent studies have found large discrepancies among physician initiatives, patients' expectations and published guidelines. The development of methodology to improve the effectiveness of provider-patient contacts within the core system of Public Health would be a fruitful approach to challenge uncontrollable hypertension. [9].

Economic situation in Armenia has been deteriorating in recent years because of earthquake, war in Karabach. These factors also affected health care system. Governmental funding, budget limitations do not allow to cover actual expenditures. According to literature, consistent inverse relationships exist between social-economic status (SES) and the level of BP, serum cholesterol and cigarette smoking in US and other countries (Symc, Oaks and Fiedman, 1914, Keil, Sandifer and Loadhold, 1981). Differences in level of risk factors by SES do not explain all the excess morbidity and mortality of CHD and stroke among those, who with less schooling and who has less prestigious occupations. Perhaps inadequate medical care, lack of knowledge about the health and low income is also involved.

Chronic life situations and life events have been studied for their relationships to diseased CHD (Rissanner, Rono and Siltanen, 1978). The variables that had receive the most attention - are major life changes and the work environment. Cassel (1976), Berkman and Syne (1979) and Blazer (1989) have suggested that loss or disruption of social bonds with other people has increased risk of disease.[10]. Among life changes that have been studied were the job loss, marital status and residential changes. (Kasl and Cob, 1980, Kasl et al 1980). Increasing rates of CHD mortality had been identified among socio-cultural and geographically mobile groups. SES affects on behavior, social support, job and personal flexibility, knowledge about health, access to medical care and doctor's communication with patient within inner city population. Lower SES had an adverse impact on prevalence of hypertension and its control. [12]. Although access to medical care has been shown to contribute to hypertension control, the observations show a high prevalence of uncontrollable hypertension despite availability of medical care in inner city. Access to medical care does not necessary equal to effectiveness of care. Communications between physician and patient may be less effective, when the patient is of lower SES. [9]. Waitskin (1984) has described the effects of SES and gender on doctor patient relationship. Physician talks on one way to non-physician profession peers and quite another way to blue collar worker. The information given, the details, possibilities of treatment, outcome and advice on prevention are sometimes stated differently by the same physician to patients of differing gender and SES. [10].

III. Specific Aims and Objectives of The Study.

The project proposes to conduct a quantitative research regarding the barriers and motivations of drug compliance among hypertensives in Yerevan, Armenia. In order to obtain precise information about adherence to treatment and to measure the extent of compliance to the established criteria for hypertension treatment will be conducted a survey among hypertensives in Yerevan. We propose to conduct the survey in Yerevan, because it will be less expensive and will not take so many financial and human resources, as it will take the nationwide survey. The proposed polyclinic-based survey will be focused on the most important topics revealed by performing the qualitative research. The results gained from this survey will contributed to a national database of hypertension and provide policy makers of the Republic of Armenia with extensive information to further designing a comprehensive antihypertensive program.

A preliminary qualitative research was conducted as a step in developing proposed quantitative study. On the base of data obtained from qualitative part was developed the questionnaire for survey (see Appendix D).

The qualitative research design was chosen for better understanding of issues related with topic and for to reveal what people think and what they may feel regarding drug compliance of hypertensive patients.

Research questions that were addressed

- 1. What behavioral and environmental factors influence on appropriate drug compliance of hypertensive patients in Yerevan, Armenia?*
- 2. What is the current drug compliance among hypertensive patients in Yerevan, Armenia?*

IV. Methodology.

QUALITATIVE RESEARCH.

There are currently no published studies, which investigated the drug compliance among hypertensive patients in Armenia. In order to get a better understanding of process that leads to certain behavior, particularly, to drug compliance, was conducted exploratory qualitative research.

DESIGN.

The methodology includes specialized qualitative techniques: semi-structured interviews, ethnographic interviews-in order to obtain in depth responses and understandings of knowledge, attitudes regarding practice of drug compliance among hypertensive patients in Yerevan, Armenia.

STUDY POPULATION.

In conducted qualitative research, purposive sampling was used to determine the Key informants. The Key informants are the people who faced the problem of adherence to treatment of hypertensives and could provide in depth information. [11]. They were identified in the several Yerevan polyclinics based on inclusion criteria:

Eligibility Criteria:

1. Experienced hypertension (regardless of presence other disease).
2. Yerevan resident - both male and female starting from 45 years and older.
3. Not familiar with interviewer.

K-INFORMANT INTERVIEWS.

Data collection was conducted during the period from August 15 to September 20, 1999 in Yerevan. Individual in depth interviews were conducted in one-on-one basis between the informants and interviewer, trained in qualitative research theory and methodology. There was done a preliminary contact with informants and appointed the time and place for conducting interview. Total 21 informants participate in this study. Demographic information was collected for all informants. The 15 of 21 informants were currently working, 7 were already retired. The ages of informants were 45 to 73, with mean age 56 years old. An Interview Topic Guide was developed and was used for doing the interviews, questions concerning current drug compliance among hypertensives, knowledge attitude to treatment, doctor-patient relationships, availability and affordability of drugs, family support (see Appendix B, C).

The Ethnographic Field Guides consist following sections:

1. Introduction – disclosure statement, presentation of interviewer and purposes of the interview, oral consent.
2. Interview guide, includes open-ended questions, probing.
3. Demographic information.
4. Closing.

Initial 8 in depth interviews were conducted in the several polyclinics of Yerevan during the period from August 15 to September 1. In order to obtain more detailed information on certain topics, Field Guide was revised and modified. The additional 13 interviews were conducted in polyclinics, using revised Field Guide. On each question was used extensive probing. Each interview took about 45 minutes -1 hour. All interviews were recorded, using field notes in native languages (Armenian or Russian - according to preferences of respondent). The field notes were expanded into a written report after each of conducted interview and then were translate into English. The written report contained detailed description of the place, time, and informant. During preliminary analysis of K-informant interviews, the main domains were identified, including knowledge about hypertension and its treatment, attitudes toward treatment, doctor- patient relationships, affordability of drugs. The identified domains were formulated according to stated research questions.

THE RESULTS OF K-INFORMANT INTERVIEWS.

21 Key Informant interviews were conducted in order to enhance in depth understanding of the barriers and motivations of appropriate drug compliance among hypertensive patients in Yerevan. The informants were selected based on previously stated eligibility criteria. All participants express the willingness to answer on questions, to share their experience. Maybe emotional contact was

achieved with them. The analysis of K informant interviews was done in relation to research questions of the study. The gained information enlightened different aspects of the topic of research.

Knowledge about hypertension and its treatment.

The part of informants was aware what kind of disease is hypertension and shows sufficient knowledge about it. As the important factor, that influence on adherence to treatment they mentioned the knowledge that hypertension is life-long disease and there is a need of ongoing BP controls.

