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Preferences for Surveillance Strategies for Women Treated for High-Grade Precancerous Cervical Lesions

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Abstract

Objectives—Data are lacking on how women view alternative approaches to surveillance for cervical cancer after treatment of high-grade cervical intraepithelial neoplasia. We measured and

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compared patient preferences (utilities) for scenarios with varying surveillance strategies and outcomes to inform guidelines and cost-effectiveness analyses of post-treatment surveillance options.

Methods—English- or Spanish-speaking women who had received an abnormal Pap test result within the past two years were recruited from general gynecology and colposcopy clinics and newspaper and online advertisements in 2007 and 2008. Participation consisted of one face-to-face interview, during which utilities for 11 different surveillance scenarios and their associated outcomes were elicited using the time tradeoff metric. A sociodemographic questionnaire also was administered.

Results—65 women agreed to participate and successfully completed the preference elicitation exercises. Mean utilities ranged from .989 (undergoing only a Pap test, receiving normal results) to .666 (invasive cervical cancer treated with radical hysterectomy or radiation and chemotherapy). Undergoing both a Pap and HPV test and receiving normal/negative results had a lower mean utility (.953) then undergoing only a Pap test and receiving normal results (.989). Having both tests and receiving normal Pap but positive HPV results was assigned an even lower mean utility (.909). 15.9% of the respondents gave higher utility scores to the Pap plus HPV testing scenario (with normal/negative results) than to the "Pap test alone" scenario (with normal results), while 17.5% gave the Pap test alone scenario a higher utility score.

Conclusions—Preferences for outcomes ending with normal results but involving alternative surveillance processes differ substantially. The observed differences in utilities have important implications for clinical guidelines and cost-effectiveness analyses.

INTRODUCTION

Widespread cervical cancer screening has accompanied large declines in cervical cancer incidence and mortality in the United States.(1,2) Identification and treatment of preinvasive cervical cancer is the cornerstone of screening effectiveness. However, optimal strategies for surveillance of women who have been treated for high-grade precancerous cervical lesions (cervical intraepithelial neoplasia (CIN)) have not been determined. Contemporary guidelines published by the American College of Obstetricians and Gynecologists and the American Society for Colposcopy and Cervical Pathology (ASCCP) suggest that various combinations of cytology, testing for oncogenic human papillomavirus (HPV) types and colposcopy may be employed.(3-5)

The implications of various surveillance strategies on resource allocation decisions and cost-effectiveness analyses, including how they affect health-related quality of life, are important to quantify. However, women's preferences (or "utilities") for the different post-treatment surveillance strategies have not been adequately measured. As part of a larger analysis of the comparative effectiveness of various surveillance strategies after treatment of high-grade CIN (grade 2/3), we conducted a study of patient preferences for the process and outcomes of these strategies among a diverse population of women with varying levels of familiarity and experience with cervical cancer screening and treatment of precancerous lesions.

METHODS

Participants

Institutional review board approval was obtained from the UCSF Committee on Human Research. English- or Spanish-speaking women who had received abnormal Pap test results within the past two years were recruited to participate in this study. We chose to elicit preferences from this group as we felt they would more readily understand the meaning of high-grade precancerous lesions than would members of the general population. We were

interested in assessing preferences among sociodemographically diverse women who had a wide range of experiences related to cervical cancer prevention. We therefore recruited participants from the colposcopy clinics at San Francisco General Hospital (a county facility which primarily serves women of lower socioeconomic status, many of whom have limited English proficiency) and the University of California, San Francisco, Medical Center, whose clientele tends to be more affluent. We also recruited women from a prior study of the management of non-cancerous uterine conditions (6) who had agreed to be contacted for future studies, as well as via advertisements in the UCSF newspaper and "Craigslist," a central network of online communities, featuring free online classified advertisements.(7)

