

Identification of Maternal Risk Factors Responsible for Infant Birth
Defects in Yerevan, Armenia

(Research Grant proposal)

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Executive Summary

Congenital malformations have always been one of the major medical and social problems. Birth defects remain the leading cause of death for infants and among the leading causes for younger age groups in the United States. In Armenia they are the second leading cause of infant mortality. In addition, mortality rate from birth defects increased from 23.9 to 28.5 per 10,000 live births from 1995 to 2003 in Armenia.

Objective of the study: The goal of the study is to explore what factors determine the occurrence of infants' birth defects. The objectives of this study are:

To test the existence of a relationship between infants birth defects and maternal vitamin use, prenatal care, and prenatal exposure to environmental tobacco smoke or infections

To determine the prevalence of above mentioned factors during pregnancy

Methods: A case-control design will be used. A face-to face interview will be conducted with mothers of infants with birth defects and with mothers of infants without birth defects, to define the association between maternal risk factors and birth defects.

Study population: Children on pediatric polyclinic registries aged 0-1 years old and their mothers who are willing to participate in the study and have residence in Yerevan.

Sampling methodology: The Simple Random Sampling method will be used to select 260 cases and 260 controls. Both cases and controls will be obtained from the same pediatric polyclinics in Yerevan and the same district to control for socioeconomic status and environment.

Analysis: Pearson chi-square test of association will be used to identify the associations between each independent and dependent variables. Also simple logistic regression will be performed to calculate odds ratio (OR) and 95 % Confidence Interval (CI) to show the strength of association between variables. To control potential confounders and test interaction between variables multivariate logistic regression will be used.

The overall duration of the study is six months. The overall estimated budget is about seventeen thousand dollars (\$16,834).

It is planned that the results of the study will be used to make appropriate recommendations for developing preventive strategies for birth defects.

Specific Aims

Birth defects are defined as abnormalities of structure, function or body metabolism that are present at birth. These abnormalities can lead to mental or physical disability or are fatal (1, 2). The American College of Obstetricians and Gynecologists states that out of every 100 babies born in the United States, 3 have some kind of major birth defects. Of the 37,520 infants born in 2004, in Armenia, 557 were born with birth defects (N. Davidyan, personal communication, August 16, 2005). Birth defects are lifelong diseases with significant consequences on child development. This is considered a serious public health problem, posing a significant burden in mortality, morbidity and cost.

The aim of this study is to define the main and specific risk factors (maternal vitamin use, prenatal care, and prenatal exposure to environmental tobacco smoke and infections) that are involved in the development of birth defects among infants in Yerevan, Armenia. The research question of the proposed study is the following: what factors determine the occurrence of birth defects?

The objectives of this study are:

- To define the association between infants birth defects and maternal vitamin use, prenatal care, and prenatal exposure to environmental tobacco smoke and infections.
- To determine the prevalence of above mentioned factors during pregnancy.

Since many risk factors of birth defects are known world-wide, this study is a case-control study proposed to investigate the risk factors such as maternal vitamin use, prenatal care, and prenatal exposure to environmental tobacco smoke and infections contributing to birth defects in infants in Yerevan.

The rationale for choosing these risk factors was supported by the following facts. Living standards decreased dramatically in the years following independence which had a

significant impact on the health sector decreasing accessibility to health services for a large segment of the population, especially for vulnerable groups of the population (women and children) (3, 4); Deterioration of living conditions are resulting in poor nutrition of pregnant women and insufficiency of vitamins in their diet (3); Prevalence of men who smoke is very high (3, 5) therefore, the probability of exposure of women (including pregnant women) to secondary smoke is also high.

Background

Birth defect is a physiological or structural abnormality that develops at or before birth and is present at the time of birth (1, 2). There are more than 4,000 different birth defects known ranging from minor (that do not cause harm) to major ones that can result in unavoidable death or require immediate medical intervention (6, 2). Although many of birth defects can be treated or cured, they are among the leading causes of death during the first year of life (7).

Of the 4 million infants born annually in the United States, about 3 to 5 % are born with birth defects (8, 2). Birth defects account for 20 % of all infant deaths in the United States, more than any other single cause and contribute significantly to morbidity and long term disability (7, 8). Congenital malformations have always been one of the major medical and social problems. Birth defects remain the leading cause of death for infants and among the leading causes for younger age groups (7, 9).

According to the data obtained from the National Statistical Service of the Republic of Armenia and Ministry of Health, birth defects accounted for 16.8 % (proportionate mortality rate) of all infant deaths in 1995 and increased to 24.2% in 2003 (10). Furthermore, birth defects are the second leading cause of infant mortality in Armenia (10) (Table 1).

Considering the fact that infant mortality due to birth defects has increased in the recent years in Armenia, the aim of this study is to identify potential risk factors mostly contributing to birth defects (maternal vitamin use, prenatal care, and prenatal exposure to environmental tobacco smoke and infections).

Birth defects can be caused by genetic, environmental or unknown factors. In fact, about 60 % to 70 % of birth defects have unknown causes (8, 11). At the same time many birth defects appear to be caused by a combination of genetic, environmental factors and

multiple exposures present during pregnancy (11, 12).

There are known factors associated with pregnancies that increase the risk of birth defects development. A number of large case-control studies have identified risk factors for birth defects that can be used to develop primary prevention strategies. Evidence from a few case-control studies showed that many of birth defects, for instance, anencephaly and spina bifida (neural tube defects - NTD) might be prevented when mother gets adequate amount of folic acid before (400mg/day) and during pregnancy (800mg/day), especially during the first trimester (13, 14,15). According to the same studies, women using multivitamins or folic acid supplements during the first 6 weeks of pregnancy experienced a three to four fold reduction in spina bifida and anencephaly in their offspring. It has been found that spina bifida and anencephaly are pandemic, affecting 225,000 children a year (16). A survey of women living in Vancouver, Canada aimed at identifying “Folate intakes and awareness of folate to prevent neural tube defects” has shown, that most (95%) of the women had heard of folate, but only 25% knew that it could have prevented birth defects (17). Furthermore, studies have found that dietary folic acid is likely to be inadequate for maximal protection against NTD (14, 15).

Case control studies have shown that maternal smoking during pregnancy appears to increase the risk of having a child with idiopathic clubfoot and the number of cigarettes smoked influence that risk, overall odds ratio (OR) for smoking was 2.4 (95% CI 1.6-3.6) (18). European multicenter case-control study including 161 infants with oral cleft and 1134 control infants, showed an increased risk of cleft lip with or without cleft palate associated with smoking (OR=1.79; 95 % CI 1.07-3.04) and an increased risk of cleft palate associated with alcohol consumption (OR=2.28; 95 % CI 1.02-5.09). The former risk increased with the number of cigarettes smoke (19). Another study states that alcohol use during pregnancy can cause serious birth defects such as fetal alcohol syndrome (FAS). FAS is characterized by

slowed growth, heart problems, mental retardation, and abnormalities in facial features (20).

Exposure to teratogens (any substance that can cause or increase the chance of a birth defect) (21) and drug use (22, 23) during pregnancy are recognized risk factors for birth defects. Exposure to environmental chemicals and ionizing radiation increases the risk of development of embriopathy (fetus disorders) (8, 11, 12). Deferent infections, such as rubella, toxoplasmosis, listeriosis, cytomegalovirus, and syphilis can cause birth defects in the infants of women who have these infectious diseases during pregnancy (12, 24, 25, 26). According to studies epilepsy and diabetes increase the chances of birth defects (9, 22).