"I know that the hypertension is a chronic condition and I always should be cautious with my blood pressure".

"Several years ago I felt a systematic terrible headaches, but I had no idea what was the reason of that. I visited to a doctor and she diagnosed me with hypertension and prescribed the medicines, gave me recommendations. I received the drugs, when I had a headache. When I finished the course of treatments, I visited her again. Although at that time I had not headache, doctor measured my BP, and it was high - 180/110 mm Hg. I recognized that the high BP could be and without any symptoms and my BP should be always controlled."

"All my family - my mother, brothers and aunt had a hypertension. My mother had a renal disease and even when she received the medicines, her BP was very high. Every time when I measured her BP, I tried to measure mine, because I supposed that my family has a predisposition to renal disease and my BP should be controlled. When I was diagnosed with hypertension - it was 4 years ago, I already knew which drugs are necessary and how to deal with hypertension."

The half of the informants (except for two persons) mentioned the cardiovascular disease, stroke, MT as a complication of hypertension. One informant meant that his coronary heart disease (he knew the diagnosis from his doctor) is not related with hypertension.

"I have a hypertension almost 15 years, a coronary heart disease was diagnosed, I don't remember, may be, 6-8 years ago. I do not see the relation of each other. Hypertension is simply related with age. Now I am 74."

Another informant said.

"I have no hypertension, you are wrong. I simply have a high BP."

There was a one man of K-informants, who experienced a stroke a few years ago. He knew about the consequences of uncontrolled hypertension from his own practice. He received the treatment in hospital and was aware that he need the ongoing control of his BP and the repeated courses of treatment, although he had completely recovered after the stroke.

"I know very well what drugs I need, I can name them. I receive its every time, when I have an elevated BP. I am entirely sure that I am controlling the hypertension, because I undergo repeated courses of treatment at home every 3 months as my doctor recommend it. I use a few drugs, which act in different ways and help me to control the BP and to avoid the repetition of stroke. I am very afraid of it, because I know that the second event will be more heavy, that the first one."

Another informant remarked that she always measures BP when she feels bad, because she is aware that she has a hypertension.

"I am a former nurse. Although now I am retired, I have another work now. I saw the patients with stroke, cardiovascular disease. Hypertension was diagnosed 5-6 years ago and during these years I received a prescribed treatment, measured BP in any occasion. I am regularly seeing my doctor and counseling with her. She made some changes in her prescriptions, discussed it with me, tailoring treatment individually."

Regarding the question: "What are the side-effects of drugs and can they list them?" the great part of informants responded that they don't need to know what are the side effects of the drugs, it's the polyclinic's doctor's responsibility to take it into account, and they never read the instructions that came with medicines:

"I don't want to know about it. It is doctor's responsibility to take it into account."

"When I received the prescribed drug, I felt very bad: my temperature increased, I felt chill. My son called 03 and emergency arrived. After that episode I am trying to do not use any drug, even when it is necessary". Two persons answered that they are aware about the side effects of the drugs because of medical background that they have (1 nurse and 1 physician - both are retired and currently one of them do not work).

Another informant explained that:

"I never use the antihypertensive drugs, because I think that they could have a bad effect on my heart. I have the asthma, coronary heart disease. As a part of treatment of the coronary heart disease, doctor prescribed me the diuretics, and that is enough."

Sources of Information.

K informant responses about the sources of information, answering the question: "Where do you get the information regarding hypertension and the drugs that are needed?" was following:

"From doctors, books, TV, radio."

"After finishing my treatment of stroke and came home, I had got an encyclopedia and read there everything about hypertension."

"I liked to read the medical journals in past. Now they are not published in Armenia."

"I always watched Armenian TV, particularly, TV program 03, where was a conversation with doctor regarding hypertension."

"Doctor explained me why hypertension is dangerous. I didn't knew it before."

"The great part of my friends, neighbors have a hypertension. They told me in details about their drugs (treatment)."

"I often read the medical journals and knew about hypertension treatment before I became ill."

Attitude toward treatment.

The part of informants shows significant negative attitude toward treatment.

"Drugs do not help me. I customize to fight against elevated BP by diet - yogurt, etc."

"Often I don't receive the drugs, even when I have a headache, and measuring shows the high BP. It is a usual event, and after certain time the BP decreases without any intervention."

Almost all of informants said that the drugs are harmful for their organism.

"The drugs contain a chemical components and are harmful."

"The drugs by themselves are harmful, and also have the side effects."

"I receive the drugs, but they never help me. Contrary, I feel bad after taking them."

"It is better to have sometimes a headache, bad feeling, than to poisoning the organism with drugs."

"The prescribed drugs affected on my heart and I stopped to receive it."

The fact that the hypertension is a chronic life-long disease also affects on attitude toward treatment.

"If hypertension is not curable, I don't want to receive the drugs, which cannot help."

"Why should I undergo the repeated courses of treatment? I once have received the course of treatment, I can not use the drugs all my life. I cannot afford it."

Attitude toward hypertension as to not serious condition was mentioned by almost half of informants.

"The hypertension is not a serious health problem. It is related to age. Almost all my peers have a hypertension. It's normal."

"I worried more about my asthma, than about the hypertension".

"Regarding the high BP, I am sure that it will normalize after a certain period of time."

"Everyone today has a hypertension, even young people. I do not see, why I should pay attention to it and receive the repeated courses of treatment."

"I have so much diseases - diabetes, coronary heart disease, that hypertension is the less serious disease for me."

"Doctor insisted that I received the drugs, but I don't think that the hypertension is so serious disease. I think that the danger of the hypertension is exaggerated."

Doctor -Patient relationships.

All informants attended their polyclinic doctors on a regular basis once a month or two months. The motivations for attending the clinic were: the feeling that they do any possible care for their health, the desire to know what is their current condition, or the bad symptoms and the worsening of condition forced them to come. There were a few informants that did not attended polyclinic, because someone from their surrounding had a medical background and they do not believe that the attendance of polyclinic will be helpful for them. The majority of informants needed in the regular doctor's examinations and prescriptions of drugs.

"I went to the doctor because of headaches. Doctor measured my BP and said that I have a hypertension. He prescribed me a few drugs, arguing that all they are necessary for me and explained in which ways they could help me. Although I listened about these drugs before- from my peers, friend, neighbors - his explanations conceived me that I need to receive all these drugs."

"When I had a hypertension crisis - a very high BP - 220/ 120 mm Hg - during the week. Doctor from polyclinic attended me every day, prescribed additional medicines, and called every morning to know how I feel. Even after crisis she called me several days to make sure that I feel better and my condition is improved."

"Doctor advised me to receive the diuretics at least once a month. He said that it would be useful both for my hypertension and my heart."

"I trust my doctor. We know each other for many years and there were many health problems when her advice was helpful for me. I suppose that she is a knowledgeable and experienced doctor."

