RESEARCH COMMUNICATION

Cost Effectiveness of a Program to Promote Screening for Cervical Cancer in the Vietnamese-American Population

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Abstract

Objectives: To conduct a randomized controlled trial to evaluate the cost effectiveness of a lay health worker-administered cervical cancer screening intervention for Vietnamese-American women. Methods: The study group included 234 Vietnamese women in the Seattle, Washington area who had not received a Pap test in the last three years. Experimental group participants received a lay health worker home visit. The travel distance and time spent at each visit were recorded. Our trial end-point was Pap smear receipt within six months of randomization. Pap testing completion was ascertained through medical record reviews. Results: For all Vietnamese women, regardless of their prior history of screening, the cost per intervention was $104.0 (95% CI: $89.6-$118.4). The change in quality-adjusted life days per intervention was 1.26 (95% CI: -5.43-7.96), resulting in an incremental cost-effectiveness ratio (ICER) of $30,015 per quality-adjusted life year. The probability that the ICER exceeds $100,000 is 9.1%. Conclusions: The degree of cost effectiveness of such interventions is sensitive to the assumed duration of behavioral change and the participants' prior history of screening.

Keywords: Cervical cancer - screening - cost effectiveness - lay health worker

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Introduction

According to the US Census Bureau, the cervical cancer incidence rate among Vietnamese-American women is over twice the cervical cancer incidence rate among non-Latina white women (16.8 versus 8.1 per 100,000) (Miller et al., 2008). Survey data reveal that only 70% of Vietnamese women aged 18 years and older had received Pap testing in the previous three years, compared to approximately 85% of other women (Holtby et al., 2006). Sexually active women with an intact uterus should be screened for cervical cancer at least every three years, depending on their risk factors for disease and previous screening history, according to American Cancer Society and US Preventive Services Task Force guidelines (Saslow et al., 2002; US Preventive Services Task Force and Agency for Healthcare Research and Quality, 2003).

One possible remedy to this problem is a program of interventions by lay health workers. Although not certified health care professionals, these workers have been trained to promote health and/or provide healthcare services (Freeman et al., 1995; Mock et al., 2007).

In this report, we report findings from a cost-effectiveness evaluation conducted alongside a randomized controlled trial to evaluate the impact of a lay health worker intervention aimed at improving cervical cancer screening among Vietnamese immigrants in Washington State (Taylor et al., 2010). Because agencies are constrained by their limited budgets, our findings have implications for agencies that may consider funding such interventions vs. other uses of limited resources.

Materials and Methods

Description of the Community Lay Health Worker Trial

The study was a prospective, randomized, controlled trial of lay worker interventions to improve adherence to cervical cancer screening among Vietnamese women who had never been screened or who had failed to adhere to the recommended schedule of screenings.

Institutional Review Board approval was granted on November 23, 2005. Informed consent from each participant was obtained during the initial survey of Vietnamese women.

Patient Population

The trial was conducted in 33 zip codes within the metropolitan Seattle geographic area. Trial participants were selected from a group of women of Vietnamese descent who participated in a baseline, community-based survey over a 12-month period during 2006 and 2007 (Coronado et al., 2008). Vietnamese women were eligible for baseline survey participation if they were aged 20-79 years and able to speak Vietnamese or English.

The 234 baseline survey respondents who were with uteri and non-adherent to guidelines for interval Pap testing were randomly assigned to an experimental group or a control group. Because interval Pap testing is no

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longer recommended for women aged 70 to 79 years who have a history of previous testing, survey respondents in this age-group were only randomized if they had never been screened (Saslow et al., 2002). Women aged 20-69 years were randomized if they had not been screened for cervical cancer in the previous three years. The random assignment was performed separately for the 106 women who had never received a Pap smear and the 128 women who had received at least one Pap smear (but had not been screened recently).

Intervention

After random assignment, individuals in the experimental group received a cervical cancer lay health worker intervention. Control group participants received a mailing of physical activity print materials (pamphlet and fact sheet), as well as a pedometer with instructions for use. Our primary trial outcome was Pap testing completion within six months of randomization. Outcome ascertainment was based on both follow-up survey responses and medical record reviews. All study materials were translated into Vietnamese using standard methods (Eremenco et al., 2005). Project personnel with direct participant contact (survey interviewers and lay health workers) were all bicultural, bilingual Vietnamese-American women. Detailed descriptions of our baseline survey methods are provided in an earlier article (Coronado et al., 2008).

