

CERVICAL CANCER SCREENING IN ARMENIA

Master of Public Health Thesis Project Utilizing Community Service Grant

Proposal Framework

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Executive Summary

Cervical cancer is the most common form of cancer in the female population and simultaneously the leading cause of cancer death among women. Up to 300,000 women die annually from cervical cancer worldwide. Developing and underdeveloped countries contribute the most to cervical cancer mortality.

Cervical cancer develops over several years, moving through precancerous, early cancer, and finally advanced cancer stages. Detection and treatment of precancerous and early stage of cervical cancer can effectively prevent the progression to invasive disease, which have low survival rates. Widespread comprehensive cervical cancer control programs have helped some developed countries to achieve up to 80% reduction in incidence and mortality from cervical cancer. The best explanation of high mortality from cervical cancer in developing countries is that 60-80% of cases are seen in advanced stages (III & IV), if ever diagnosed, with a low probability of long-term survival. The high cervical cancer mortality rate in Armenia is also due to late diagnosis. One of the main reasons for late diagnosis is low awareness among women especially in rural areas about the importance of regular gynecological observation.

This proposal seeks \$56,000.00 to increase awareness of the importance of regular medical check-ups for cervical cancer. This aim will be addressed by the use of TV and Radio spots explaining the importance of cervical cancer screening, and calling for regular cervical cancer check-ups. This approach is the best way to provide basic educational information that will facilitate change in the attitude of target population toward cervical cancer screening in Armenia.

Evaluation will utilize one group pretest and posttest design. Women visits rate for cervical cancer checks before conducting the program will be compared with the same data twelve months after the program starts. A 30% increase in the visit rate for cervical cancer will indicate the success of the program.

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1. Objectives

The proposal seeks to increase awareness about the importance of regular Ob/Gyn visits in order to be checked for cervical cancer among women of reproductive age (18-45) in Armenia. Increased awareness will result in 30% increase of Ob/Gyn' and family physician visits for cervical cancer checks. This will lead to a higher rate of cervical cancer detection in early stages, and consequently to a decrease in the cervical cancer mortality rate.

2. Introduction

Cancer of the uterine cervix is the most common form of cancer in the female population and simultaneously the leading cause of cancer death among women. (1) Uterine cancers account for approximately 12 % of all malignances in women. (2) From 200,000 to 300,000 women die every year from cervical cancer, the vast majority citizens of developing and underdeveloped countries. (1-4) Invasive cancer of the cervix occurs when abnormally dividing cells, which arise in the outer layer (or epithelium), invade the deeper tissue layers. The resulting mass (or tumor) continues to divide and enlarge as it invades the surrounding tissue. Cells may break off from the primary tumor and spread (metastasize) via the lymphatic or blood vessels to distant sites. The size and degree of invasion of the cancerous tissue will determine the stage of the disease. (1, 5-7)

2.1. Risk Factors

The immediate cause of cancer of the cervix is unknown, but there is strong evidence that risk factors are related to sexual relations of females and males.

- The disease is very rare in virgins (3).

- The incidence is higher in married than in single women and in women who married young or began sexual intercourse early (3).
- The disease is related to socioeconomic conditions – the incidence is higher in the low-income groups than in the high-income groups of a given population (3).
- The incidence rises with the number of pregnancies, although this finding is less consistent (3).
- Circumcision is of unknown significance (3).
- The relationships of herpes simplex type II (HSV 2) and human papilloma-virus (HPV) infections are under extensive investigation (3).
- Smoking and long-term use of oral contraceptives have also been implicated (3).