" When polyclinic receives a new portion of medicines from humanitarian aid, doctor always calls me for I come and could take an additional drugs."

The part of informants had an opposite point of view.

"Although I completely trust my doctor, but because I worried about my health, I always asked about new drugs that we received from abroad (humanitarian aid) and were prescribed me from pharmacists in shops, familiar doctors. When the others - friends, neighbors speak about effectiveness of particular drug, that was prescribed me, I feel me calm."

"Doctor never said me anything that I did not know. Doctor diagnosed me (but I could do and by myself) and that is enough. My friends could tell me what drugs they receive (because they also have a hypertension) and I can do the same."

"The doctor from polyclinic is very good and kind, but I always feel that she is busy and hurry to finish the consultation."

"I am a physician, and my daughter is a physician too. We are counseling together and I believe that she is a better doctor, than the doctor from polyclinic. However, I need the consultation of polyclinic's doctor for my husband who also has a hypertension. He doesn't listen to me and to my daughter, when we talk about necessity of treatment. He even does not allow to measuring his BP. Maybe, polyclinic's doctor will have more authority and could convince him to be adherent with treatment."

"I feel that my doctor paid me exactly so much attention as it is deemed by her profession, no more."

"My doctor never explained me why the high BP is dangerous. He said : "You have a hypertension, you need to receive this drug." About the stroke, cardiovascular disease, MI as a consequences of hypertension told me my proxy, who is doctor too."

Family members.

Regarding the questions about family members were obtained similar responses from informants, when they were asked what kind of support they received from their family.

"I always feel that my children are careful with me. They ask me how I feel, what drugs doctor prescribed me. They provide me by drugs and with everything what is necessary. When I feel bad, they invite another doctor - not from polyclinic, because want to confirm the treatment. I know that they need me."

"My son and daughter are careful to me. I receive not only financial support from them (they buy me necessary drugs), but also emotional support."

A few informants mentioned that their children are not in Armenia (in Russia, etc.), but they receive financial aid from them.

"My son has a good job in Moscow and he sends me money, that helps me to survive."

"My son is abroad and sends me money in any occasions."

In such cases, when the family members were absent, informants mentioned that the neighbors helped them.

"I felt bad and called my neighbor - she is a nurse. She helped me to measure BP and to get the medicine. My neighbors never refuse me in help."

"Doctor visited me and left the prescriptions. I asked my neighbor's son to go to the pharmacy and to buy the drugs for me."

"I am a single woman, my husband died 2 years ago from stroke. But I can ask for help, if it is necessary, my neighbors or daughter of my friend."

Availability of drugs.

In the former Soviet Union, it was difficult to buy the necessary drugs because there was lack of drugs. The patient was forced not only to pay, but to get them, using his liaisons. Now in the Republic of Armenia the number of pharmacies are so large, that one can buy any drug. Besides, Armenia receives a humanitarian aid. Drugs through Ministry of Health are distributed to polyclinics and patient can receive free a part of prescribed drugs.

"My doctor gave me antihypertensive drug, I customized to it and it helped me well. But now that drug is ended and I don't know how to get it, because I cannot afford to buy it from pharmacy."

The problem is that the polyclinic distributes the certain limited amount of drugs, and the patient do not sure that he will receive exactly necessary drug during the whole course of treatment.

Access to medical care.

All informants mentioned that they have a sufficient access to medical care. Polyclinic's doctor visits them whenever they call to the polyclinic (or ask someone to call).

"I asked my neighbor to call my doctor and next day she visited me."

Affordability of drugs.

Informants mentioned that not all drugs help them. They customize to some drugs, feel that they are more effective for them. The drugs received from polyclinics cover only the part of drugs that they need, but not all types of drugs that are needed.

"I receive "ednit" and "propanolol," which gave me a doctor, but I forced to buy diuretics from pharmacy, because they were absent in humanitarian aid."

"My pension is so miserable, that if my daughter would not work, we would not afford not only drugs, but food."

"Yesterday we did not buy the bread, but I bought my drug."

"I have a "clofelin" dependency and feel very bad if do not receive it. However, polyclinic does not provide me with "clofelin", because there are a new drugs and I am forced to buy it on my own pension, which is very little. Doctor wants to substitute it by other drugs, but I don't want it."

DISCUSSION.

The data obtained from qualitative study were allocated into two groups: group of factors that either positively or negatively influenced on the drug compliance of hypertensives. The Table 1.shows the result of K informants interviews, classifying as the factors having a whether positive or negative impact on drug compliance of hypertensives.

Table1. Positive and negative behavioral and environmental factors that influence on drug compliance of hypertensives in Yerevan.

Positive factors	Negative factors
<p>Knowledge about hypertension asymptomatic advancement of hypertension</p> <ul style="list-style-type: none"> ▪ hypertension leads to life-threatening complications ▪ hypertension is a chronic life-long disease and needs in regular control of BP <p>Knowledge about treatment</p> <ul style="list-style-type: none"> ▪ drugs ▪ several types of drugs ▪ side-effects of drugs ▪ regular, repeated courses of treatment every six months[15] <p>Multiple sources of information (booklets, TV)</p> <p>Doctor relationships with patient</p> <p>Family members</p> <p>Availability of drugs</p> <p>Access to medical care</p>	<p>Attitude toward regular use of drugs</p> <p>Attitude toward hypertension</p> <p>Psychological factors (stress, apathy)</p> <p>Presence of another disease</p> <p>Financial problems</p>

As a most positive and useful factor for adherence to treatment, all informants mentioned the knowledge that ignorance of drugs and control BP will lead to much worse conditions. The recognition that the widely acknowledged in people life-threatening diseases such as stroke, CHF are related with hypertension, and could be prevented by recommended behavior, significantly increases

the awareness and adherence to regular treatment. All informants that knew about the consequences of uncontrolled hypertension reported regular usage of prescribed drugs, performing control on BP.

Knowledge about the drugs that are necessary also had a positive impact on compliance with treatment. The sources of knowledge could be different: doctor from polyclinic, friends, neighbors, TV programs. The conversations with friends, neighbors had aim to make sure that they receive are the most effective and necessary drugs.

However, at the same time near the half of informants cannot remember the name of drugs that was prescribed them and that they regularly used, and needed to look at the paper where name of drugs were written down. These informants supposed that the use of one drug is enough and did not receive the complex treatment.

Knowledge that the hypertension is a chronic life-long disease had an ambiguous impact on drug compliance. The part of informants supposed that it is implicit the regular BP control and treatment. The other part considered that it is no need to receive the drugs all their life if they do not help. They had a prejudice that the all drugs are dangerous, because they are composed from chemical components and its usage could lead to drug dependence. This point is very important for drug compliance and should be take into consideration in planning educational program.