Cost-Effectiveness Evaluation

The incremental cost-effectiveness ratio (ICER) of the intervention vs. control, expressed as costs per quality adjusted life year (QALY), was calculated from the societal perspective over the individual's lifetime starting from the age at which the intervention takes place. Future costs and health states were discounted at 3% per annum. Data from the controlled trial provided estimates of the cost of the intervention, the change in Pap test frequency between the two arms of the trial and the age distribution of the target group. The number of years since the previous Pap test was assumed to be six. Other costs related to the intervention (e.g., treatment of cervical cancer), efficacy of Pap smear screening, survival and quality of life (expressed as health state utilities) were based on previously published sources. We constructed a simulation model to project the benefits of screening beyond the trial to a lifetime perspective. The reported ICER is population-weighted across each of six age groups recruited in the trial (20-29, 30-39, 40-49, 50-59, 60-69 and 70-79). The age of the patient when the intervention took place was set to the median age of each age group.

Within Trial Economic Data Collection

Survey forms were created to estimate variable costs associated with the intervention. To estimate these costs, lay health workers maintained records of each attempted home visit, noting the miles travelled and time spent. The mode of transportation to each home was by automobile. However, no information on visiting routes was recorded and therefore it is unknown whether the lay health workers minimized their transportation costs.

Modeling Costs and Outcomes beyond the Trial Horizon Intervention ICER vs. Pap ICER

An ICER is the ratio of the incremental cost and the incremental QALY of a medical procedure or health-related intervention. Incremental refers to the difference between the intervention of interest and the next best alternative intervention. The Pap ICER measures the cost-effectiveness of a Pap test regimen whereas the intervention ICER measures the cost-effectiveness of a program intended to increase the frequency of Pap tests. The formulas for calculating the values of the two ICERs are related as follows:

$$\text{Pap ICER} = \frac{\text{Incremental Pap Cost}}{\text{Incremental QALY}}$$

$$\text{Intervention ICER} = \frac{\text{Cost of intervention} + (\text{Incremental Pap Freq} \times \text{Incremental Pap Cost})}{\text{Incremental Pap Freq} \times \text{Incremental QALY}}$$

where Incremental Pap Cost=cost of a Pap test-cost of not having a Pap test, Incremental QALY=QALY with a Pap test-QALY without a Pap test, Incremental Pap Freq = frequency of Pap tests with lay health worker intervention -frequency without intervention and Incremental Pap Cost=cost of Pap tests with intervention -cost of Pap tests without intervention.

Event Pathway

The event pathway follows screening and diagnostic recommendations by the American College of Gynecology (Wright et al., 2007), accounting for patient adherence. In both the lay worker intervention and control population, there is a chance that a woman will be screened for cervical cancer. Screening results can be normal or abnormal. Abnormal Pap smear results are treated one of two ways: advised to wait for the results of the next scheduled screening or have a colposcopy-directed biopsy to confirm the finding of pre-cancerous lesions. Women who do not screen or miss scheduled screenings are at risk for developing invasive cervical cancer.

Because screening is scheduled to occur regularly, to project outcomes beyond the trial horizon, we used a state-transition Markov process model with yearly intervals. All calculations and transition probability calculations were performed using an Excel spreadsheet application. A transition probability is the probability of transitioning from one state, i.e. cancer-free, to another state, i.e. cancer.

Duration of Efficacy Lay Worker Intervention

The trial measured the efficacy of the lay health worker intervention for the first six months following the intervention. Our baseline calculation assumes the efficacy of the intervention lasts for two screenings three years apart.

Cost of Lay Worker Intervention

The lay health workers tracked the time and travel distance of each home visit. The hourly wage rate was $22.26, including costs of fringe benefits. The cost of travel distance was set to the federal travel reimbursement rate for 2008, i.e. $0.505 per mile.

Costs of Cervical Cancer Screening and Related Tests and Procedures

The costs of tests and procedures were based on the Resource Based Relative Value System (RBRVS). We used the non-facility Medicare payment amounts of HCPCS/CPT codes for King County, Washington in 2008. The codes for obtaining a Pap test, screening by the physician, colposcopy-directed biopsy of the cervix, cautery of the cervix and an office visit are Q0091($40.37), P3001($24.76), 57455($142.49), 57510($131.51) and 99201($38.27) respectively.