Data suggest that the number of birth defects increases with maternal age and for women less than 20 years old. For example, a woman who's 35 has 1 in 350 chances of having a baby with Down syndrome, and a woman who's 45 has 1 chance in 30 (12, 27).

Genetic factors also play a significant role in development of birth defects. The number or structure of chromosomes can cause birth defects (28). Inherited or mutated genes cause Down syndrome (27, 28), achondroplasia (a form of dwarfism), Marfan syndrome (a connective tissue disease), and polydactyl (extra fingers or toes) (1, 27, 28). There is also a form of inheritance called X-linked, such as hemophilia, color-blindness and Duchenne muscular dystrophy (progressive muscle weakness) (1, 28). Genetic disorders are not limited to these syndromes only. They can cause abnormalities in all organ-systems, the clinical appearance of which cannot be identified wholly at the time of childbirth (1, 28).

It is still difficult to identify the specific causes of inborn abnormalitie s because many birth defects appear to be caused by a combination of genetic and environmental factors. Some examples include cleft lip and palate, clubfoot, ankle or foot deformities, spina bifida, anencephaly, and some heart defects (8, 11, 12). Thus, taking into account that birth defect is a lifelong disease with significant consequences on child development and creates an economic burden on the society; the determination of the main risk factors leading to the

development of birth defects is essential for the prevention of the disease.

Situation in Armenia

The economic crisis that Armenia faced after independence had a significant impact on the health sector resulting in a dramatic decrease in the level of health expenditures and a deterioration of the health system (4). During this period, budgetary spending on health care plunged from about 2.7 % of the GDP in 1990 to 1.5 % in 2004 (4, 29).

These conditions have significantly affected the medical demographic situation in Armenia. Birth rate decreased in Armenia from 22.5 per 1000 population in 1990 to 11.2 in 2003 (10). At the same time infant morbidity from birth defects has increased in Armenia in the last years; it increased from 8.3 to 13.8 per-1000 full term births from 1990 to 2003 and from 25.5 to 44.7 per-1000 preterm births from 1990 to 2003 (10). Thus, birth defect is a serious public health problem in Armenia.

Living standards decreased dramatically in the years following independence and currently more than half of the population lives below the poverty line (29). This trend has had negative impact on health status of the population, particularly affecting vulnerable segments of the population including women and children. The diet of the majority of women in Armenia has changed significantly in the recent years. Although not all pregnant women will be able to receive complete vitamin nutrition only through diet, vitamin supplements are rarely taken in Armenia. Women associate them with medicine and think that they may harm the fetus to some extent (personal communication with gynecologists, May, 2005).

In spite of the fact that the prevalence of smoking in women is low (3.1 % compared with 23% of the European region), high prevalence of smoking among Armenian men (67.5

%) contributes to the increase in the second hand (passive) smoking among women. In fact second hand smoke poses a real risk to both a pregnant woman and her unborn baby (8, 11). In Armenia, even if women are aware of the risks of secondary smoke, they often are not in control of their environment. Study conducted by the California Birth Defects Monitoring Program in 1999 showed that mother's smoking (including passive smoking) during pregnancy increased the risk of having baby with oral clefts.

There are a number of steps a woman can take to reduce the risk of her baby having a birth defect. One important step is a pre-pregnancy visit with health care provider. Pregnant women who get adequate prenatal care are more likely to have healthy babies and fewer complications during labor and recovery (2, 8). However, an increasing number of pregnant women in Armenia are not visiting prenatal clinics. Of all 36,824 pregnant women 2,619 (7 %) did not visit prenatal clinics in 2003 and of 37, 839 pregnant women 3,044 (8 %) did not visit prenatal clinics in 2004, in Armenia (30).

No epidemiological studies have been conducted in Armenia to investigate contributing factors of birth defects, despite the public health importance of this issue. The present research addresses the situation of birth defects in Armenia and identifies which factors play crucial roles for the development of birth defects.

Pilot Study

A small study was conducted to pre-test the questionnaire and obtain preliminary data on the birth defect situation in Yerevan. The survey was conducted between July 15, 2005 and August 5, 2005. Three polyclinics (# 19, “Arabkir”, and polyclinic of the “Second Clinical Union”) were randomly selected from all pediatric polyclinics in Yerevan. The cases and the controls were selected from these pediatric polyclinics using the same methodology as described in the study.

From 44 eligible women 40 interviews were obtained, 1 woman refused to respond and 3 women were not at home. 20 mothers of infants with birth defects and 20 mothers of infants without birth defects were interviewed at their home using face -to face interviews. It took about 15-20 minutes to complete one interview. The response rate was 95% among cases (1 out of 21 women was not at home) and 87 % among controls (1 out of 23 one woman refused to participate and two were not at home).

The analysis of the 40 completed questionnaires was performed using STATA 7.0 statistical package. Statistical analysis included descriptive statistics (frequencies, means, and standard deviation) and simple logistic regression.

Demographic characteristics

The mean age of the cases (mothers) was 26.9 ± 3.9 (the age range from 21 to 34) and the mean age of the controls (mothers) was 25.2 ± 4.8 (with the range of 18-36). The mean age of first pregnancy was 24.4 ± 3.3 for cases (with the range of 20-31) and 22.8 ± 3.9 (with the range of 18-34) for controls. All the results of simple logistic regression with demographic characteristics are summarized in the Appendix 1.

Of 20 cases 9 (45 %) had high education, while of 20 controls 16 (80 %) had high

education. The prevalence of the other demographic characteristics such as occupation, medical background, monthly family expenditure, marital status, number of pregnancies, number of children, number of abortion, and miscarriages were similar in both groups (cases and controls).

Gender distribution among infants shows that there are more males than females in the group of cases (60 % vs. 40 % respectively) and equal number of males and females in the group of controls (50 % vs. 50 % respectively).

Maternal risk factors

The results of the pilot study have shown that mothers of case patients more likely to use vitamin during pregnancy (70 % of all cases and 45 % of all controls). About 65% of cases and 80 % of controls mentioned that they made changes in diet during pregnancy.

The study has also revealed that cases have had influenza or other respiratory infectious illnesses and gestoses (toxicoses) during pregnancy two times as often as controls (respectively 80% vs. 40% and 45% vs. 20%).

All mothers received prenatal care from professional providers. Most of the women applied for prenatal check up late in their pregnancy (4th month). However, after the first prenatal care visit almost all women attended the health care facility regularly (at least twice per month). Cases were less likely to receive prenatal consultation during the first trimester (35%) comparing with controls (45%).

According to the results of the pilot study only one woman reported current smoking and smoking during pregnancy (one cigarette per day). However, 80 % of cases and 70 % of controls live in a household in which other people smoke on a daily basis. The majority of cases (69 %) and controls (79 %) reported that family members who smoke regularly were smoking in the same room during their last pregnancy. Compared to controls, cases were less

likely to consider that second hand smoking during pregnancy was harmful for fetus (50 % cases and 60 % of controls).

Drinking is not widespread among women. The overwhelming majority of the respondents 95 % of cases and 80 % of controls had never drunk during the last pregnancy, while 5 % of cases and 20 % of controls used 30-50 ml cognac or wine at least twice during pregnancy.

The results of simple logistic regression analyses with different maternal risk factors and corresponding 95% Confidence Intervals (CI) as well as the total number of responses for each variable are summarized in the Appendix 1.