The attitude toward treatment was negative in many informants. Considering the hypertension as a normal condition related with age, they neglected the treatment, and showed ignorance toward usage of prescribed drugs. The presence of another disease also had a negative impact on antihypertensive treatment. These diseases informants often consider as more important and gave them priority in treatment.

The great part of informants described that the trust to doctor, to his/ her prescriptions and personality of doctor has a reinforcing effect on drug compliance. In many cases, with giving the prescriptions of drugs doctor explains to patient why he need exactly that drugs and why the disease should be controlled. However, the economic situation also reflected on doctors and not all of them have a mood and willingness for careful attitude to patients.

All informants considered that the family support, not only financial, but also emotional, is a very strong positive psychological factor affected on drug compliance. All informants considered the access to medical care as a sufficient. Anyone from informants (even those who have medical background) at least two - three times a year had visited to the polyclinic's doctor and had the opportunity to get the prescription of necessary drugs and information about them. All informants meant that the drugs are available, but the lack of money does not allow buying them.

Psychological problems - stress, apathy - were mentioned by informants as definitely negative for drug compliance and were related not only with their health status, but also with unstable economic situation in Armenia. All informants, except for 2-3 persons, mentioned that the difficulties in drug's purchase because of lack of money influenced them negatively and the drugs should be free. Due to the reform in the health care system in Armenia the situation is getting worse in a recent years. The

financial problems had the very strong negative impact on drug compliance. All informants suggested that drugs will be free or the salary and pensions would allow buying them.

CONCLUSION.

The results of preliminary qualitative research give a better understanding of the role of factors influencing on the extent of adherence to treatment of hypertensive patients in Yerevan. As a most important factors could be determined the knowledge about hypertension and its treatment, attitude toward treatment, doctor's prescription and, particularly, affordability of drugs. The data give the guide in which areas should be focused the further quantitative research for gathering additional information about the behavioral patterns and influencing on it factors. The gathered information will help also in planning the program, targeting health promotion and education.

LIMITATIONS OF QUALITATIVE RESEARCH.

The limitations of the study are:

- 1.Generalizability of the data, since there was used purposive, not probability sample.
- 2.Subjectivity of qualitative data.

However, the qualitative research design was used in order to obtain the wide range of patients perceptions of drug treatment, to get ideas and develop hypothesis what are the barriers and motivations of appropriate drug compliance of hypertensive patients in Yerevan.

RECOMMENDATIONS.

Considering the results of qualitative study among hypertensives in Yerevan the following could be recommended:

- 1.To conduct the quantitative research for obtaining precise information and to test developed hypothesis regarding the knowledge, attitudes, doctor-patient relationships, affordability of drugs, reflecting on drug compliance of hypertensives in Yerevan during the March of 2000y. The combination of qualitative and quantitative data will provide with valuable information for further interventions. We propose to conduct the survey only in Yerevan, because it will be less expensive and will not take so many financial and human resources, as it will take the nationwide survey.
- 2.To develop and implement the program, which will include the patient's education, training of health personnel, provision with drugs and the evaluation of program.
- 3.To develop and distribute the educational materials - the booklets regarding importance of treatment of hypertension.

QUANTITATIVE RESEARCH.

Hypotheses that will be tested

Hypotheses 1. Drug compliance behavior is positively associated with high level of knowledge about hypertension, its treatment and doctor prescriptions.

Hypotheses 2. The main barriers of drug compliance of hypertensives are attitude toward treatment, lack of knowledge and money.

1.Ho. Drug compliance of hypertensive patients with high score on knowledge is not differ of drug compliance of hypertensive patients with low score on knowledge.

Ha. Drug compliance of hypertensive patients with high score on knowledge about hypertension is differ of drug compliance of hypertensive patients with low score on knowledge.

2.Ho. Drug compliance of hypertensive patients with positive attitude toward treatment is not differ of drug compliance of hypertensive patients with negative attitude toward treatment.

Ha. Drug compliance of hypertensive patients with negative attitude toward treatment is differ of drug compliance of patients with positive attitude toward treatment.

3.Ho. Drug compliance of hypertensive patients who received doctor's prescription or advice is not differ from drug compliance of hypertensive patients who did not receive it.

Ha. Drug compliance of hypertensive patients who received doctors prescription/advice is differ of drug compliance patients who did not received doctor's it.

4. Ho. Drug compliance of hypertensive patients who can afford the drugs is not differ from drug compliance of hypertensive patients who cannot afford the drugs.

Ha. Drug compliance of hypertensive patients who can afford the drugs is differ from drug compliance of hypertensive patients who cannot afford the drugs.

DESIGN.

The proposed polyclinic-based survey will be focused on the most important topics revealed by performing the qualitative research and will be designed as a cross-sectional study. The survey will allow to test hypotheses to obtain the precise data regarding the most important behavioral and environmental factors, such as knowledge about hypertension and its treatment, attitude toward treatment, doctor-patient relationship, affordability of drugs.

STUDY POPULATION.

The target population will consist of all the residents of Yerevan both male and female, 45 years and older, who have a hypertension. The sampling frame will include not only those who have ISH (isolated hypertension), but also those who have a combination of hypertension with other diseases (asthma, CVD, diabetes).

SAMPLE SIZE.

The total sample size could be calculated according to the formula [13]:

$$N = 4Z\alpha^2 \times P(1-P)/W^2$$

Or according to formula [14]:

$$N = Z^2 \alpha^2 \times P(1-P)/d^2$$

Where $Z\alpha$ - standard normal deviate for two tailed test and

$$Z = 1.96$$

$$p = 0.5$$

$$q = 1 - p = 0.5$$

W = desired width of confidence interval = 0.1

$W = 2d$, d - desired precision = 0.05

There is two tailed test, $\alpha = 0.05$, power = 0.8

Taking into account the expected response rate 80% - adjusted sample size will be:

$$n = 384 / 0.80 = 480$$

The face to face interviews will be conducted because of following reasons:

1. This type of interview could get higher response rate than interviews through phone or mail (80-85%).
2. Decreases "don't know" responses.
3. Interviewer can make the observation that might be pertinent - enhance the quality of the data.

From hypertensives that were considered as an eligible the interview may not be obtained because of a number of reasons:

1. Refusals - refuse to participate in the study or break-off the interview, once it begins.
2. Too ill for participate - have mental or physical limitations.
3. People who may be away during the interview field period estimated.

The stratified random sample will be used to determine respondents for survey in the 29 polyclinics, located in the all districts of Yerevan. The sampling frame will be the list of hypertensives, registered in 1998 year in 29 polyclinics in Yerevan. From sampling frame- list of hypertensives, obtained from polyclinics, and stratified by 10-year age groups- will be chosen sampling elements (hypertensives based on systematic random sampling). The probability design will allow generalizing survey results on whole population of hypertensives in Yerevan.