The use of diaphragms and condoms with or without spermicide creams has been occasionally found protective for cervical cancer (3). In the absence of strong evidence on which is/are the responsible agent(s) and on the effectiveness of any proposed technique to avoid infection, recommendations for primary prevention are empirically restricted to the standard norms for prevention of sexually transmitted diseases and particularly to the use of condoms. This is probably more important for women with conjunctival intraepithelial neoplasias (CIN) /human papillomavirus (HPV) related lesions and for males with known HPV genital infections in order to protect their partners from the virus. If the HPV hypothesis is confirmed, the prospects for a vaccine might substantially alter the perspectives for primary prevention. Avoidance of smoking might also reduce the incidence of cervical cancer. (4)

Cervical cancer is a disease of young women and most commonly occurs around the mid 40s. It can affect a wide age range and women in their 20s may develop the

disease. (3, 4, 14) The incidence rate of cervical cancer varies significantly depending on geographical area. The highest incidence rates are reported in Latin America, South East Asia and Sub-Saharan Africa; the lowest rates in the Middle East, Ireland, and Spain. (1-6) The average age of women with invasive cervical cancer ranges from 48 to 52 years. (1-6)

2.2. Diagnostic Procedures

The most important diagnostic procedures are:

Routine Pap smears which detect stage 0 cancer in an apparently normal cervix before there is any visible evidence of lesion.

The Papanicolaou (Pap) smear is used to screen for cervical cancer to detect lesions when they are still highly curable. The lead time from the development of precancerous lesions to invasive cancer is estimated at 8-9 years. The American College of Obstetricians and Gynecologists (ACOG) recommends obtaining cellular samples from both the endocervical canal (using an endocervical brush) and from the portio, which includes the entire transformation zone. Use of both an endocervical brush and a spatula has been shown to collect a better sample of cells than either a spatula alone, or a spatula used in combination with a cotton-tipped swab. (1-5, 7-9, 12-14)

A recent meta-analysis reports that the ranges for sensitivity and specificity of a single screening Pap test for detecting cervical intraepithelial neoplasia (CIN) grades I and II are from 96% to 99%. Case-control studies have clearly demonstrated that women with invasive cervical cancer were less likely to have been screened compared to controls, and decreased mortality and incidence of invasive cervical cancer have been described in populations following implementation of Pap screening. (12-14)

Two major issues with important public policy considerations are cost and patient compliance. Regular triennial screening would achieve 91%-96% of the benefit of annual screening, while greatly reducing the cost, potential harms, and inconvenience. (13)

Increasing the screening interval from one to three years would reduce the total number of smears obtained by two-thirds. The recommendation of many current guidelines that three initial annual screens be performed has been shown by mathematical modeling to have substantial cost, with little benefit (13). Advocates of annual testing, however, have concerns about patient compliance; women may receive Pap tests at a frequency lower than guidelines, and a three-year interval is more difficult to track than a one-year interval. Results from a mathematical model, however, show that even if women are not screened precisely every three years, screening at four years retains 99% of the effectiveness of the three-year interval. For women over age 65 with a history of regular screening and negative smears, continued screening produces diminishing yields and increasing costs. Screening is more cost-effective, however, for women over age 65 with a history of inadequate screening. Similarly, efforts to expand screening to women who have not undergone regular Pap testing (and who are often at increased risk for cervical cancer) may offer a more dramatic public health benefit than adjusting screening protocols for women who are already undergoing regular testing. (12-14)

The other cervical cancer diagnosis tools are:

- Thorough gynecological examination, including vaginal inspection, vaginal and rectal palpation. The method reveals the clinical extent of disease in the pelvic region (for accurate staging, this should be done under anesthesia). Only rectal palpation allows a thorough examination of the parametria.

- Biopsy of the cervical lesion, where infiltration, ulceration or tumor is clinically evident. The specimen should be taken from the border of the lesion to avoid the necrotic and inflammatory changes which are usually associated with neoplastic growth in this region and which mask the true nature of the disease.
- Curettage. Where to growth is evident, an extensive examination of the endocervical region is necessary. Scraping by curettage or aspiration of the endocervix are possible techniques.
- Colposcopy. Colposcopic examination, using an operating microscope to visualize and further localize abnormal areas for biopsy or removal.
- Cystoscopy. It is of value in excluding bladder invasion.
- The Schiller test. The test in which iodine stains normal (glycogen-containing) cells black, but leaves abnormal (non-glycogen-containing) cells unstained; these nonstained areas are then biopsied.
- Cone biopsy. It is carried out in patients with positive cytology, but no visible lesion. This diagnostic procedure may also be therapeutic for in situ lesions. (2-5)

Most (but probably not all) cancers of the cervix go through this pre-cancerous phase and its detection and treatment can effectively prevent the progression to invasive disease. It is believed that the majority of pre-cancerous changes are caused by infection with the human papilloma virus, or wart virus (HPV) (3, 4, 12). Not all types of HPV cause pre-cancerous changes but certain strains of this virus are more prone to incorporate themselves into the nucleus of the cell and cause abnormal division of that cell which initiates the growth of the abnormal tissue. This process is called neoplasia (new growth).