Methods

Study design

Taking into consideration that the objective of the study is to define the association between the risk of birth defect and maternal vitamin use, prenatal care, and prenatal exposure to environmental tobacco smoke and infections, a case-control design is proposed to investigate the relationship between the dependent variable (outcome) and the independent variables (predictors). This type of study is chosen because of its efficiency. It is relatively short in length, inexpensive, and can study association of a disease with several exposures (it is possible to eliminate the effect of multiple confounders and to test the interaction of number of factors).

Study variables

The dependent variable, birth defect, is defined as a binary variable. Independent variables are maternal risk factors (maternal vitamin use, prenatal care, and prenatal exposure to environmental tobacco smoke and infections) defined as binary. Intervening variables are mothers' age, education, medical background, marital status, socio-economic status, age of the first pregnancy, presence or absence of birth defects among family members or relatives. Summary of the study variables and their measurement scales are presented in table 2.

Table 2. Study variables by name and types

Variables	Type	Measure
Dependent (outcome)		
Presence or absence of birth defect	Nominal/Binary	Measured as 0 (control group) or 1 (cases)
Independent (predictors)		
Maternal risk factors		
Vitamin use	Nominal/Binary	Measured as 0-No or 1- Yes
Prenatal care	Nominal/ Binary	Measured as 0-No or 1- Yes
Prenatal exposure to environmental tobacco smoke	Nominal /Binary	Measured as 0-No or 1- Yes
Prenatal exposure to infections	Nominal/Binary	Measured as 0-No or 1- Yes
Intervening variables		
Family history	Nominal/Binary	Measured as 0-No or 1- Yes
Mothers' age	Numerical	Measured as continuous variable
Age of first pregnancy	Numerical	Measured as continuous variable
Education	Ordinal	Measured as 1-School (8 year); 2-School (10 year); 3-College; 4-Institute/University
Medical background	Nominal/Binary	Measured as 0-No or 1- Yes
Marital status	Nominal	Measured as 1-Married; 2-Single; 3-Divorced; 4-Widowed
Socio-economic status*	Ordinal	Measured as 1-Below 20,000 drams 2 -20,001 - 40,000drams 3 -40,001 – 60,000 drams 4 -60,001 – 80,000 drams 5 -More than 80,001 drams

**Socio-economic status of each respondent was determined taking into account the amount of money respondent mentioned during interview as the sum her family spends on average per month.*

Study population and sampling methodology

The target population is infants aged 0-1 years old living in Yerevan. As was noted earlier, mortality rate from birth defects is high (compared to other causes of infant deaths); it is the second leading cause of all infant deaths during the first year of life. Thus, in order to have incidence cases and to decrease recall bias infants aged 0-1years old will be selected as target population. To have a more representative sample, it is appropriate to choose the samples from all of the 22 pediatric polyclinics in Yerevan.

Sampling frame: Registries in pediatric polyclinics are more accurate and for feasibility of the study the pediatric polyclinics' registration list will be used to identify the

study population. In each polyclinic, a list of infants with birth defect aged 0-1 years and infants without birth defect will be generated. The Simple Random Sampling (SRM) method will be used to select the study population since the list of patients will be available.

Numbers will be drawn randomly between the last and the first ones on the list, sampling without replacement, using a computer (or calculate) generated method. Random sampling will give to every eligible individual an equal chance of being selected. For each case one control will be chosen. Both, the cases and the controls will be obtained from the same polyclinic and the same district to control socioeconomic status and environment.

Definition of cases and controls

According to the World Alliance of Non-Governmental Organizations for the prevention of birth defects and most U.S. governmental and academic organizations birth defect was defined as "Any structural or functional anomaly manifesting at any age of environmental or genetic nature (inherited or not) due to causes acting before birth" Cases are infants with birth defect and their mothers. Controls are infants without birth defect and their mothers.

Inclusion criteria

Eligibility criteria for the selection of sample units are the following:

Children on the pediatric polyclinics registries aged 0-1 whose parents reside in Yerevan.

Mothers of children age 0-1 years; who have Yerevan residence and willingness to participate in the study.

Sample size

To determine sample size for two equally independent samples, the following formula is used

$$n = \frac{\{z_{1-a/2} \sqrt{2P(1-P)} + z_{1-b} \sqrt{P_1(1-P_1) + P_2(1-P_2)}\}^2}{(P_1 - P_2)^2}$$

$$P_1 = \frac{(OR)P_2}{(OR)P_2 + (1 - P_2)} \quad (\text{proportion exposed in cases})$$

P_2 = proportion exposed in controls

The sample size calculation was accomplished using STATA statistical package. Defining the value for $\alpha = 0.05$ (two sided), $\beta=0.2$ (power =0.8), let P_2 denote the estimated exposure among controls (namely, exposure to infections during pregnancy among controls) and = 0.15, then with $OR=2$ (18, 19), $P_1=0.26$, the required sample size was calculated as equal to 229 cases and 229 controls.

Estimated sample size for two -sample comparison of proportions

Alpha = 0.05 (two -sided), Power = 0.8

p1 = 0.2600 and p2 = 0.1500

n1 =n2 = 229

During the pilot study, the response rate, as calculated by dividing the number of completed interviews by the total number of eligible women has been estimated to be 90 %. Thus, it is proposed to select 260 participants in each group to assure the needed sample size in case of non-responses.

Study instrument

The study instrument is a questionnaire comprised of demographic questions and domains on the pregnancy history including maternal health, diet and substance use during pregnancy (Appendix 2, 3). Part of the questionnaire (pregnancy history) was adapted from the Final Report for the Jinishian Memorial Program “Effectiveness of a health education program for pregnant women in Yerevan” (31). The questionnaire has been pre-tested during the pilot study. The average duration of the questionnaire’s completion during the pilot study was about 15-20 minutes.

As a result of the pilot, the questionnaire was minimally changed. Some changes were made in the wording of questions, as well as in some of the skip commands.

Data collection

Data will be collected from the infants' medical records. Also data concerning prenatal exposure to various risk factors will be collected by means of face-to face interviews conducted with the mothers at home. The trained interviewers, upon obtaining the answers from the respondents, will complete the questionnaire. Before answering questions, mothers will be familiarized with the study and will sign the consent form.

Data analysis

Data will be entered into SPSS-11 software package. Double entry and subsequent cleaning will be used to ensure the accuracy of the data entry. Afterwards the data will be transferred to the STATA statistical package and statistical analysis will be carried out.

The chi-square test will be used to identify the association between each independent and dependent variables. Also, odds ratios with 95% confidence intervals will be calculated by simple logistic regression, to assess the strength of association. In order to control potential confounders and test interaction between variables multivariate logistic regression will be used. For the confirmation of the association, the 5% of statistical level is selected. Under the p-value of the chi-square or logistic regression test statistic less than 0.05, it will be concluded that there is an association between the variables of interest. Otherwise, the association will be rejected.

Study Limitations

- Recall bias-typical for case-control studies: Although infants aged 0-1 years old will be selected as study population to minimize this type of bias, the differential recall between cases and controls still can be a source of recall bias.
- Lack of external generalizability: Since the study will be conducted in Yerevan, the results of the study may not be completely generalized to all infants and their mothers of Armenia, especially to those living in rural regions.
- Ascertainment diagnosis bias: Ascertainment of cases and controls was based on medical records from different pediatric polyclinics.
- Selection bias: Exclusion of infants who are registered in maternity hospitals: For feasibility of the study, registries in pediatric polyclinics will be used. Although after the child is born he/she stays in the maternity hospital for a short period of time (on an average 3-4 days) and then they are attached to pediatric polyclinics, in some cases children born with severe birth defects are left in the maternity hospital and these children wind up in the specialized clinic, the orphanage in Gyumri. Thus, these infants with severe cases will be not included in the study population. However, the number of these children is small (3 children in 2004 and 2 children in 2005) and will not bias the results of the study (Table 3). This information was obtained through personal communication with employees from Ministry of Labor and Social Issues.