Probabilities of Abnormal Test Result

The estimated probability of an abnormal pap test was derived using the National Health Interview Survey (NHIS) Cancer Screening subsamples taken in 2000 (National Center for Health Statistics, 2002) and 2005 (National Center for Health Statistics, 2006). The respondents represented the entire US female population, not just Vietnamese-American women. We estimated a population-weighted logistic regression model. The dependent variable equaled 1.0 if the respondent had ever had an abnormal result from a Pap test and zero otherwise. The number of years since the respondents last Pap test was not recorded. Therefore, to control for the number of years since the last Pap test, the sample was restricted to women who claimed to have a Pap test annually. The probabilities of having an abnormal Pap test result adjusted for age and the number of years since the previous Pap test were estimated using the results of the logistic regression model.

Probability of Incurring Additional Procedures

For the probabilities of follow-up exams and procedures we used the answers to two NHIS questions for respondents reporting an abnormal Pap test result: (1) “did you have any additional follow-up exams or tests?” and (2) “did you have surgery or other treatment?” We assumed the follow-up exam or test was a colposcopy-directed biopsy (CPT code 57455) and the treatment was a cautery of the cervix (CPT code 57510).

Incidence of Cervical Cancer

For our purposes, we needed to estimate the incidence of cervical cancer for each of the two arms of the trial. To determine the change in cancer incidence caused by a Pap test, we estimated incidence as a function of age and the number of years since the last Pap test was taken using data from three different sources. The distribution of years since the last Pap test among screening eligible women was based on 2005 NHIS data (National Center for Health Statistics, 2006). We restricted the sample to women who specified their race to be “Other Asian”. This excluded Chinese, Filipino and Indian Asians. The incidence of cervical cancer by age was estimated with data from the Surveillance, Epidemiology and End Results (SEER) program (National Cancer Institute, 2009). We restricted the sample to Asian/Pacific Islander women ages 20 to 79. The relative protection by year from testing was based on data from the International Agency for Research on Cancer (IARC Working Group on evaluation of cervical cancer screening programmes, 1986).

SEER provides an estimate of the incidence of cervical cancer for all women in each age group regardless of frequency of Pap test. The IARC provides estimates of the relative protection from cervical cancer provided by Pap tests for different time intervals. To estimate the change in cervical cancer incidence associated with a Pap test, we needed to calculate the average protection experienced by the current population. We were able to do this by using the distribution of years since the last Pap test for the US adult female population from NHIS in combination with the data from the IARC. Our calculations resulted in an average protection of 6.4 years. To calculate the incidence of cervical cancer for a specific age group and number of years since the last Pap test, we multiplied the average incidence for the age group (from SEER) by the relative protection for the number of years since the last Pap test (from IARC) divided by the average relative protection for all women.

Cost of Treating Cervical Cancer

The costs of treating cervical cancer for the three stages at diagnosis (localized, regional and distant) were found in Goldie, Kim & Wright (2004). These three costs were converted from 2001 US dollars to 2008 US dollars using the Consumer Price Index (CPI). The converted values were Localized: $26,178, Regional: $28,017 and Distant: $44,874. Due to the age of these estimates, we compared the converted values to a more recent study by Insinga, Ye, Singhal & Carides (2008). Insinga et al. estimated the average cost of treating cervical cancer for all stages in the US in 2008 to be $29,649. This estimate corresponds closely to the converted values from Goldie et al.

Life Expectancy

The change in life-expectancy caused by cervical cancer is calculated from life-expectancy tables found in Arias (2007) and the age-adjusted relative five-year survival rate (74.3%) found in the National Center for Health Statistics (2007). A detailed explanation of the calculation method for the life-expectancy tables is provided in Anderson (1999).

Utility Weights

We used the health and activity limitation index (HALex) values developed by Gold Franks, McCoy & Fryback (1998) to determine QALY values for normal health and cervical cancer. The average QALY for women with cervical cancer was set to the mean HALex for women with genital cancer (0.68). The HALex for women without any reported illnesses ranged from 0.91 to 0.78 depending on age. We assumed that the lay health worker intervention and the Pap test itself did not directly affect health state utilities.