The time scale from the initiation of the neoplastic process to the development of invasive cancer is usually over many years and therefore regular smear tests can detect this process before invasion occurs. When pre-cancerous cells are identified on a smear, the next step is an examination of the cervix to identify and, where appropriate, treat the abnormal area on the cervix. (3, 4, 12-14)

Accurate staging of cervical cancer is vital in determining optimal treatment. There are two main types of cervical cancer: cancers arising from squamous epithelium (squamous carcinoma), which covers the outer cervix i.e. that portion which protrudes into the vagina, and glandular cancers (adenocarcinoma) arising from the gland bearing epithelium of the cervical canal (leading up to the cavity of the uterus). (5) Squamous cancers are the most common type of cancer of the cervix and it is this type of cancer that the cervical screening program is specifically designed to prevent, although adenocarcinoma may also be detected/prevented by cervical smears. (5, 7)

Clinical symptoms associated with the progress of the disease in the pelvic region are not pathognomonic for cancer. In the early stage, only a slight vaginal discharge and/or bleeding, and irregularities of menstruation, may be noticed, especially following sexual intercourse. As the disease progresses, the infiltration and destruction of several anatomical structures of the pelvic region give rise to different clinical symptoms, their severity depending on the extent of the growth. In the final stage, renal failure secondary to ureteral obstruction by external iliac lymph node metastases usually occurs. This is the most common cause of death. (2-4)

Death from cervical cancer is especially tragic, because unlike many other types of malignant tumors, cervical cancer develops relatively slowly, can be detected by using

simple and cheap diagnostic tools, often even visually, and, if detected in its early stage, can be cured. Widespread comprehensive cervical cancer control programs have helped some developed countries to achieve up to 80% reduction in incidence and mortality from cervical cancer. In developing countries, 60-80% of cases are seen in advanced stages (III & IV), if ever diagnosed, and have low probability of long-term survival. (13-14)

2.3. Screening Program

Although no screening program can be 100% effective, it is estimated that, for example in Pakistan, a cervical cancer screening program prevents between 1,100 and 3,900 cases each year. (11) The aim of cervical cancer screening is to detect abnormalities of the cervix at the pre-invasive stage of the disease. This is usually termed pre-cancer and implies an abnormality of the outer skin or epithelial layer of the cervix, which, if untreated may progress to invasive cancer. Cells shed from an area of pre-cancer may be detected by the cervical smear test. (2-4, 11) No nation has succeeded in conducting a program of sufficient magnitude and quality to accomplish the ultimate aim of essentially eliminating cervical cancer as a cause of death. However, significant progress has been made, since in some countries 70%-80% of all cases are now detected at stages 0 and 1. (11)

2.4. Situation in Armenia

Dr. K. Arustamyan, Deputy Director of The Center of Maternal and Infant Health Protection (personal interview, 12 April 2003), in Armenia stated that mortality rate from cervical cancer in Armenia is high, mainly due to late diagnosis in stages III and IV, when curable treatment is impossible. She further reported that late diagnosis is due to

low awareness of Armenian women, especially in rural area, about importance of regular gynecological examinations. (12)

Women in rural areas generally visit maternity facilities only to deliver or undergo induced abortion. Although almost all the maternal facilities in Armenia are equipped for cervical cancer diagnosis, they are underutilized. (12)

Cervical cancer death rate in Armenia can be decreased by a screening for early detection and effective treatment. Three major elements necessary for a successful cervical cancer screening program are availability of trained physicians, modern diagnostic tools and awareness of women of reproductive age about the importance of regular observations. (9) Although two first major elements necessary for a successful screening program are mainly present in Armenia and only the last one, which poses a problem in Armenia, has to be achieved as a result of the proposed program, there are some minor barriers that need to be mentioned. One of these barriers is connected with financial issues. Gynecological observation is paid medical service in Armenia and although it is relatively cheap (500dram, which is less than \$1) it still can be an obstacle for women from lowest socioeconomic group. The second barrier is transportation. In rural areas there are villages that have no medical facilities and female population of these villages need to reach nearest built up area for cervical cancer screening.