Ethical Considerations

The AUA committee on Human Research (IRB) approved the study as a grant proposal. Before answering questions, mothers will be familiarized with the study and will sign the consent form. It includes a description of the nature of the research, information about the benefits and risks for the study participants and information that participation in the study is voluntary (Appendix 4, 5). Giving a unique identifier to each interview will ensure confidentiality of participants. Only the study investigators will have access to the name and identification numbers of the participants.

Time Frame for the Study

The time frame for the project will be planned in a way to manage all activities. The duration of the study is anticipated to be 6 months. Before initiating the study, the personnel (9 persons) will be hired. During the first month preparatory work will be performed: appropriate office and supplies preparation, copies of questionnaires. The project assistant will perform the training that aims to standardize interviewers' behavior in asking questions during the first month.

Data collection will take place the next month. Completion of the questionnaire will take approximately 15-20 minutes and it is proposed that each interviewer be able to conduct 5 interviews per day. In addition, interviewers will work with infants' medical records and fill the necessary information into abstract forms. It is anticipated that 5 medical records be reviewed per day. As 4 interviewers will be hired for the project, they will complete about 20 interviews and fill about 20 abstract forms per day. Taking into account that a total of 520

interviews will be conducted and 520 medical records will be reviewed, data collection will require at least 1.5 month (taking into account time for correction and picking up some problems). During data collection coding and data entry will start. Afterwards, during the last two months the data analysis and the preparation of the final report will be performed.

Timeframe

Activity	Months					
	1	2	3	4	5	6
Hiring the staff, preparation of supplies, equipment, copies of questionnaire, etc.						
Data collection						
Data entry						
Data analysis						
Preparation of the final report						

Logistic consideration

Personnel responsibilities

The program coordinator is responsible for all program activities, for the study management and administration. The project assistant is responsible for training the interviewers, as well as for data collection, data entry and analysis. The analyst is responsible for performing statistical analysis of the data and preparing the final report. Four trained interviewers will complete the questionnaires and fill the abstract forms. Each interviewer will conduct a total of 130 interviews and fill 130 abstract forms. The accountant will be responsible for the accounts preparation and the financial statement preparation.

Budget

The estimated budget for implementing the proposed study is 16,834 US \$. This amount is calculated to cover the operational costs (car rent, car maintenance, fuel, office rent, office supplies, communication and electricity), the capital assets (computers, printer, copier) expenses and staff salaries.

Salaries together with taxes comprise about 67 % of total expenditures. The program coordinator will be paid \$600 per month during the six months of the study (\$3,600), the program assistant will be paid \$500 per month during the six months of the study (\$3,000); each interviewer will fill 130 abstract forms and conduct 130 interviews and the cost of the filled questionnaire and abstract form is \$3. The total cost of 520 filled questionnaires and 520 abstract forms is \$1,560. The accountant will receive \$50 per month during the six months (\$200). Two drivers for two months (first two months) will be paid \$400.

The cost of capital assets is about 12 % (\$1,900) of the total expenditures including the cost of two computers (for data entry and analysis), one copier and one printer. The operational cost is covered by 15 % (\$2,580) of total expenditures, including the cost of office rent, office supplies, communication and electricity for six months; also the cost of car rent, car maintenance, and fuel for two months.

The total expenditure for printing and copying the 7- page questionnaires, 2- page consent form, and 1- page abstract form is \$150 ($0.03 \times 10 \times 520$); and additional \$50 is needed for training materials: this covers 1.2 % (200) of the total budget. 5 % of the total budget covers unexpected expenditures (Table 4).

Project Feasibility

The proposed research is feasible due to many factors:

Technical considerations. The survey will be conducted by the special team, including Public Health specialists, who have also skills and knowledge in health statistics. Besides, trained interviewers and analyst with previous experience will perform the study. The office room, office equipment and statistical packages for data entry and data analysis will support the technical feasibility.

Logistic considerations. The duration of the study is anticipated to be 6 months.

Financial considerations The proposed project is not very expensive. However, its implementation depends on the financial support of governmental and non-governmental organizations. Considering the importance of the problem of birth defect, it is anticipated that there are organizations which will be interested in children's health protection and the conducting of this research.

Administrative considerations. The coordinator of the proposed research should have good managerial and communication skills and work experience, which will support and simplify the conducting of the project.

Political considerations. Taking into consideration that birth defects are lifelong diseases with significant consequences on child development contributing to long term disability and create an economic burden on the society, health policy makers of the Ministry of Health should be interested in the project implementation and further preventive strategies development.

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Table 1. Infant mortality by main classification of causes. Infant mortality rate per 10,000 live births from different causes (cause specific death rate), Armenia, 1995 -2003

	Total					Per 10 000 live births				
	1995	2000	2001	2002	2003	1995	2000	2001	2002	2003
Deaths by all causes	697	540	497	450	422	142.4	155.6	153.5	139.6	117.9
Of which										
Infectious and parasitic disease	99 14.2%	56 10.4%	37 7.4%	31 6.9%	27 6.4%	20.2	16.3	11.5	9.6	7.5
Disease of the respiratory system	154 22%	95 17.9%	75 15.1%	56 12.4%	47 11.1%	31.5	27.7	23.4	17.4	13.1
Disease of the digestive system	7 1.0%	1 0.18%	1 0.2%	0	2 0.5%	1.4	0.3	0.3	0	0.6
Congenital anomalies	117 16.8%	134 24.8%	120 24.1%	123 27.3%	102 24.2%	23.9	39.1	37.4	38.2	28.5
Conditions originating in the perinatal period	259 37%	211 39.1%	228 45.9%	207 46%	193 45.7%	52.9	61.1	71.1	64.2	53.9
Accidents, poisoning, injuries	17 2.4%	10 1.9%	7 1.4%	7 1.6%	5 0.96%	3.5	2.9	2.2	2.2	1.4

Statistical Yearbook of Armenia. Yerevan. 2004.

Table 3. Number of infants with birth defects wind up in specialized clinic, the orphanage in Gyumri (Armenia), 2004-2005.