Results

Estimates of the change in the frequency of Pap tests are presented in Table 1. The ever-screened sub-analysis, those women who have had at least one Pap test during their lifetime, resulted in a greater value of intervention

Table 1. Frequency of Pap Tests by Group

	Intervention Group				Control Group					
Analysis	**N**	**Pap**	**%**	**Age**	**N**	**Pap**	**%**	**Age**	**OR**	**95% CI**
All-underscreened	118	18	15.3%	51.2	116	8	6.9%	51.3	2.43	1.01-5.84
Ever-Screened	64	13	20.3%	53.7	64	4	6.3%	51.5	3.82	1.17-12.46

Table 2. Variable Cost of Home Visits, Tests and Procedures

Variable Cost of Intervention				
Participants	**Average**	**95% CI**		**n**
		Lower	**Upper**	
All	$96.81	$84.73	$108.90	115
Ever-screened	$98.07	$82.49	$113.65	62

Table 3. Estimated Incremental Cost-Effectiveness Ratios and Quality-Adjusted Life Years

ICER Component	Mean	SE
Cost of intervention	$96.81	$6.16
Incremental Pap freq.	8.36%	4.59%
Incremental Pap cost*	$103.99	$7.36
Incremental LYS*	15.2 days	1.52
Incremental QALY*	15.1 days	1.51
Cost per Pap test	$1,158	-
Pap ICER	$2,071/QALY	-
Intervention ICER	$30,015/QALY	-

*Standard error assumed equal to 10% of mean.

efficacy than the all-underscreened analysis.

Table 2 presents the average variable costs of the lay health worker home visits for all participants ($96.81) and separately for ever-screened participants ($98.07). The mean values of the number of minutes and miles for the home visits were 179.6 and 59.8 respectively.

Table 3 presents the estimated Pap and intervention ICERs and their associated incremental QALYs. The incremental QALY of a Pap test regimen of two screenings three years apart is 15.1 days. Without utility weights, the life years saved (LYS) would equal 15.2 days. The incremental cost of such a regimen, net of cost savings from a lower incidence of cervical cancer, is $103.99. The resulting value of the Pap ICER is $2,071 per QALY. With an intervention cost of $96.81 and an incremental effect on Pap test frequency of 8.36%, the intervention ICER equals $30,015 per QALY.

Sensitivity Analysis

Figure 1 is a tornado diagram that illustrates a one-way sensitivity of our results to changes in parameters of the model (Ramsey et al., 2005). Each parameter name is listed next to its range. Except for the number of screenings, cost of treatment by stage, discount rate and years since the last Pap test, the range of the parameter equals one standard error from the mean. No estimates of the standard errors for the incidence of cervical cancer, utility weight and the costs of the procedures are available, so the standard errors were assumed to be 10% of their mean value.

The intervention ICER is most sensitive to the change in Pap test frequency between the two arms of the trial. It ranges from $20,111 to $64,037 as the change in Pap test frequency decreases from 13.0% to 3.8%. The number of screenings after the intervention takes place, a measure of the durability of the effect of the intervention, also has a relatively large impact on the value of the intervention ICER. As the number of post-intervention screenings decrease from 3 to 1, the intervention ICER increases from $24,183 to $42,180. Changes in the parameters borrowed from other studies have very little effect on the value of the intervention ICER.

N-way Uncertainty Analysis

Figure 2 presents the cost-effectiveness acceptability curve. This graph plots the probabilities that the value of the intervention ICER is below a range of maximum willingness-to-pay levels (Briggs et al., 2002; Fenwick et al., 2004). There is a 77.0% probability that the intervention ICER is below $50,000 and a 90.9% probability that it is below $100,000.

Discussion

Comparisons with previous studies

We know of no other study that measures the cost per QALY of a program to improve adherence to cervical cancer screening guidelines; however, there have been other studies that measure the cost of alternative Pap test regimens. Thompson et al., (2007) reported that the cost per Pap test, calculated as the cost of the intervention

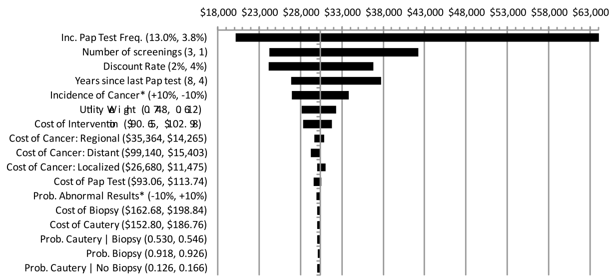

Figure 1. Tornado Diagram *Percent change from the mean value

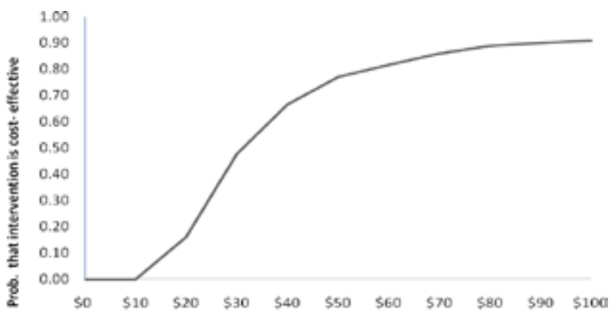

Figure 2. Threshold for Willingness to Pay

divided by the change in Pap test frequency, for Chinese women in Vancouver, BC and Seattle, WA who received a home visit from a lay health worker was $414.86. A similar calculation using the results of the present trial equates to $1,129 per Pap test. The relative cost-effectiveness of the Thompson et al. study is due to a lower cost per intervention which was also nearly twice as effective as the intervention for Vietnamese women.