The sample size adjusted for expected response rate 80% and adjusted for sample design effect is (see the Table 3):

$$N = 693.$$

Taking into consideration that the total sample size will be no less than 693, the sample size for each of 29 polyclinics was calculated according to proportion of hypertensives, who are receive medical care in each polyclinic. For these calculations was used formula:

$$n=a/x$$

Where n- sample size for particular polyclinic, a - total number of hypertensives in each polyclinic, x- 15060- total number hypertensives in Yerevan in 1998y. The calculated sample sizes for each polyclinic are presented in Appendix E.

Table 2. Study variables.

<u>I</u> Dependent variables	Level of measurement
1. The use of prescribed drugs: regularly or occasionally	ordinal
2. Number of days during the month that the drugs were used	numerical
3. Combinations of drugs received with diet	ordinal
<u>II</u> Independent variables	
1. Knowledge about hypertension	nominal
2. Knowledge about necessity of adherence to treatment	nominal
3. Knowledge about drugs that are necessary	nominal
4. Knowledge about side-effects of the drugs	nominal
5. Knowledge about necessity of ongoing BP control	nominal
6. Knowledge about life style	nominal
7. Knowledge about diet	nominal
8. Knowledge about necessity of several types of drugs	nominal
9. Attitude toward treatment	nominal
10. Attitude toward necessity of control BP	nominal
11. Receiving the doctor's prescription	nominal
12. Receiving the drugs not prescribed or advised by doctors	nominal
13. Talks about personal and general problems with doctors	ordinal
14. Have an opportunity to buy necessary drugs	ordinal
15. Family income	ordinal
<u>III</u> . Control variables.	
1. Age	numerical
2. Education	ordinal
3. Gender	nominal

Questionnaire Development.

The survey instrument -questionnaire- was developed using the data of K-informants interviews to

determine the most important and relevant questions. Appropriate phrasing and wording of questions also were taken into consideration. The questions concerning mainly to knowledge about hypertension and its treatment, attitudes toward treatment, doctor-patient relationship, socio-economic conditions as well as practice of drug compliance (see Table 2). The questionnaire was written in English, then was translated into Armenian. In questionnaire development were taken into account following:

1. Do the respondents understand the questions, as they were intended and answer exactly on them?
2. Do the skip patterns between questions work properly?
3. Is there evidence that respondents falling to invariant response category?

In order to check the questionnaire it was pre-tested - were taking 6 interviews with respondents similar to those who will be included in the final study. Then the questionnaire in some parts were redesigned to ensure the better understanding of question's meanings, appropriate wording and provided comprehensive response categories. The final version of questionnaire included the sections (see Appendix D).

1. Introductory statement.
2. Knowledge questions regarding hypertension, its treatment, and ongoing control of BP. In this part each knowledge question was provided by weighed point according to its importance. The sum of these points will present the overall knowledge score of respondents. In analysis part it will allow to calculate the mean knowledge scores of study participants.
3. Questions regarding attitude toward hypertension and its treatment.
4. Questions regarding doctor's prescription of drugs.
5. Questions about affordability of drugs.
6. Demographic information.

The process of hiring interviewers for survey will include the considerations of applicant's physical (age, social history), personal (education, intelligence), behavioral (accuracy) characteristics. The interviewers will pass training, containing the general information to all surveys and the specific information to this study on which interviewers will work. The validity of survey could be ensured by making phone calls by supervisor.

Table 3. Survey Sample Size for Major Study Variables according to Hulley S.B. Cummings S.R.[13].

Knowledge about necessity of treatment	Attitude toward treatment	Doctor's prescriptions	Affordability of drugs	Compliance with treatment
1. Type of estimate percentage - (proportion)	Type of estimate percentage - (proportion)	Type of estimate percentage - (proportion)	Type of estimate percentage - (proportion)	Type of estimate percentage - (proportion)
2. Population of interest- entire sample	Population of interest -entire sample	Population of interest -entire sample	Population of interest -entire sample	Population of interest- entire sample

3. Expected value of proportion of hypertensives who have knowledge about necessity of treatment $p=0.5$ $q=1-0.5=0.5$	Expected value of proportion of hypertensives who have knowledge about necessity of treatment $p=0.2$ $q=1-0.2=0.8$	Expected value of proportion of hypertensives who have knowledge about necessity of treatment $p=0.5$ $q=1-0.5=0.5$	Expected value of proportion of hypertensives who have knowledge about necessity of treatment $p=0.1$ $q=1-0.1=0.9$	Expected value of proportion of hypertensives who have knowledge about necessity of treatment $p=0.5$ $q=1-0.5=0.5$
4. Standard error of percentage $SE = \text{SQRT} [px(1.00-p)]/n$	Standard error of percentage $SE = \text{SQRT} [px(1.00-p)]/n$	Standard error of percentage $SE = \text{SQRT} [px(1.00-p)]/n$	Standard error of percentage $SE = \text{SQRT} [px(1.00-p)]/n$	Standard error of percentage $SE = \text{SQRT} [px(1.00-p)]/n$
5. Tolerable range of error in the estimate $= \pm 0.5$	Tolerable range of error in the estimate $= \pm 0.5$	Tolerable range of error in the estimate $= \pm 0.5$	Tolerable range of error in the estimate $= \pm 0.5$	Tolerable range of error in the estimate $= \pm 0.5$
6. Desired level of confidence 95% $= 1.96 \times SE = 0.05$ $n = Z^2 \times pq/d^2 = 1,96^2 \times .05 \times 0.5/0.3^2 = 384$	Desired level of confidence 95% $n = Z^2 \times pq/d^2 = 1,96^2 \times 0.2 \times 0.8/0.5^2 = 246$	Desired level of confidence 95% = width of $= 1.96 \times SE = 0.05$ $n = Z^2 \times pq/d^2 = 1,96^2 \times .05 \times 0.5/0.3^2 = 384$	Desired level of confidence 95% $n = 1.96^2 \times 0.1 \times 0.9/0.5^2 = 139$	Desired level of confidence 95% = width of $= 1.96 \times SE = 0.05$ $n = Z^2 \times pq/d^2 = 1,96^2 \times .05 \times 0.5/0.3^2 = 384$
7. Adjusted for estimated sample design effect $DEFF = 1.3$ $n = 384 \times 1.3 = 499$	Adjusted for estimation sample design effect $DEFF = 1.3$ $n = 246 \times 1.3 = 320$	Adjusted for estimated sample design effect $DEFF = 1.3$ $n = 384 \times 1.3 = 499$	Adjusted for estimated sample design effect $DEFF = 1.3$ $n = 139 \times 1.3 = 181$	Adjusted for estimated sample design effect $DEFF = 1.3$ $n = 384 \times 1.3 = 499$
8 Adjusted for expected response rate 80% $n = 499/0.8 = 624$	Adjusted for expected response rate 80% $n = 320/0.8 = 400$	Adjusted for expected response rate 80% $n = 499/0.8 = 624$	Adjusted for expected response rate 80%	Adjusted for expected response rate 80% $n = 499/0.8 = 624$

Statistical analyses.