Years	Number of children wind up in specialized clinics			
	In Armenia		In Yerevan	
	From maternity hospitals	Total	From maternity hospitals	Total
In 2004	13	31	3	9
In 2005 (first six months)	-	15	-	2

Personal communication with employees from Ministry of Labor and Social Issues, August, 2005

Table 4. Budget of the proposed study “Identification of Maternal Risk Factors responsible for Infant Birth Defects in Yerevan, Armenia”

	\$	Duration	Total
Personnel	Salary/month		
Program coordinator	\$ 600	6 months	\$ 3,600
Program assistant	\$ 500	6 months	\$ 3,000
Interviewer	\$ 3 /interview	520 interview	\$ 1,560
Data analyst	\$ 300 per month	2 months	\$ 600
Accountant	\$ 50 per month	6 months	\$ 300
Driver	\$ 100 per month	2 months, two drivers	\$ 400
Subtotal			\$ 9,460
Salary taxes			\$ 1,892
average 20% of the subtotal			
Subtotal			11,352
Operational costs			
Office rent for 6 months	\$ 100 per month	6 months	\$ 600
Office supplies	\$ 50 per month	6 months	\$ 300
Communication and electricity	\$ 80 per month	6 months	\$ 480
Car rental and maintenance	\$ 200 per month	2 months, two cars	\$ 800
Fuel cost	\$ 100 per car/per month	2 months, two cars	\$ 400
Subtotal			\$ 2,580
Capital assets			
Computer	\$ 600	2 computer	\$ 1,200
Copier	\$ 400	1 copier	\$ 400
Printer	\$ 300	1 printer	\$ 300
Subtotal			\$ 1,900
Training materials and copying	\$ 100 per month	2 months	\$ 200
Total			16,032
Unexpected expenses	5 % of the total cost		802
Total cost of the project			16,834

Appendix 1. Results of the Pilot Study

Odds Ratios (ORs) associated with mothers' demographic characteristics:

Pilot study, Yerevan, 2005

Variable	Case % (n)	Control % (n)	OR	95 % CI
Age, (years) mean (SD)	26.9 (3.946)	25.2 (4.804)	1.10	0.95-1.28
Age categories:				
Younger (<25) ²	35 (7)	60 (12)	1.00	0.77-10.04
Older (≥25)	65 (13)	40 (8)	2.79	
Age of first pregnancy, mean (SD)	24.4 (3.331)	22.8 (3.932)	1.14	0.95-1.37
Medical background:				
No	80 (16)	70 (14)	0.58	0.14-2.50
Yes	20 (4)	30 (6)		
Education status:				
School (8 year)	5 (1)	00	* ¹	
School (10 year)	50 (10)	20 (4)	6.25	1.21-32.21 †
College	25 (5)	30 (6)	2.08	0.40-10.95
Institute/University ²	20 (4)	50 (10)	1.00	
Education status:				
Low (school 8-10years) ²	55 (11)	20 (4)	1.00	0.05-0.83 †
High (college/university)	45 (9)	80 (16)	0.21	
Marital status :				
Married ²	95 (19)	95 (19)	1.00	0.05-17.18
Single	5 (1)	5 (1)	1.00	
Employment status:				
Employed ²	25 (5)	35 (7)	1.00	(0.41-6.34)
Unemployed	75 (15)	65 (13)	1.62	
Average Monthly Expenditure :				
Below 20,000 drams (below US\$ 50)	10 (2)	0.00	* ¹	
20,001 - 40,000drams (below US\$ 100)	35 (7)	45 (9)	0.65	0.14-3.04
40,001 – 60,000 drams (below US\$ 150)	10 (2)	10 (2)	0.83	0.08-8.24
60,001 – 80,000 drams (below US\$200)	5 (1)	15 (3)	0.28	0.02-3.58
More than 80,001 drams (above US\$ 200) ²	30 (6)	25 (5)	1.00	
Number of abortions, mean (SD)	0.55 (1.669)	0.55 (1.317)	1.00	0.66-1.53
Number of miscarriages, mean (SD)	0.10 (0.308)	0.05 (0.224)	2.1	0.18-25.35
Number of pregnancy, mean (SD)	2.05 (0.212)	2.10 (0.774)	0.97	0.72-1.36
Number of children, mean (SD)	1.55 (0.686)	1.50 (0.761)	1.12	0.46-2.67

† Statistically significant association ($p= 0.05$)

*¹ For this variable the data was insufficient to obtain interpretable results for simple logistic regression

² Reference group

The levels of some independent variables were reduced for the analytic reasons. Mothers' educational level was defined as high (more than 10years of school education) and low (less or equal to 10 years of school education).

OR of birth defects for continues independent variables compared a group that is one year older than another.

Appendix 1. Results of Pilot Study

Odds Ratios (ORs) associated with maternal risk factors during pregnancy:

Pilot study, Yerevan, 2005

Risk factors	% (n)		OR	95% CI
	Cases	Controls		
First prenatal consultation: After 12 week pregnancy ²	65 (13)	55 (11)	1.00	0.18-2.35
Before 12 week pregnancy	35 (7)	45 (9)	0.66	
Vitamin use during pregnancy:				
No	30 (6)	55 (11)	2.85	0.78-10.47
Yes	70 (14)	45 (9)		
Vitamin use :				
During 1 trimester				
No	67 (8)	88 (7)	3.5	0.31-39.15
Yes	33 (4)	13 (1)		
During 2 trimester				
No	50 (6)	13 (1)	0.14	0.01-1.55
Yes	50 (6)	88 (7)		
During 3 trimester				
No	42 (5)	75 (6)	4.2	0.59-30.10
Yes	58 (7)	25 (2)		
Changes in diet during pregnancy				
No	35 (7)	20 (4)	0.46	0.11-1.94
Yes	65 (13)	80 (16)		
Eat more fruits and vegetables:				
No	15 (2)	25 (4)	1.83	0.28-12.07
Yes	85 (11)	75 (12)		
Eat more dairy products				
No	62 (8)	63 (10)	1.04	0.23-4.70
Yes	39 (5)	38 (6)		
Presence of family members who smoke:				
No	20 (4)	30 (6)	1.71	0.40-7.34
Yes	80 (16)	70 (14)		
Second hand smoking during pregnancy				
No	31 (5)	21 (3)	0.6	0.11-3.15
Yes	69 (11)	79 (11)		
Second hand smoking during pregnancy negatively affects the fetus				
No	50 (10)	35 (7)	0.58	0.16-2.10
Yes	50 (10)	60 (12)		
Alcohol use during pregnancy: ¹				
Never	95 (19)	80 (16)	0.21	0.02-2.08
Other	5 (1)	20 (4)		
Influenza/respiratory infectious illnesses during pregnancy:				
No	20 (4)	60 (12)	6.0	1.46-24.69 [†]
Yes	80 (16)	40 (8)		
Influenza/respiratory infectious illnesses during pregnancy:				
During 1 trimester				
No	47 (7)	75 (6)	3.43	0.52-22.8
Yes	53 (8)	25 (2)		
During 2 trimester				
No	38 (6)	38 (6)	1.0	0.17-5.77
Yes	65 (10)	63 (5)		

During 3 trimester				
No	50 (8)	63 (5)	1.67	0.29-9.45
Yes	50 (8)	38 (3)		
<hr/>				
Gestoses (Toxicoses) during pregnancy:				
No	55 (11)	80 (16)	3.27	0.80 - 13.35
Yes	45 (9)	20 (4)		

¹Statistically significant association ($p=0.05$)

²Reference group

¹Nobody chose every day, once a week, once a month options

8. Including yourself how many people usually live in this household?
Record Number _____
9. How many rooms does your apartment /house have, including kitchen, living room, dining room, and bedroom?
Record Number _____
10. On average how much money does your household spend monthly?
- | | |
|--------------------------|--------------------------|
| 1. Below 20 000 dram | <input type="checkbox"/> |
| 2. 20 001 to 40 000 dram | <input type="checkbox"/> |
| 3. 40 001 to 60 000 dram | <input type="checkbox"/> |
| 4. 60 001 to 80 000 dram | <input type="checkbox"/> |
| 5. More than 80 001 dram | <input type="checkbox"/> |
| 88. Don't know | <input type="checkbox"/> |
| 99. Refused to answer | <input type="checkbox"/> |