An education program should be conducted to raise women's awareness about the importance of regular gynecological observations for early detection and curative treatment of cervical cancer.

If the women at risk were screened at appropriate intervals, then a major reduction in the incidence and mortality from cancer of the cervix could be achieved.

The female population must be educated and motivated to present themselves for screening at appropriate intervals and to learn to use health services wisely; after two normal smears, it has been suggested that the patient be screened every 3 years. (8, 9)

Personnel must be trained to take Pap smears and sufficient cytotechnologists trained to interpret them while automated cytological techniques are being developed. (13-14)

Screening for cervical cancer by regular Pap tests should be performed in all women who are or have been sexually active, and should be instituted after a woman first engages in sexual intercourse. If the sexual history is unknown or considered unreliable, screening should begin at age 18. At least two initial screening tests should be performed one year apart. For women who have had at least two normal annual smears, the screening interval may then be lengthened at the discretion of the patient and physician after considering the presence of risk factors, but should not exceed three years. Screening may be discontinued at age 65 if the following criteria are met: the woman has been regularly screened, has had two satisfactory smears, and has had no abnormal smears within the previous nine years. For all women over age 65 who have not been previously screened, three normal annual smears should be documented prior to discontinuation of screening. Clinicians should use proper techniques in collecting specimens, should submit them to qualified cytopathologic laboratories for analysis, and should provide appropriate follow up on test results. (7-9, 11, 13-15) In Armenia where cervical cancer mortality is high the screening program for early detection of pre-cancer diseases of the uterine cervix and first stage of cancer could be very effective.

All marzes have medical facilities that can serve as local screening facilities. All rural medical facilities have medical staff that can perform screening. Although only a few centers in Yerevan have the necessary equipment to perform a Pap-smear investigation, cervical cancer screening could be performed using a “Clinical Downstaging” that is unaided visual inspection. Frequency of screening based on Clinical Downstaging is 2-3 years. The screening based on the Clinical Downstaging results in a 30% reduction in cervical cancer mortality.

3. Methodology

The main challenge of this proposal is to encourage the target population of women 30-60 years old to seek regular gynecologist or family physician examinations once every 2-3 years. Traditionally women in Armenia, especially in rural area attend gynecologists only for delivery, artificial abortions and in case of serious reproductive health disorders. The aim of the program is to change this traditional behavior. Behavior change will lead to regular medical facility attendance for gynecological observation. The behavior change will be a result of the education program. It is anticipated that the education program will increase in 30% Ob/Gyn and family physicians visits for cervical cancer checks.

Behavior change is a process that goes through certain steps from knowledge to sustained behavior change.

The education program will be an important component to explain the importance of cervical cancer screening for women’s health and life. The education program will allow increasing attendance of all women for regular gynecological observation thus

increasing rate of early diagnosed cervical cancer cases that are still curable. Importance of regular checks for cervical cancer in order to determine the disease in its early stage and possibility of cervical cancer cure if it is detected in the early stage-these are the messages that the education program has to introduce to the target population. In order to be effective in encouraging health behavior the message of the program has to follow seven basic rules: (16)

Command attention,

Cater to the heart and head,

Clarify the message,

Communicate a benefit,

Create trust,

Call for actions,

Consistency counts (16).

An education program will be designed to reach a certain target population. The target population for cancer screening is all women that can be affected by this pathology. According to literature on cervical cancer these are women of reproductive age and older, irrespective of their race, ethnicity, marital status, educational level, occupation, social status. (1-4) Although some groups of women are more predisposed to cervical cancer development (married women, women in low socioeconomic conditions, elder women) (3, 4) comparing with others we have to include all the women of reproductive age and older when speaking about risk group. Thus the target population for educational program on cervical cancer screening in Armenia should include all women of reproductive age and older.

