

Effect of applying post medical school graduates to intensive mobile outreach for cervical cancer screening on prevalence of Pap testing in rural Dominican towns

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A. Study Purpose and Rationale

Cervical cancer is the third most common cancer worldwide and, for women, the second most common after breast cancer. Each year there are about 466,000 new cases globally, and around 232,000 women die of cervical cancer. Eighty per cent of cases occur in developing countries, where it is the leading cause of cancer-related death among women.¹ Because precursor lesions (high-grade dysplasias) precede the development of cancer by years, appropriate screening programs and early diagnosis and treatment, cervical cancer is a preventable public health problem. Data for the past 5 years however, show that only about 5% of women in developing countries are screened, compared with 40/0-50% of women in developed countries. Vaccine testing against the implicated viruses HPV 16 and HPV 18 has been hopeful, however clinical trials are ongoing and release of the vaccine worldwide remains uncertain.² Yearly screening through Papanicolaou (Pap) testing for cervical cytology remains the standard of care for early detection of precancerous lesions. Barriers to the routine widespread use of screening via Pap testing in developing nations include cost, education and access to medical care. Intensive education and mobile outreach has been shown to increase education in rural towns of Thailand.^{3,4}

The Dominican Republic (D.R.) in particular is a nation where cervical cancer is the most common cancer among women and it is diagnosed most frequently at stage III or stage IV. As in many developing nations the Dominican population lives in large part in rural areas. The health care infrastructure in these rural regions includes a system of rural service for medical school graduates (MSG) who are obliged to spend a year in rural health clinics prior to beginning residency training. Such training is not uncommon in other developing nations as well. The work done during this service time is dedicated to staffing health clinics.

The hypothesis is that providing a modest educational curriculum, review of cervical cancer screening guidelines, a Pap testing teaching module and a mobile outreach plan for MSG health care providers would positively impact screening at a modest cost. Such a model could help bring screening to developing nations who require rural health service of their medical school graduates.

B. Study Design and Statistical Analysis

This is a prospective prevalence study. The goal is to determine the proportion of eligible women who are obtaining Pap testing when an educational program and health care providers are assigned the task of screening and outreach. Twenty comparable rural towns will be randomized to either usual care (Pap testing upon request) or aggressive education, mobile outreach and Pap testing. Each town will have

¹ Ferlay J, Bray F, Pisani P, Parkin DM. GLOBOCAN 2000: cancer incidence, mortality and prevalence worldwide, version 1.0. IARC CancerBase No.5. Lyon: IARC Press, 2001. Available (in part) at: <http://www-dep.iarc.fr/jglobocan/jalobocan.html> (accessed April 2004).

² Koutsky LA, Ault KA, Wheeler CM, et al. A controlled trial of a human papillomavirus type 16 vaccine. *N Engl J Med* 2002; 347: 1645-1651.

³ Swaddiwudhipong W, Chaovakiratipong C, Nguntra P, et al. A mobile unit: an effective service for cervical cancer screening among rural Thai women. *International Journal of Epidemiology* 1999, 28: 35-39.

⁴ Swaddiwudhipong W, Chaovakiratipong C, Nguntra P, et al. Effect of a mobile unit on changes in knowledge and use of cervical cancer screening among rural Thai women. *International Journal of Epidemiology* 1995, 24: 493-498

an assigned MSG who will work there. Pap smears done at other local sites will also be included in the prevalence. For a power of 80% and to identify an effect of 10% between groups ten MSGs will be required in each arm of the study. The unpaired t-test will be used to compare a change in proportions of women tested from the baseline year to the year of the study, The variable will be the change in the percentage of women who are tested in each town compared to the baseline year such that the percentage of women tested in each arm will have a mean and distribution. This will help take in to account differences between MSGs and towns. Prevalence of Pap testing in each town will also be compared to the Pap testing rates of the year before.

Each MSG would receive a teaching module as well as a census of the town. An attempt to screen all eligible women in each town would be made. Women would receive education, a personal invitation to have screening and have a Pap smear done at no additional cost.

Before randomization, towns will be matched for: size, age distribution among women, distance from major city hospital, distance from health center, percent of the town that has seen health care agent in past year, percent of women with history of one or more sexually transmitted diseases, socioeconomic status and level of education.

a. Primary outcome measure

- rate of Paps in towns with and without the intervention.

b. Secondary outcome measures

- prevalence of cervical cancer
- prevalence of cervical intraepithelial neoplasia (CIN) lesions
- prevalence of HPV,
- STD prevalence
- assessment of patient knowledge of cervical cancer
- prevalence of known risk factors (smoking, sexual activity < 18 y, multiple partners, low SES).