PREGNANCY HISTORY

SECTION 1. BACKGROUND INFORMATION

1. What was your age at first pregnancy?
Years old _____

	Record number	99.Refused to respond	88.Don't know
2. How many times have you been pregnant?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. How many children do you have ?	<input type="checkbox"/>		
4. How many abortion have you had ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. How many miscarriages have you had?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. How many stillborns have you had ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. How many infants have you had that have died?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION 2. FAMILY HISTORY

8. Is there anybody of your children with the confirmed diagnosis of birth defect?
- 1. Yes (*specify*)
 - 2. No
 - 99. Refused to Respond
9. Were you or your husband ever diagnosed with birth defect?
- 1. Yes (*specify*)
 - 2. No
 - 99. Refused to Respond
10. Is there anybody of your relatives with the confirmed diagnosis of birth defect?
- 1. Yes (*specify*)
 - 2. No
 - 88. Don't know
 - 99. Refused to Respond

SECTION 3. PRENATAL CARE

11. Did you visit prenatal consultation for this pregnancy ?
- 1. Yes
 - 2. No (*skip to Q. 15*)
12. How many times did you visit the prenatal consultation?
- During the first trimester? _____
88. Don't know
- During the second trimester ? _____
88. Don't know
- During the last trimester ? _____
88. Don't know
13. Did you follow your doctor or nurse advice?
- 1. Yes
 - 2. No

SECTION 4. VITAMIN SUPPLEMENTS

14. During your prenatal consultations, did your doctor or nurse talk to you about taking vitamin supplements during your pregnancy?
- 1. Yes
 - 2. No

15. Did you take vitamin supplements during pregnancy?
1. Yes
2. No (*Skip to Q.19*)
16. If yes what vitamin did you take? _____
17. How long did you take vitamin supplements?
Record number _____
88. Don't know
18. When did you take vitamins?
During the first trimester ?
88. Don't know

During the second trimester ?
88. Don't know

During the last trimester ?
88. Don't know

SECTION 5. NUTRITION.

19. Did you make significant changes in your eating habits during your pregnancy?
1. Yes
2. No (*skip to Q. 21*)
20. What changes did you make ?
1. Eat more than usual
2. Eat more fruits and vegetables
3. Eat more frequently in small quantities
4. Eat more dairy products
21. What kind of food did you prefer to eat during this pregnancy?

SECTION 6. SMOKING AND PREGNANCY

22. Do you smoke now ?
1. Yes
2. No

23. Did you smoke during pregnancy?
1. Yes
 2. No (*Skip to Q.25*)
24. How many cigarettes did you smoke per day ?
1. Less than one cigarette a day
 2. One cigarette a day
 3. 3-4 cigarettes a day
 4. 5-7 cigarettes a day
 5. 10 cigarettes a day
 6. More than 10 cigarettes a day
25. Did anyone smoke in your house (husband, father-in-law, etc.) during your pregnancy?
1. Yes
 2. No (*Skip to Q. 28*)
26. Did your husband or others smoke in the same room as you?
1. Yes
 2. No
27. If yes, how much your husband or others smoke in the same room as you?
1. Less than one cigarette a day
 2. One cigarette a day
 3. 3-4 cigarettes a day
 4. 5-7 cigarettes a day
 5. 10 cigarettes a day
 6. More than 10 cigarettes a day
28. Do you know that passive smoking during pregnancy can affect your fetus?
1. Yes
 2. No

Now, I am going to ask about alcohol use during pregnancy.

29. Approximately, how often did you drink alcohol, including vodka, beer, and wine during pregnancy?
1. Every day
 2. Once a week
 3. Once a month
 4. Never
 5. Other _____

30. On the days that you drink, about how many drinks do you usually have each day? (One drink for vodka is equal to 50ml, for wine 150 ml, and for beer 330ml).
- 1. One
 - 2. Two
 - 3. 3-5
 - 4. 6-9
 - 5. 10 and more

Now, I am going to ask about infectious illnesses during pregnancy.

31. Did you have Influenza or other Respiratory infectious illnesses during pregnancy?
- 1. Yes
 - 2. No (*Skip to Q 33*)
32. If yes when did you have those infections?
- During the first trimester ?
 - 88. Don't know

 - During the second trimester ?
 - 88. Don't know

 - During the last trimester ?
 - 88. Don't know
33. Did you have Bladder, Kidney or Urinary Tract infections during pregnancy?
- 1. Yes
 - 2. No (*Skip to Q 35*)
34. If yes when did you have those infections?
- During the first trimester ?
 - 88. Don't know

 - During the second trimester ?
 - 88. Don't know

 - During the last trimester ?
 - 88. Don't know
35. Did you have sexually transmitted diseases during pregnancy?
- 3. Yes
 - 4. No (*Skip to Q 37*)
36. If yes when did you have those infections?
- During the first trimester ?
 - 88. Don't know

During the second trimester ? []
88. Don't know []

During the last trimester ? []
88. Don't know []

37. Did you have the following disease/condition during pregnancy? (*Check all that apply*)

	Yes	No
Gestoses (Toxicoses)	___	___
Diabetes	___	___
Preeclampsia	___	___
Virus Hepatitis		
X-rays	—	—

38. Did you have any other Medical conditions during your pregnancy?

That's the end of the questions I have to ask you. Is there anything you would like to add?

Thank you for sharing your thought with us. Thank you for spending time and effort!
END TIME: _____

³ ÁÇÝ 5. èÝáóÝ¹.

19. æÙè ÑÓÇáóÁÏ³ Ý ÁÝÁ³ óúáóÙ, æ áóÙ ÷ á ÷ áÉ»±É »ù áóí »Éáó Ó»ñ
 èáí áñáóÙÁÝ»ñÁ
 1. æÙá []
 2. àã (æÝó»ù Ñ³ ñó 21) []
20. °Á»³ Ìá, Ç±Ýã ÷ á ÷ áÉáóÁÏáóÝÝ»ñ »ù Í³ ï³ ñ»É (Ýß»ù µáfáñ ÑÝ³ ñ³ í áñ
 á³ ï³ èÉ³ ÝÝ»ñÁ)
 1. Í»ñ»É »ù³ í »ÉÇÝ ù³ Ý èáí áñ³ µ³ ñ
 2. æí »ÉÇ ß³ ï Ùñ»ñ/µ³ ÝÇ³ ñ»Ó»Ý »ù ù· ï³ · áñÍ »É
 3. Í»ñ»É »ù³ í »ÉÇ Ñ³ ×³ È³ ÷ áúñ ù³ Ý³ ÍÝ»ñáí
 4. æí »ÉÇ ß³ ï Í³ ÁÝ³ ÙÁ»ñù »ù ù· ï³ · áñÍ »É
21. Æ±Ýã èÝÝáóÝ¹ çÇù· »ñ³ Ì³ éáóÙ áóí »É³ Ìè ÑÓÇáóÁÏ³ Ý ÁÝÁ³ óúáóÙ
-