Previously reported Pap ICER values from Eddy (1990), van den Akker-van Marle, van Ballegooijen, van Oortmarssen, Boer & Habbema (2002), Maxwell et al. (2002) and Goldie et al., (2004) range from $4,017 per LYS to $13,331 per LYS and are each greater than the Pap ICER from our study. Much of the diff erences can be attributed to the different methodologies and assumptions utilized. Each of these studies computes the expected incremental costs and effects of a Pap test regimen that begins at a specific age and continues at a regular interval until age 70 compared to a regimen of no Pap tests at all. Eddy and Maxwell et al. assume a regimen of Pap tests every three years that begin near age 20. Goldie et al. assume a regimen of Pap tests every four years starting at age 20. Van den Akker-van Marle et al. assume a regimen of two Pap tests at ages 40 and 52. Our study computes the average incremental costs and effectiveness for a regimen of two Pap tests three years apart starting at various ages.

While still beneficial, additional Pap tests beyond the initial one will tend to be less effective than the initial test. Since the costs of additional Pap tests will be equal to the cost of the initial test, the Pap ICER of a two-test regimen will be less than the Pap ICER of a life-long regimen, other things the same. For example, an increase in the number of post-intervention Pap tests from 2 to 3 would increase our Pap ICER from $2,071 to $2,354. Thus our relatively low Pap ICER is derived using a conservative approach concerning the durability of the effect of the intervention. Ironically this leads to a relatively optimistic estimate of the cost-effectiveness of the Pap test regimen itself. However, this same conservative assumption leads to a higher intervention ICER, and therefore a less optimistic estimate of the intervention program, than would otherwise be the case. For example, an increase in the number of post-intervention Pap tests from 2 to 3 would lower the intervention ICER from $30,015 per QALY to $24,183 per QALY, as illustrated in our tornado diagram. Therefore by assuming the duration of the intervention effectiveness is short-lived, we estimate that a lay health worker intervention is less cost-effective than had the duration been long-lived.

The observed disparity of cervical cancer incidences between Vietnamese-American and other women in the United States makes screening for cervical cancer a promising focus of lay health workers. From our randomized controlled trial we conclude that only Vietnamese women who have been screened at least once previously are susceptible to this intervention. Vietnamese women who have never been screened do not respond favorably to home visits from lay health workers. Consequently, a program that targets only the Vietnamese women who have been screened before is likely to be the most cost-effective.

Other means of promoting screening for cervical cancer, such as telephone calls and mailings, were not considered in this study. Although these alternative methods may be cost-effective, our randomized trial was restricted to home visits by lay health workers due to financial and resource constraints.

We did not include the cost of testing for Human Papillomavirus (HPV). At the time of the intervention, HPV testing was not a routine step in the Pap screening algorithm. Subsequently, it has been added, but the proportions of cases requiring HPV administration has not been established. Consequently we have limited ability to calculate the additional costs. That said, while this is a limitation of our model, the costs are not significant and are unlikely to make a substantive change in the cost efficacy analysis.

Our baseline survey included questions about health care access, doctor interactions, and heart disease as well as women's health (including Pap testing). It is possible that the tendency to be screened for cancer by some women in the control group could have been affected by the survey. If so, the estimated effectiveness of the lay health worker visitation would be diminished.

We did not include costs of the interventions in the control arm. Pamphlets on screening are typically available (although less often in Vietnamese). The very small costs of the pedometer and pamphlets were not considered because they were promotional for study recruitment.

The supervisor's time and cost were not tracked. Fixed costs, including lay health worker training, amounted to $1,750; however, they are not included in the ICER calculation. The effect that fixed costs have on the ICER will be highly sensitive to the assumed scale of the intervention program. The larger the number of interventions the smaller will be the effect on the ICER value. For example, a program that contacts only 118 women will likely never be cost-effective even with very small fixed costs; however a program that contacts over a thousand women will. Rather than simply assume a large program, we explicitly excluded fixed costs from the ICER calculation.

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