Measures

We elicited utilities for the various surveillance strategies and their associated potential outcomes employing the time tradeoff metric,(8) which has been used widely for evaluating the quality-of-life effects of clinical conditions for use in cost-effectiveness analyses. The time tradeoff preference elicitation exercise asks participants to choose between living their full life expectancy with a less-than-ideal outcome (e.g., receiving a diagnosis of early cervical cancer at the time of colposcopy and undergoing a hysterectomy) or living a shorter time with a hypothetical ideal outcome (i.e., never having had abnormal cells on their cervix). Time spent with the ideal outcome is varied until the subject is indifferent between the two options. The time tradeoff utility score is calculated by dividing the number of years with the ideal outcome by the number of years with the less desirable outcome at the indifference point, yielding a value between 0 (which occurs when the respondent would give up her entire life expectancy to avoid the less desirable outcome, meaning she equates it with death) to 1 (which occurs when the respondent would not give up any life expectancy to avoid the outcome, suggesting that she equates is with the ideal outcome). After reviewing a set of cards that described the procedures that would be addressed, utilities for 11 different surveillance scenarios and their associated outcomes, all of which described a 6-month time period (see appendix for procedure and outcome descriptions), were assessed using ProSPEQT, a computer-based preference elicitation tool.(11).

In addition, we administered a questionnaire which included items about the participants' sociodemographic characteristics, prior experience with cervical cancer screening and treatment procedures, and cancer history. The questionnaire included the SF-12, a widely used measure of health-related quality of life from which physical component summary (PCS) and mental component summary (MCS) scales are derived.(9) To assess the extent to which the participants were concerned about the possibility of developing cervical cancer, we used an adapted version of the Cancer Worry Scale,(10) which included 3 frequency items asking "[d]uring the past month, how often have 1) you thought about your own chances of developing cervical cancer, 2) thoughts about getting cervical cancer affected your mood, and 3) thoughts about your chances of getting cervical cancer affected your ability to perform your daily activities?" Response options for these items included 1=not at all or rarely, 2=sometimes, 3=often and 4=all of the time. The 4th question was asked "[h]ow much have you been bothered by thoughts or worry about your chances of getting cancer?"; response options ranged from 1="not at all" to 4="extremely." Scale scores were calculated by summing up the values of the responses; the lowest score possible was therefore 4 (least worried), and the maximum score possible was 16 (most worried).

Interviews

Participation in the study consisted of one face-to-face interview. After the participant signed informed consent, the interviewer reviewed a series of cards describing the various interventions and health outcomes to be assessed. The participant and interviewer then

completed a practice utility elicitation exercise, after which the participant assessed the 11 scenarios. The questionnaire was then administered by the interviewer.

Analysis

To ensure that we included data only from participants who understood the preference measurement task, we applied *a priori* exclusion criteria. Specifically, we stipulated that if a participant's time tradeoff score for having a Pap test and receiving normal results was lower than that of being diagnosed with and treated for invasive cervical cancer, we would assume that she did not understand the assessment task (i.e., had provided "misordered" data). Additionally, we stipulated that women who assigned values of 1 to all outcomes would be assumed to be unwilling or unable to engage in the measurement task. Data from participants who met these criteria were excluded from the analysis of utility scores.

We began our analyses by describing the demographic and clinical characteristics of the enrolled sample and the reduced sample whose data was included in the utility analysis. We then employed standard tests for association in bivariate contingency tables, using the Fisher's exact test instead of the Chi-square test for tables with small expected cell frequencies, to compare these two samples. Utility score distributions obtained from the women whose data were not excluded were described using sample means, standard deviations, select quantiles and interquartile ranges.

To investigate how women felt about undergoing HPV testing in addition to having a Pap test, we compared the utility score reported for undergoing only a Pap test and receiving a normal result with those of the scenarios in which both Pap and HPV testing was performed and, in addition to receiving normal pap results, the woman was found to be HPV negative or HPV positive. To test the null hypothesis that the mean differences in compared utility scores were zero, we used the random permutation paired t-test, drawing 25,000 random permutations for each paired comparison. This method is a closely related but distribution-free alternative to the standard parametric paired t-test.(12,13)

We then used logistic regression analysis to assess whether select characteristics were associated with a respondent providing a higher utility score for the scenario of undergoing both Pap and HPV testing and receiving normal/negative test results, compared to the scenario consisting of undergoing just Pap testing and receiving a normal test result. For this analysis, a binary dependent variable was coded "1" in cases where the utility score for the combination test scenario was higher than for the solitary Pap test scenario and "0" in cases where the utility score for the latter scenario was equal to or greater than the utility score the former scenario. All but one of the terms in the final model were selected from a set of candidate predictors using clinical judgment in tandem with correlation analysis that did not involve the outcome terms (or the utility scores on which it was based). The aim of these correlation analyses was to select a parsimonious and minimally correlated set of predictors to capture important respondent demographics (age, race/ethnicity and socioeconomic status). Based on clinical judgment, we opted to control for health status, as well, and we used bivariate analysis of the outcome with the SF-12 summary scales to guide us, opting to exclude the PCS scale and include the MCS scale on the basis of testing at a significance testing at a modified (10%) type-1 error rate.