³ ÁÇÝ 6. Ì È»ÉÁ ÑÓÇáóÁÏáóÝÁ

22. æ áóÙ Í Èáó±Ù »ù
 1. æÙá []
 2. àã []
23. æ áóÙ Í È»±É »ù ÑÓÇáóÁÏ³ Ý ÁÝÁ³ óúáóÙ
 1. æÙá []
 2. àã (æÝó»ù Ñ³ ñó 25) []
24. ØÇÇÝ á³ ÷ áí, ùñ³ Í³ Ý ù³ ÝÇ± Í È³ Èáí »ù Í È»É
 1. Ø»Í Í È³ Èáí Çó ùÇá ùñ³ Í³ Ý []
 2. Ø»Í Í È³ Èáí ùñ³ Í³ Ý []
 3. 3-4 Í È³ Èáí ùñ³ Í³ Ý []
 4. 5-7 Í È³ Èáí ùñ³ Í³ Ý []
 5. 8-10 Í È³ Èáí ùñ³ Í³ Ý []
 6. 10-Çó³ í »É Í È³ Èáí ùñ³ Í³ Ý []
25. Ó»ñ ÁÝí³ ÝÇùáóÙ áñ³ ç Ù»Í Á (³ ÙáóèÇÝÁ, èÍ »èñ³ ñÁ Í³ Ù³ ÌÉáù) Í Èáó±Ù
 çñ Ó»ñ ÑÓÇáóÁÏ³ Ý ÁÝÁ³ óúáóÙ
 1. æÙá []
 2. àã (æÝó»ù Ñ³ ñó. 28) []
26. Ó»ñ³ ÙáóèÇÝÁ Í³ Ù áóñÇßÝ»ñÁ Í Èáó±Ù çÇÝ ÝáóÙÝ è»ÝÙ³ Í áóÙ áñí »Ó æ áóÙ
 çÇù· ï³ Ýí áóÙ
 1. æÙá []
 2. àã []

27. °Á»³ ðá,³ á³ Ó»ñ³ ÛáðèçÝÁ í³ Û áðñçßÝ»ñÁ ù³ Ýç± íÉ³ Éáí ççÝ
 íÉáðÙ ÝáðÙÝ è»ÝÙ³ íáðÙ áñí »ð áðù ççù · ÿ Ýí áðÙ

- 1. Ø»í íÉ³ Éáí çó ùçá ùñ³ í³ Ý []
- 2. Ø»í íÉ³ Éáí ùñ³ í³ Ý []
- 3. 3-4 íÉ³ Éáí ùñ³ í³ Ý []
- 4. 5-7 íÉ³ Éáí ùñ³ í³ Ý []
- 5. 8-10 íÉ³ Éáí ÿ ùñ³ í³ Ý []
- 6. 10-çó³ í»É íÉ³ Éáí ùñ³ í³ Ý []

28. áðù · çí ±ù, áñ áðñçßÝ»ñç íÉ»ÉÁ ÝáðÙÝ è»ÝÙ³ íáðÙ áñí »ð ÑÓçÝ ç
 · ÿ Ýí áðÙ (á³ èçí í³ Û »ñí ñáñ¹³ ðçÝ íÉ»ÉÁ) í³ ñáð ç³ ½¹»É áí Óç íñ³

- 1. áá []
- 2. àà []

áÙÁÙ »è Ò»½ Ûç ù³ Ýç Ñ³ ñó ÿ ÿ Û³ Ò³ éí áñáé³ ðçÝ ÉÙçáùÝ»ñç ù · ÿ³ · áñí Û³ Ý Û³ èçÝ
 ÑÓçáðÁÙ³ Ý ÁÝÁ³ óùáðÙ:

29. Øáí áí áñ³ á»è, áñù³ ±Ý Ñ³ ×³ É ççù ÉÙáðÙ³ Éí áñáé³ ðçÝ ÉÙçáù
 ÑÓçáðÁÙ³ Ý ÁÝÁ³ óùáðÙ, Ý»ñ³ éú³ É · ÿ³ ñ»çáðñ, ß³ Ûá³ ðÝ í³ Û Éçí ðáñ

- 1. áÙ»Ý ùñ []
- 2. ß³ µ³ Á³ í³ Ý Û»í³ Ý · ÿ³ Û []
- 3. áÙçéÁ Û»í³ Ý · ÿ³ Û []
- 4. °ñµ»ù áçç ÉÙáðÙ []
- 5. áé _____ []

30. áÙÝ ùñ»ñçÝ »ñµ ÉÙáðÙ ççù Ûáí áí áñ³ á»è ù³ Ýç± á³ ÷³ µ³ ÁçÝ ÉÙçáù
 ççù ÉÙáðÙ ùñ³ í³ Ý (Ù»í á³ ÷³ µ³ ÁçÝÁ í³ ½ÙáðÙ ç 330 · ñ³ Û · ÿ³ ñ»çáðñ,
 50ÙÉ ùðç í³ Û 150 · ñ³ Û · ççç)

- 1. Û»í []
- 2. »ñí áð []
- 3. 3-5 []
- 4. 6-9 []
- 5. 10³³ í»Éç []

ΔΌςάδΆλσ Υ ί »νςςΥ »ν»ù σ ÛςεΥ»νς ΆΥΆσ όύάδύ _____
 88.ά· Çì »Ù

37. δόδύ άόΥ»ό»É »ù Υ»νύάΝςβλσ É Νςί σ Υ¹ άδΆδύ»ν/ί Ç×σ Ι Υ»νΑ
 ΝΌςάδΆλσ Υ ΆΥΆσ όύάδύ (ΥΒ»ù μάέάν ΝΥσ ησ ί αν άσ ι σ εÉσ ΥΥ»νΑ)

	2llá	àã
Δ»εϊ ά½ (ί άùεÇÍ ά½)	_____	_____
ρσ υσ ησ Èì	_____	_____
än»-ιÉσ ÛάεÇσ	_____	_____
ι Çñάόεσ ÛςΥ Ν»άσ ι Çì	_____	_____
ε»Υì · »Υ Ν»ì σ ½ái άδΆδύ	_____	_____

38. δόδύ άόΥ»ό»É »ù σ ÛÉ Νςί σ Υ¹ άδΆδύ»ν/ί Ç×σ Ι Υ»ν σ Ûε ΝΌςάδΆλσ Υ
 ΆΥΆσ όύάδύ

ì »νςάδύ ÇΥά Ι όσ Υì σ Υσ Ûςù σ ί »Éσ όΥ»É

ρΥάνΝσ Ισ ÉάδΆδύ Ό»ñ çσ Υù»νς · ι ησ Ûσ ησ Ι Άσ Ûσ Υσ Ις Νσ Ûσ η

Δσ ηόσ ½ñάδύσ σ ι σ ηì Á _____

Appendix 4. English Version of Study Consent Form

American University of Armenia Department of Public Health

Institutional Review Board/Committee on Human Research

CONSENT FORM TEMPLATE

CHR#

Title of Research Project: Identification of the main Maternal Risk Factors responsible for Infants Birth Defects in Yerevan, Armenia.

EXPLANATION of RESEARCH PROJECT:

Hello, my name is Gayane Ghavalyan. I am second year student of Public Health Department of American University of Armenia. As a part of course requirement I am conducting a research regarding Birth Defects. The purpose of this study is to identify potential risk factors mostly contributing to birth defects of infants (aged 0-1) in Yerevan. You have been chosen to participate in the study, as you have a child aged 0-1 year old who has some health problem that we are interested in and who is served in one of the pediatric polyclinics in Yerevan.

PROCEDURES:

Infants aged 0-1 and their mothers will be eligible to participate in the study. Children on the pediatric polyclinics registries aged 0-1 whose parents reside in Yerevan and their mothers who have willingness to participate in the study will be included in the study.

Children more than one year old and children whose parents don't reside in Yerevan will be excluded from the study. Also, mothers who are unwilling to participate in the study will be excluded from the study population.

The interview will take place only once and last 15-20 minutes.