The analyses of results of survey will be done using computerized statistical program STATA5.0 software package or using 2x2 table. Since the distribution of variables is unknown, we assume that it is normal. There will be done stratified by age, gender analyses for controlling potential confounders. The Table 4 presents the main study variables, the level of measurement and appropriate statistical technique for measuring each variable.

Table4.The Study Main Variables, Levels of Measurement and Appropriate Statistics (According to Hulley S.B. and Cuning S.R.). [13].

In order to find associations between the knowledge of hypertensives about hypertension, its treatment and socio-demographic variables (age, genders, and education), the data will be put into a logistic model. Also the variables of the study will be measured by aggregating the summary scores of each variable, e. g. for measuring the knowledge we derived the knowledge scale -the sum knowledge scores, presented in each knowledge question multiplied by their weights. In the questionnaire there are 14 knowledge questions (#12-25q.) (see Appendix D).The weight of each response categories are summarized and derived maximum total knowledge scores of 44.For each respondent will be calculated the percent from total knowledge scores. In the same way will be calculated attitude. The questionnaire has total 8 questions regarding attitude (#26-33). The weights of answers on attitude questions will summarized, yielding maximal attitude scores of 24, divided on 0.693 (n=693) to determine a variable, where score of 100 designated as best possible attitude to treatment.

Validity and Reliability.

In order to assure reliability and validity of the measures of survey following possible threats should be taken into account: the reliability will be affected by:

- 1.Instrument - refining the questionnaire to increase clarity, avoid ambiguities, then revising it again and pretest- to check the appropriate wording and understanding the questions by respondents.
- 2.Observer-interviewers will be trained in lead the interviews, using standardized procedures. Interviewer skills, mood, fatigue could affect on reliability. Inter-rater reliability- to compare the measurements obtained by different interviewers.
- 3.Subject- respondents mood, fatigue, anxiety from unusual experience of participation in survey.
- 4.Situation- conditions under which the interview will be conducted-noise, presence of members of family, neighbors.

Threats to validity:

- 1.Content validity- do the questions adequately represent the concept of being compliant with treatment and factual adherence to treatment.
- 2.Construct validity- to distinguish between to be compliant and not compliant with treatment.
- 3.Criterion validity-correlation with gold standard and comparison how many relationships predicted by theory can be moved out.

The validity will be affected by:

- 1.Observer bias- consistent distortion, conscious or unconscious, the perception and reporting of interviewer- e.g., underestimate the knowledge in patients, who receives the treatment. It is necessary to train interviewers lead the interviews in standardized way, to supervise and observe their work, especially in initial interviews.
2. Subject bias- consistent distortions of study variables- knowledge, attitude, etc. Subject can show selective recall of reporting a compliance- use the probes for clarification, reread the questions, use key events, records.

3. Instrument bias- occurs when used the technique inappropriate to objectives-it is necessary the field editing of questions before go to data entry.

Strengths of study.

1. Sample design- probability sample- the results of the study can be generalized.
2. Adjustment for sample design effect - relevant Standard Error formula by $DEFF=1.3$

Limitation of the study.

1. Validity of information obtained- the adherence to treatment information is based on self-report.
2. Recall bias.
3. Interviewer bias- because of different skills of interviewers, regardless of training.
4. Low criterion validity- the instrument was not compared with international standards.
5. Interview setting- household- limitations, distractions, disturbance.

V.HUMAN SUBJECT.

The proposed survey, although the topic of the study is not too sensitive and do not leads to financial loss, do not reduces employability, will meet with following ethical issues:

1. Emotions and disturbance when the respondent describes the details of disease advancement.
2. The asking to remove other members of family for conducting face to face interview.

To address these issues several strategies could be used:

1. Before each interview participant will be introduced the written consent form, includes the nature of research, assure that the participation is voluntary, the confidentiality will be protected.
2. Training interviewers to conduct adequate interactions with subjects of the study, show interest and respect to them, achieve emotional contact with them. Potential threats to confidentiality as well as measures that will be taken should be discussed with study subject, before he decides to participate.

Since the topic of the study is not too sensitive, it is anticipated that participants will probably show the reluctance and willingness to answer on questions frankly and openly. Each interview will have a coding number for ensuring anonymity.

FEASIBILITY OF PROJECT.

The proposed project is feasible because of following considerations:

1. **Technically**- the survey will be conducted by a team, including trained specialist of Public Health, statistician, analyst, who have the experience of participating in survey. The available equipments for analyzing data and statistical packages, office room with supply- supports it.

2. **Logistically**-planned data collection, analyses and evaluation will take a one month period during the March of 2000. However, the frame of time could be shifted according to demands of process. Logically data collection and entry will take a place firstly, then after 15 days will start their job as statistician and analyst.

3. **Administratively** - PH specialist, who had a managerial experience of working both in governmental and non- governmental organizations, will head the research.

4. **Politically**- the health policy makers in Armenia would like to have the data regarding health-directed behavior among hypertensives that contribute in the main public health indicators- morbidity and mortality from CVD in Armenia.

5. **Financially**- the proposed study is not too expensive and the project accomplishment depends on interest and support of NGO-s, as well as MOH. The assistance anticipated from organization with interest to medical and social problems, related with elderly- such as WHO, UMCOR and from Health Department of Yerevan.

VI. BUDGET.

The conduction of qualitative research, development of the questionnaire, as well as the qualitative data collection and analyses have been complied budget on "stage 1"(see Appendix A)

The required budget for stage 2 -survey, analyses, evaluation is presented in Table 5. The justifications of expenditures that would be necessary for each budget item are followings

Training.

For data collection will be hired 6 people, according to their social, behavioral, personal characteristics. These people will receive 2 day training during 6 hours. It is planned that the room for training might be rented at American University of Armenia.

1. It is assumed that trainer will be a specialist and will receive \$20 per day.
2. Cost for room per day will be \$20.
3. Each of interviewers will receive \$5 per day-to cover expenditures for transportation and food. The cost of training will be \$140.

Personnel.

It is planned that each interviewer will conduct approximately 8 interviews per day so 6 interviewers will do 48 interviews a day. Total 693 interviews will be performed during 15-days period.

The proposed salaries are calculated on lowest possible level based on established cost for 1 interview-\$5. Therefore, each interviewer will receive per day \$40 and compensation for food-\$5 (total \$45). Daily expenditures will cost \$270 for 15-days period. Subtotal-\$4050.