C. Study Procedure

Towns are matched for certain characteristics (see above) and then separated into two groups. Each student upon graduation is assigned to a town for service per the current system. All MSGs who are assigned to one of the ten selected towns will be provided with a review of WHO guidelines for Pap testing and a review of the procedure. Gyn screening will include Pap testing, gonorrhea and Chlamydia testing, Those MSGs who are placed at intervention sites will also undergo training to teach, distribute information, provide outreach and to document survey data. MSGs will launch a week-long education and invitation campaign by walking through public areas of the towns using known census data.

Those women who present to the health clinic will: be consented verbally and in written format via the consent form, receive a survey, undergo Pap testing including HPV DNA testing and standard STD screening. Pap smear tests will be sent to the large regional hospital of Hospital Jose Maria Cabral y Baez in Santiago. Positive results will be reported to patients who will be referred to the regional hospital for colposcopy and/or other treatment.

D. Study Drugs

N/A

E. Medical Device

N/A

F. Study Questionnaires

A questionnaire to assess patients' knowledge of cervical cancer screening, Pap smear availability, as well as a survey of demographics will be issued to patients. Data will be gathered by trained medical school graduates.

G. Study Subjects

Study subjects will include all women that have not had a hysterectomy who are either over the age of 18 years of age or sexually active.

H. Recruitment of Subjects

All appropriate women in those towns randomly selected to participate in the intervention arm will be approached for inclusion.

I. Confidentiality of Study Data

Survey data will be stored in a unique location, accessible only to investigators. Study data will be coded with a unique code. Results will also be documented by the MSG in the subject's medical chart.

J. Potential Conflict of Interest

None

K. Location of Study

Twenty rural towns outside of Santiago.

L. Potential Risks

Patients will be subject to the discomfort of Pap smear testing and potentially the need for further testing if a positive test result is obtained.

M. Potential Benefits

Education for self and family members as well as diagnosis of precancerous or cancerous cervical lesions and referral for treatment. Patients will also have the benefit of STD education and testing and referral for treatment for positive results.

N. Alternative Therapies

N/A

O. Compensation to Subjects

N/A

P. Costs to Subjects

N/A

Q. Minors as Research Subjects

N/A

R. Radiation or Radioactive Substances

N/A

Survey:

ID Code: _____ Date of Birth: _____

Birth place: _____

	1	2	3	4	5
Level of education Completed	Primary	Secondary	Other non-secondary	College	
Number of people per room in household	< 1	1-1.9	2-2.9	>3	
No. of pregnancies	0-2	3-4	>5		
No. of lifetime sexual partners	0-1	2-3	4-9	>10	
Age at first coitus	>19	<19			
Smoking	1/2 pack per day or more	>1 00 cig ever	No		
Hormonal Contraception	No	Yes	I don't know		
Barrier contraception	No	Yes	I don't know		
History of Chlamydia	No	Yes	I don't know		
History of gonorrhea	No	Yes	I don't know		
History of trichomonas	No	Yes	I don't know		
Have you ever heard of cervical cancer?	No	Yes			
How common is cervical cancer among cancer-related deaths in women?	Not very common	Very common	One of the most frequent	I don't know	
Do you know anyone with cervical cancer?	No	Yes			
Have you heard of the Pap test?	No	Yes			
Have you ever had a Pap test?	No	Yes			
What were the results of your Pap test?	Normal	CIN lesion	Cancer	I don't know	N/A
Do you know how frequently women over the age of 18 should be tested?	No	Yes			
Are there any other reasons you have not had a Pap test?					

Official Use:

	1	2	3	4	5	6	7
Pap testing performed	Yes	No					
Symptoms of Irregular bleeding, post coital bleeding or pain.	Yes	No					
Pap test visual findings	Normal cervix	Exophytic lesions	Mass	Discharge	Erythema		
Pap test results	Normal	ASCUS	CIN I	CIN II	CIN III	Carcinoma (any stage)	Poor sample
Gonorrhea testing	Normal	Positive	Not done				
Chlamydia Testing	Normal	Positive	Not Done				
Trichomonas	Normal	Positive	Not Done				
History of Pap in chart	Yes	No	#				
Ever had abnormal Pap	Yes	No	Year				
Was there a follow-up Pap?	Yes	No					

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