3.1. Proposed Program

The education program will use TV and radio in order to cover the large target population, all women of reproductive age and older. A half minute publicity TV spot will be prepared. The spot, in a popular form, will explain the importance of a regular medical check-up for avoiding cervical cancer and call upon women to undergo cervical cancer check-up once every third year. The spot will be prepared in collaboration with Ob/Gyn specialists, family physicians and TV specialists. The spot will be broadcasted twice a day two times a week during one year period. The spot will be broadcasted on public TV channel and Armenia TV channel, because the broadcasting of these two TV channels covers the whole territory of Armenia.

3.2. Preparation

In order to find out the best time for the broadcasting (when maximally possible number of target population can be reached by TV) three focus group discussions will be conducted. One focus group discussions will be conducted in Yerevan, with participation of women living in Yerevan, two other focus group discussions will be conducted in two different rural districts of Armenia, with women residing in these districts. This will be done in order to reveal possible differences in attitudes toward TV between residents of the capital and rural area. Free time that could be allocated for watching TV can also differ significantly between Yerevan and rural audiences. In case of discovering of such differences in reality one of the broadcastings of the spot will be adopted to cover Yerevan residents and the second broadcasting of the spot will be done at the same day at time that is most convenient for rural audience.

In order to insure the most complete involvement of the target population into the educational program, another mass media mean – Radio will be used simultaneously with TV. Exploring the benefits of radio are comparatively less expensive than TV. The two minutes radio spot will be created and broadcasted twice a day everyday. The radio spot will more fully (comparing with TV ones) explain the possibility of cervical cancer complete cure in case of early diagnosis, and the importance of regular screening for cervical cancer diagnosis in its early stage. The Radio spot will be prepared in collaboration with Ob/Gyn specialists, family physicians and Radio specialists. The best time for the Radio spot broadcasting will be determined by the same way as it will be done for TV (conducting a focus group discussion).

3.3. Complementation

The education program will be provided as it was described above by the team of obstetricians, family physicians and TV/Radio specialists, who will prepare and broadcast TV/Radio spots.

Generally, complementing the power and reach of mass media, community-based field activities are important, especially for rural areas, for their participatory, normative role (16). Community activities should be an integral part in the overall strategic design (16). But in this particular project, the education materials will be disseminated by the means of mass media and community activities have a contribution to the program. It is anticipated that the information from the spots will be discussed among target population and these discussions will make women more aware about threats of cervical cancer, ways to avoid it and adopt the practice to watch over their health.

3.4. Program Management

Whether the health communication program is run in a hierarchical fashion by one agency or as a team effort, specific individuals or groups need to be responsible for specified activities (16). All the individuals involved should have a clear understanding of their own responsibilities (16). The permanent staff of this project includes manager of the project, project assistant and the monitor of the project. The manager of the project is responsible for organizing all the activities connected with the implementation of the project. To implement this program, additional personnel may be needed (16). This involves recruiting more staff and consultants, particularly ob/gyn specialists, family physicians who will create a medical message of the spots. Commercial advertising and distribution agencies will be needed to shoot the spots. Hiring of the additional staff and cooperation with the distribution agencies is a responsibility of the manager of the project. He is also responsible for organizing the activities in the manner to meet the time table. The project assistant should arrange appointments and organize meetings, keep all the needed materials in folders and computer files, answer calls and many other minor tasks. Regular and accurate monitoring helps ensure that outputs are produced and distributed as planned (16). The project monitor measures whether project activities are carried out as specified in the work plan. Particularly TV/Radio spots must be carefully followed to be checked whether public advertisements are aired on schedule and that broadcast quality is acceptable.

As the educational program will be broadcasted by TV and Radio there shouldn't be need for purchasing any special equipment, as TV/Radio spots will prepared by commercial, advertising and distribution agencies using their own means. For the needs

of the program it is necessary to rent office and buy office equipment: computer, printer, fax, TV, VCR and Radio set.