1 statistician-for data entering and cleaning with salary \$10 a day-total for 7 days = \$70. One expert analyst with salary \$20 a day-total for 10 days is equal to 200\$.1 evaluator for process evaluation receives \$20 a day-for 30 days -total-\$600. One financial manager receives-\$10 a day -for 30 days - \$300. One co-ordinator for supervising, co-ordinating, monitoring and evaluating process of data collection receives-\$20, for 30 days cost will be \$600.

Total cost \$5820.

Operating cost.

Office-room rent -\$20x30= \$600 for data editing, entry in computer.

Office supply-\$10x30=\$300

Facilities-\$50 a dayx30=\$1500

Transportation 3 cars for 2 interviewers, gasoline cost per 1 liter is \$0.5. Assuming that the cars will spend 10 liters a day for 15 days period cost will be for fuel for 3 cars -\$225. Cars rent for \$30 a day demands \$90 a day. Total for transportation-\$1,575. 3 drivers will be hired with daily wages \$10 for 15 days, it will be \$450.Total for transportation-\$2025.

Total operating cost-7593\$.

Data collection and analyses.

Total 693 interviews multiplying on cost for 1 interview will be \$6, 390. Editing and cleaning data entry into computers (\$1x7days) will be \$7. Total with training of interviewers-\$6,517.

Computers-\$1,000 with appropriate computer program (STATA, Excel, Access).

Printer- \$500.

Miscellaneous-\$200.

Total cost for equipment-\$1,500.

Total budget-\$18,324

Table 5. The budget required for stage 2 –survey.

ACKNOWLEDGMENT.

We would like to thank cordially the Head Doctors and the staff members of polyclinics # 1 and #2 for their assistance in data collection for this study.

We express our gratitude to all staff members of Public Health Department of American University of Armenia. Special thanks to Associate Director Mrs. Sosig Salvador for her interest and advises.

We express our deep gratitude to our adviser Mrs. Kim Arzoumanyanyan for selection the topic of the project, support and advise during the overall process of this thesis project.

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APPENDIX A.

One person on voluntary basis, free of charge (MPH candidate) did the performance of qualitative research and developing the Field Guide and questionnaire for survey. For data collection were needed 21 copies of Field Guide-42 pages. Multiplying 42 on 40 (cost per pages for Xerox) -the overall cost equals to 1,680 Drams. The cost for transportaion-480 drams daily (summary cost for transportation and food-800drams per day). Taking into account that the data collection takes 15 days, the overall cost for stage1-qualitative research - is equals to 13,860 Drams or 28 US\$.

Table 6

The expenses spent on 1st stage.

The expenditures of 1st stage were covered by person free of charge using her own resources.

APPENDIX B

Key informant interview disclosure statement.

Good afternoon, I am a student of Public Health Department of AUA. I am conducting the research regarding the drug compliance in hypertensive patients in Yerevan. Your opinion about this issue, your experience is very important for us. You are free to express your own opinion and be as honest as possible and I will very appreciate it.

I assure that all information received will be kept confidential and will be used only for research purposes.

Your participation in today's activity is completely voluntary. You have the right to stop the interview any time. You are free not to answer on question you consider too sensitive.

The interview will take about hour and I hope you are able to devote this hour.

I am going to take notes during the interview in order not to miss any information from you.

Can we start now?

Thank you, let's begin.

APPENDIX C.

ETHNOGRAPHIC FIELD GUIDE(second version).

The interview should be led by the answers, obtained on open-ended questions for revealing the unexpected issues that could be important. Try to yield complete information regarding the topic, use probes. Read the consent form, ask to sign it after reading. If participant is not agree with any statement in consent form thank him and remove.

1. Opening - My name is _____ I am a student of American University of Armenia. I am doing the research regarding the drug compliance in hypertensives in Yerevan. I am trying to find out the main factors influencing on drug compliance of hypertensives. Your name was taken from local polyclinic. Your experience and opinion will be very important and useful for research. All data will be kept confidential. The interview will take approximately 45m-1 hour. During the interview I am going to take notes in order not to miss any information.

2. Background information.

Age _____

Address _____

Occupation _____

Complete diagnosis _____

3. Question regarding knowledge.

I know that you have a hypertension. What could you tell me about the hypertension? What kind of disease is it? What symptoms it has?

Probe. Is it dangerous? What consequences it has?

Could you describe it in details?

What can you tell about the treatment of hypertension? Could you tell me please, what drugs the hypertensive patient need?

Probe. Is it necessary to use several types of drugs?

Can you tell more about it? When should hypertensive patient measure the BP?

How often?

4. Questions about the attitude toward treatment.

What do you feel is the treatment of hypertension necessary? How long should it be?

Probe. What are the reasons? Why was not it successful?

Do you think that the treatment could prevent the complications of the hypertension?

Probe. Why yes and why not? Describe it in details.

What do you think, are the antihypertensive drugs useful or harmful? Does the treatment bring more benefits or harm?

Probe. Describe it in details.

5. Questions regarding doctor prescriptions of antihypertensive drugs.

How did you receive the information regarding antihypertensive drugs? Did your doctor prescribe you any antihypertensive drugs? Do you remember what recommendations he did regarding the treatment?

6. Behavior related questions.

Describe how you perform the control of Blood Pressure? Is there anyone who helps you?

Do you receive the drugs prescribed by doctors? What are the things that would make you easier to adherent to treatment?

Probe. Anything else?

7. Questions regarding SES.

Can you afford the drugs purchase in today's economic conditions?

Does the polyclinic provide you with any kind of antihypertensive drugs?

What can you add regarding the problem related with treatment of hypertension?

8.Closing.

Thank you for interesting answers and for you spent your time to answer on my questions.

If I need to clarify some of your answers further, can I again apply to you? I would call you if it happened to appoint the time and place. Thank you, good bye.

Table 7. Codes of variables.

APPENDIX.D.

Questionnaire for survey regarding drug compliance in hypertensive patients in Yerevan.

Good day, I am a student of Public Health Department of American University of Armenia. We are conducting the research regarding the current drug compliance in hypertensive patients in Yerevan. We are interested in your opinion and experience about the issue. Your participation in study is completely voluntary. You have the right to stop interview anytime you want. The interview will take 15 min. All information will be kept confidential. Can we start? Thank you.

1. Interviewer _____ Data entry _____

2. Location _____ Time interview started _____

3. Date of interview _____ Time interview ended _____

4. Name of respondent _____

5. Address and telephone _____

Background.

6. Date of birth (day, month, year). _____

7. Gender.

1. Male
2. Female

8. How many members have your family? _____

9. Are you currently employed?

1. Yes.
2. No.

10. What is the level of education you received?

1. School (7years)
2. School (10years)
3. College (2years)
4. Institute/Unuversity (5-6 years)
5. Postgraduate training(*please, specify*) _____
6. Other (*Please, specify*) _____

11. How many years were you diagnosed with hypertension? _____

Question on knowledge about hypertension and its treatment.