The investigator may stop the procedure if necessary (if he/she realize that the participant is not eligible for the study). We appreciate your participation in this study. The information given by you will be very useful and valuable for this research.

RISK/DISCOMFORT:

There is no known risk for the participants of the study. The research possesses risk, discomfort, and inconveniences the same as encountered in your daily life. We do not think that you will have any problems or discomfort due to participation in this interview.

THIS CONSENT FORM CONTINUES ON THE REVERSE SIDE

Side two (Consent Form template/New Research Project)

BENEFITS:

You will not directly benefit from this study. However, the information provided by you may help to reveal some information about possible factors responsible for birth defects and further development of special program to prevent birth defects.

CONFIDENTIALITY:

All information received will be kept confidential and will be used only for research purposes. These data will be accessible only for the principal investigators of the study. Your names or any other identifying data will not appear in the report. Only aggregate data will be reported. Your responses will be available only for the Public Health department of the American University of Armenia.

VOLUNTARINESS:

Your participation in the study is completely voluntary. It is your decision whether to participate in the study or not. You have the right to stop providing information at any time you wish or skip any question you consider inappropriate. Your refusal to participate in the study or your decision to withdraw from that at any time will not influence your job or study.

WHOM TO CONTACT:

You should ask the person in charge any questions you may have about this research. You should ask him/her questions in the future if you do not understand something that is being done. The researchers will tell you anything new they learn that they think will affect you. The results of the study will be publicly available. The report will maintain in the Public Health Reference Library at American University of Armenia.

If you want to talk to anyone about this research study you should call the person in charge of the study: [Michael Thompson] at [phone number: (3741) 51 25 92 /e-mail: mthompso@aua.am], or [Yelena Amirkhanian] at [phone number: (3741) 51 25 68 / e-mail: yamirkh@aua.am]. The person in charge of the study will answer your questions.

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 (3741) 51 25 68.

If you agree to be in this study, please sign your name below.

Subject's signature (including children, when applicable)

NOT VALID WITHOUT THE COMMITTEE
OF IRB STAMP OF CERTIFICATION

_Witness to Consent Procedures*

Signature of Investigator

Date

CHRNo.

* Optional unless subject is illiterate, or unable to *sign*.

Note: Signed copies of this cogent form must be a) retained on file by the Principal Investigator, b) given to the participant, and c) put in the patient's medical records (when applicable)

Ñ³ Ù³ ñ á³ ÿ ÿ èÉ³ Ý³ ÿ áó Ñ»í ÿ ½áí áÓç Ñ³ Ù³ ñ: Ò»ñ ÿ ÝáóÝÁ í³ Ù³ ÿ ÝÓÁ
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Í³ Ù³ í áñáóÁÙáóÝÁ:

Ò»ñ Ù³ èÝ³ ÍóáóÁÙáóÝÁ ÿ Ìè Ñ»í ÿ ½áí áóÁÙ³ ÝÁ Éçáí çÝ í³ Ù³ í áñ ÿ ÿ ÿ Í³ Èí³ Í ÿ
Ò»ñ ÁÝí ñáóÁÙáóÝçó: áóÙ í³ ñáÓ »ù ó³ Ýí³ ó³ Í á³ ÑçÝ Ññ³ Á³ ñí »É
í »Ó»Í áóÁÙáóÝÝ»ñ ÿ ÿ ñ³ Ù³ ñ»Éáóó ÿ ÿ Éáóè³ ÷»É ó³ Ýí³ ó³ Í Ñ³ ñóç
á³ ÿ ÿ èÉ³ Ý»Éáóó, »Á» Ñ³ ñÙ³ ñ á ÿ Ýù: °Á» ¹áóÙ Ù»ñÁ»ù Ñ»í ÿ ½áí áóÁÙ³ ÝÁ
Ù³ èÝ³ Íó»É í³ Ù³ áñáß»ù ¹áóñè · ³É Íñ³ · ñçó, ³ á³ ÿ ÌÝ áç ÿ Ýíñ³ Ì³ èÝ³ Ò»ñ
áóèÙ³ Ý í³ Ù³ ÿ ÒÉ³ ÿ ÿ Ýùç í ñ³:

áóÙ ¹çÙ»É:

áóÙ í³ ñáÓ »ù ó³ Ýí³ ó³ Í Ñ³ ñóáí ¹çÙ»É Ñ»í ÿ ½áí áóÁÙ³ Ý Ñ³ Ù³ ñ
á³ ÿ ÿ èÉ³ Ý³ ÿ áó ÿ ÝÓçÝ: ¿á³ · ³ ÌáóÙ ¹áóÙ í³ ñáÓ »ù Ýñ³ Ý ÑÓ»É ó³ Ýí³ ó³ Í
Ñ³ ñó, »Á» í³ ÿ ÿ ñí³ Íçó çÝá - áñ µ³ Ý á»ù Ñ³ èí³ ó»É: ð»í ÿ ½áí áóÝ»ñÁ á»í ÿ ÿ
Ò»½ ÿ ÿ ñ³ Ù³ ñ»Ý Ó»éù µ»ñí³ Í ó³ Ý³ Í³ ó³ Í Ýáñ ÿ »Ó»Í áóÁÙáóÝ, áñÝ çñ»Ýó
Í³ ñíçúáí í³ ñáÓ ÿ ÿ ½¹»É Ò»ñ í ñ³: ð»í ÿ ½áí áóÁÙ³ Ý ÿ ñ¹áóÝùÝ»ñÁ
Ññ³ á³ ñ³ ÿ ÿ ÌÝáñ»Ý Ù³ ÿ ÿ á»Éç ÍÉçÝ»Ý: ¼»Í áóÙóÝ»ñÁ Í á³ Ñá³ Ýí »Ý ð²ð,
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»Á» ¹áóÙ çÝá-áñ Ñ³ ñó»ñ áóÝ»ù í³ Ù³ ó³ Ýí³ ÝáóÙ »ù Éáè»É áñ ÿ ÿ ÿ Ù»Íç Ñ»í
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(3741) 512568] í³ Ù³ ð³ ÌüÉ ÁáÙ÷éáÝçÝ [ð»é. (3741) 512592]:

°Á» áóÙ ó³ Ýí³ ÝáóÙ »ù Éáè»É áñ ÿ ÿ ÿ Ù»Íç Ñ»í Ñ»í ÿ ½áí áóÁÙ³ Ý Ù³ èçÝ, ù³ Ýç áñ
Í³ ñí áóÙ »ù, áñ Ò»½ Ñ»í ÿ Ý³ ñ¹³ ñ »Ý í³ ñí »É í³ Ù³ Ò»½ í Ý³ è ÿ Ñ³ èóí »É
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¿éáÓç³ á³ ÑáóÁÙ³ Ý µ³ ÁçÝ Ñ»í ÿ ÿ Ì³ É Ñ»é³ Éáè³ Ñ³ Ù³ ñáí ` (3741) 512568:

°Á» áóÙ Ñ³ Ù³ Ó³ ÌÝ »ù Ù³ èÝ³ Íó»É ÿ Ìè Ñ»í ÿ ½áí áóÁÙ³ ÝÁ, ÈÝ¹ñáóÙ »Ýù Ò»ñ
³ ÝáóÝÁ · ñ»É èí áñ ÿ:

Ø³ èÝ³ Íóç èí áñ³ · ñáóÁÙáóÝ

ð»í ÿ ½áí áÓç èí áñ³ · ñáóÁÙáóÝ

¿Ùè³ Áçí

Reference List

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