We completed the analyses using multinomial logistic regression with a three-level dependent variable that further classified respondents according to whether they equated the two outcomes (the reference category) or assigned a lower utility to having both tests and receiving PAP normal/HPV negative results. All statistical analyses were implemented in Version 9.2 of the SAS System for Windows.

RESULTS

130 women were screened, and 120 met eligibility criteria. The 10 women who were not eligible had not had an abnormal Pap test in the past two years. 76 (63%) of the eligible women agreed to participate in the study. 21% of the enrollees were identified by having participated in one of our previous hysterectomy studies. Nearly half (42%) were recruited from one of the colposcopy clinics, and the remainder (37%) had responded to our advertisements or flyers or had heard about the study from someone else.

Women who enrolled in the study constituted a sociodemographically diverse group with a wide range of experiences related to cervical cancer prevention and surveillance (Table 1). Less than half (41%) were white, over a quarter (29%) were born outside of the United States, and over half (52%) did not have a college degree. Together, the participants had a substantial amount of experience with CIN screening; in addition to having had an abnormal Pap test within the past 2 years, most of these women (89%) reported having had a colposcopy at some point, 25% had undergone a loop electrosurgical excision procedure (LEEP), and several had had cryotherapy or a cone biopsy. Nearly half (46%) reported that they had had a positive HPV test. None of these women had ever been diagnosed with cancer.

Data from eleven participants (14.5%) were excluded from the time tradeoff analysis; 6 of these women provided misordered scores and 5 assigned a value of 1 to all scenarios. Compared with women whose data were included, those whose data were excluded were more likely to have been born outside the United States (P=.01, Fisher's exact test), to be Latina (P=.001, Fisher's exact test), to have completed the interview in Spanish (P< .001, Fisher's exact test), or to have a per capita income below the median of $36,610 ($P$< .001, Fisher's exact test).

Highest utilities were assigned to the six-month scenarios that ended with receipt of normal results (after undergoing a Pap test (.989), a Pap and an HPV test (.953), or a colposcopy after receiving abnormal Pap test results (.927;Table 2)). Lower mean values were assigned to receiving positive HPV results when accompanied by normal Pap tests results (.909), or being diagnosed with CIN 1 following a colposcopy (.897) or having a loop excision following a high-grade CIN results (.806). The lowest utilities were assigned to scenarios describing diagnosis and treatment of microinvasive (.724) and invasive cervical cancer (. 666).

Utilities for scenarios for six-month periods during which no testing or treatment occurred yielded a similar pattern. The mean utility for this situation in the absence of a previous cervical cancer diagnosis was .835, for example, while the mean utility for a six-month period with no testing or treatment after having been diagnosed at some point in the past with very early (microinvasive) cervical cancer and undergone a simple hysterectomy was . 816. Six months with no testing or treatment after early or late invasive cervical cancer treated with a radical hysterectomy or radiation and chemotherapy yielded the lowest mean utility score in this category (.754).

Lower mean utilities were consistently assigned to health states involving HPV testing compared to those in which only Pap testing was used. Undergoing both a Pap test and an HPV test and receiving a normal Pap result but a positive HPV result was assigned a lower mean utility than having a Pap test with normal results (mean difference = −0.082, paired t-test p-value = 0.002). Undergoing only a Pap test and receiving normal results had a higher mean utility than undergoing a Pap and an HPV test and receiving normal results for both, but the difference was not statistically significant (mean difference=.037; paired t test p-value=.11).

Upon closer examination of the distribution of these scores we found that two thirds (66.7%) of our sample assigned the same utility to the two scenarios that involved normal Pap test results and differed only in whether or not a negative HPV test was included, while 15.9% gave higher utility scores to the Pap plus HPV testing with negative results scenario than to the Pap-alone scenario (suggesting they would receive additional reassurance or some other benefit from having an HPV test and receiving negative results). The remaining 17.4% gave the latter a higher utility score than the former, suggesting that they viewed HPV testing as a net loss of utility, even if negative results were received.