3.5. Limitations

This project, utilizing TV and radio for educational purposes mostly has certain advantages; but also unfortunately has some weak points. Other than TV/Radio broadcasting approaches (trainings, seminars, lectures) to reach such a big, multifaceted and disseminated all over the country audience seem to be much more expensive, time- and resource-consuming. At the same time, it is necessary to accept that these above mentioned forms of education will definitely provide more detailed and complete information on cervical cancer, its development and prevention. Indeed, TV and radio advertisement spots cannot provide detailed information and knowledge on the topic, rather it is used to introduce the nature of the problem to the target population and to focus attention of the target population. Measuring pro and con arguments, TV and Radio spots remain the best way to provide basic educational information that will facilitate change in the attitudes of the target population toward cervical cancer screening in Armenia.

3.6. Evaluation

Evaluation of the educational program will be done twelve months after launching the program. One group pretest posttest design will be chosen as a design for evaluation of the program. The evaluation will be based on medical records showing the number of women attending Ob/Gyns and family physicians for a cervical cancer check-up. Ten Ob/Gyn facilities and family physician offices in Yerevan, as well as ten in different rural

districts will be selected by convenience. As a pretest the rate of attendance for cervical cancer screening in these facilities will be recorded based on the information from appropriate documents (journals or medical records). Posttest will be done 12 months after the pretest. An average increase of attendance for cervical cancer check-up of 30% will demonstrate success of the program. Several variables can affect internal validity of the evaluation based on pretest-posttest design. Time is the first and the most important variable that can confound the results of evaluation. It is known that the possibility of the influence on the posttest of any event other than our activity increases with the increase of duration of time between pre and post test. (17) Thus time gets serious meaning for questioning plausibility of evaluation since long 12 month period between pretest and posttest. It will also be difficult to control for another confounding variable, Maturation that means changes in psychological perception of study population regardless of our intervention. (17) Other study compounding variables seen not to be so important for this particular evaluation.

4. Budget

Budget of the program will cover expenses connected with the designing and creation of the TV and Radio spots, buying of TV time on two channels (Public and Armenia TV channels), and Radio time, and cost of conduction of three focus group discussions and evaluation of the program will also be budgeted.

Creation of TV and Radio spots of half minute duration will cost approximately \$1200.00. This includes the technical expenses as well as the salaries of the team of TV specialist and physicians, who will create TV and Radio spot.

A minute of broadcasting on public TV channel costs \$180.00.

A minute of broadcasting on Armenia TV channel costs \$120.00.

Thus total expenses for one week of half minute broadcasting of TV spot twice a day two days a week on two TV channels will cost \$600.00.

A minute of broadcasting on National Radio channel costs \$6.00.

Thus total expenses for one week of broadcasting of Radio spot twice a day everyday will cost \$168.00.

These are the main expenses connected with educational program.

Also budget of the project will cover renting apartment for the office, purchase of the computer, fax, printer, TV, VCR and Radio set. The salaries of the permanent staff will also be included in the budget.

See all expenses in the following table:

BUDGET TABLE	
NAME	AMOUNT (USD)
TV & Radio spot	1200.00
TV BROADCAST	
TV CHANNEL	AMOUNT PER MINUTE (USD)
Public TV channel	180.00
Armenia TV channel	120.00
SUBTOTAL FOR ONE YEAR	31200.00
RADIO BROADCAST	
RADIO CHANNEL	AMOUNT PER MINUTE (USD)
National Radio channel	6.00
SUBTOTAL FOR ONE YEAR	8736.00
OFFICE EQUIPMENT	
NAME	AMOUNT (USD)
Computer	800.00
Fax	200.00
Printer	300.00
TV	280.00
VCR	130.00

Radio set	60.00
SUBTOTAL	1770.00
SALARIES	
POSITION	AMOUNT PER MONTH (USD)
Project Manager (12 months a 500)	6000.00
Project assistant (12 months a 200)	2400.00
Monitor (12 months a 350)	4200.00
SUBTOTAL FOR A YEAR	12600.00
TOTAL	55506.00

5. Ethical Considerations, Community Support

The program needs individual acceptance and community support in order to achieve its objectives. It is anticipated that the program will meet community support since it does not violate or put in question any national or religious traditions of perceptions rather it aims to modify women's behavior according to their improved knowledge about cervical cancer.

An educational program will not violate human rights in any way.

Long educational period (12 months) will lead to wide coverage of target population by program and result in sustainable behavioral change.

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