I am going to read some statements, please, decide for each statement whether it is true, false, or you don't know.

12. The hypertension is not severe disease, it's just related with age.

1. True. (1 point)
2. False (2points)
3. Don't Know.

13. The headache is the main symptom of the hypertension.

1. True (2points)
2. False (1point)
3. Don't know.

14. Any antihypertensive drug decreases BP and it is not necessary to receive the several drugs, because they affect in a same way.

1. True (1point)
2. False (2points)
3. Don't know.

15. There is no need to receive the antihypertensive drugs, because the BP will normalize after certain time without any intervention.

1. True (1points)

2.False (2Points)

3. Don't know.

16.The treatment is important (necessary), only if the complications of hypertension are already developed?

1.True (1point)

2.False (2points)

3. Don't know.

17.Any hypertensive patient should measure BP.

1. True (2points)

2.False (1point)

3.Don't know.

For following questions read answers, check one of multiple responses.

18.How often should hypertensive patient measure his BP?

1.Daily (2points)

2.Weekly (1point)

3.Monthly (1point)

4.Other (Please, specify)_____.

19. When was the last time that you measured BP?

1.This day (2points)

2.This week (1 point)

3.This month (1point).

4.Other (please, specify)

20. What was your BP when you measured it last time?_____

21. Which symptoms, if any, are indicators that BP is elevated? (check for multiple answers).

1.Dizzy. (2 points).

2.Headache. (2points)

3. Muscle pains.(1 point)

4.Weakness.(1 point)

5. Vomiting.(1 point)

6. Nausea.(1 point)

7. No symptoms (2 points)

8 Don't know.(1point)

22.What complications are the results of hypertension? (check for multiple answers).

1.Stroke (2points)

2. Stomach ulcer (1point)

3.Myocardial infarction (2point)

4. CVD (2points)

5. Blindness (1point)
6. Hearing impairments (1point)
7. Don't know.

23. Did you ever read the instructions that came with the drugs?

1. Yes (2points)
2. No (1point)

24. Where have you learnt about hypertension? (check for multiple answers)

1. Booklets. (2points)
2. Books (2points)
3. Television. (2points)
4. Radio (2points)
5. Doctor (2points)
6. Friends (1point)
7. Relatives (1point)
8. Neighbors (1point)

25. What do you think, is there any necessity in such kind educational material about hypertension and its treatment?

1. Yes (2points)
2. No (1point)
3. Don't know.

ATTITUDE QUESTIONS.

For each statement given please, reply whether you strongly agree, somewhat agree, somewhat disagree, strongly disagree.

26. The hypertension is not severe disease.

1. Strongly disagree (3points)
2. Somewhat disagree (2points)
3. Somewhat agree (1point)
4. Strongly agree. (1point)

27. The hypertensive patient does not need a special treatment.

1. Strongly disagree (3points)
2. Somewhat disagree (2points)
3. Somewhat agree (1point)
4. Strongly agree (1point)

28. Do you feel that the prescribed drugs reduce elevated BP?

1. Strongly disagree (1point)

2. Somewhat disagree (1point)
3. Somewhat agree (2points)
4. Strongly agree (3points)

29. Do you think that the treatment would prevent the complications of hypertension?

1. Strongly disagree (1point)
2. Somewhat disagree (1point)
3. Somewhat agree (2points)
4. Strongly agree (3points)

30. Do you think that hypertensive patient should receive ongoing treatment?

1. Strongly disagree (1point)
2. Somewhat disagree (1point)
3. Somewhat agree (2points)
4. Strongly agree (3points)

31. The antihypertensive drugs are harmful because of their side effects.

1. Strongly disagree (1point)
2. Somewhat disagree (1point)
3. Somewhat agree (2points)
4. Strongly agree (3points)

32. The antihypertensive drugs as chemical components are harmful for organisms.

1. Strongly disagree (3points)
2. Somewhat disagree (2points)
3. Somewhat agree (1point)
4. Strongly agree (1point)

33. What do you feel about the following statement: Antihypertensive drugs should be free like the drugs for certain other diseases (diabetes, nervous diseases)?

1. Strongly disagree (1point)
2. Somewhat disagree (1point)
3. Somewhat agree (2points)
4. Strongly agree (3points)

Questions regarding doctor's prescriptions.

34. What drugs do you use when your BP is high? _____

35. How did you receive the information about those drugs? (read the answers, check for multiple answers).

1. From my doctor (2points)
2. From other familiar doctors (2points)
3. From friends/neighbors (1point)

4. Other (please, specify).

36. Did your doctor from polyclinic provide you with drugs?

1. Yes (2points)

2. No (1points)

37. Did he provides you with...(read the options, check for only one response).

1. All drugs needed (2points)

2. Part of the needed drugs.(1points)

3. Prescription with names of drugs that needed.(1points)

Please, answer on following questions "yes", "no".

38. Did your doctor make any explanations of how the prescribed drugs work?

1. Yes (2points)

2. No (1points)

39. Are you currently taking the medications prescribed by doctor?

1. Yes (2points).

2. No (1point)(skip questions 41,42)

40. Did you ask about prescribed drugs from someone other than your own doctor who has a medical background?

1. Yes (2points)

2. No (1points)(skip question40)

41. Who it was? (do not read the answers, check for multiple responses).

1. Other doctor (2points)

2. Friend/neighbor (1point)

3. Relatives (1point)

4. Other (please, specify).

42. How often are you taking the medications, prescribed by doctor? (check for only one response).

1. Every day (2points)-(skip q. 42).

2. Every week (2points)

3. Every month (1point)

4. Other.(Please, specify).

43. What are the reasons that you do not take your medications daily?(Check for one answer).

1. Cannot afford. (2points)

2. Drugs do not help.(1point)

3. Other(please, specify).

Questions regarding affordability of drugs.

44. Can you afford the purchase of antihypertensive drugs?

1. Yes (2point)

2. No (*1point*)

45. Can you afford the purchase of all of prescribed drugs or part of them?

1. All drugs (*2points*)

2. Part of drugs (*1point*).

46. What is your family monthly income? (*check for only one response*).

1. <50 \$.

2. 50 - 100 \$

3. 100 - 150\$

4. 150 - 200\$

5. > 200\$.

6. Don't know.

47. What would you like to add about the problems associated with drug compliance?

THANK YOU FOR YOUR TIME AND PARTICIPATION.

APPENDIX.E Table8. Sample sizes calculated for each polyclinic in Yerevan, Armenia.

Note: total Yerevan population in 1998 was 1,257,000 , from them - 987,000 adults.