Results of the multivariate logistic regression analysis yielded only one borderline significant association (Table 3): women who had higher MCS-12 scores had slightly lower odds of perceiving a benefit to adding HPV testing to Pap testing (AOR=0.94 for every 1-point increase on the MCS100-point scale, p=.06). In the multinomial logistic regression analysis we found that, compared to whites, African-American women had a higher relative preference for normal Pap alone than for normal Pap and a negative HPV test, both in unadjusted and adjusted analysis. We did not find any other significant associations, either with the terms in our logistic regression model or with indicators for ever having received a LEEP or with ever having received a positive HPV test result.

DISCUSSION

We have generated a catalog of utilities that can be used to incorporate health-related quality-of-life effects into cost-effectiveness analyses of alternative surveillance approaches for women who have been treated for high-grade CIN. Other investigators (14,15) as well as our group (16,17) have reported utilities for health states associated with the management of atypical or low-grade cervical lesions. To our knowledge, this is the first presentation of a comprehensive set of utilities for the process and outcomes of alternative post-CIN treatment surveillance strategies obtained from a sociodemographically diverse sample of women with a range of familiarity with the components of alternative surveillance strategies.

Our findings indicate substantial variation in preferences among women concerning post-CIN 2/3 treatment surveillance strategies. The wide range of mean values we observed for outcomes ending with normal Pap or colposcopy results underscores the importance of the process that women go through to obtain normal results, the most common outcome of screening. It has been suggested that a utility difference of .03 or greater can be construed as clinically meaningful;(18) the difference we observed in the mean utility associated with having a normal Pap alone versus a normal Pap with positive HPV results was .08. This finding is consistent with results of observational studies suggesting that testing for and treating HPV-associated disease can have adverse psychosocial effects, especially among women treated for high-grade CIN.(19) Although a recent study in which HPV results were randomly revealed or concealed to women suggested that knowledge of HPV positivity among women with normal cytology had little impact on overall quality of life as measured by a general health questionnaire,(20) this studies differed in that our utility scores were based on scenarios with and without HPV testing whereas in the other study all women underwent the process and only knowledge of the outcome differed. Interestingly, these investigators did find that women who were told that they were HPV-positive reported decreased sexual satisfaction compared to those who were HPV-positive but were not given this information.

We also noted differences in the mean utility for the scenario of a normal Pap test without HPV testing versus a normal Pap test with a negative HPV test (.037), and we found that while two thirds of the respondents equated receiving Pap normal results to receiving Pap normal/HPV negative results, the remaining third was divided over whether having an HPV

test and receiving negative results was a net gain or a net loss. There are many possible explanations for this result. It may be that use of the word “negative” in the context of HPV test results did not provide the same feeling of benefit that use of the word “normal” in the context of Pap test results did. Also, the description of the HPV test made it clear that HPV is a sexually transmitted virus, and it may be that women preferred not to be reminded of the possibility of a sexually transmitted infection in the context of a normal Pap test. Alternatively, it could be that women are relatively satisfied with the confidence of the Pap result and the addition of HPV offers no additional utility to them, or women may prefer having only one test to having two. Future studies should focus on the reasons underlying preferences for one screening or surveillance approach over another.

How do our findings compare with those of other utility studies? Several investigators measured preferences related to management of low-grade cytologic abnormalities and screening and treatment of other gynecologic cancers. In a previous study, we used the standard gamble method of utility assessment (21) to assess preferences among 170 English- or Spanish-speaking women recruited from family planning clinics throughout Northern California’s Central Valley. We found that the mean standard gamble utility for repeat Pap with spontaneous resolution (0.96) was higher than for immediate colposcopy with normal results (0.93), but somewhat lower utilities were assigned to cryotherapy and cone biopsy following repeat Pap (0.93 and 0.91 respectively) than following immediate colposcopy (0.95 and 0.92 respectively).(16) In a study of repeat Pap versus HPV triage testing among 73 women residing in Sydney, Australia, who had not recently had a Pap test, no clinically meaningful difference was observed in the mean standard gamble utilities assigned to repeat Pap (0.9972) versus immediate HPV testing (0.9967), but the mean value for abnormal Pap followed by treatment was higher (0.9656) than for HPV positive results followed by treatment (0.9354).(14) In an analysis of the effect of the duration of time spent in various health states associated with abnormal Pap tests, time tradeoff utilities were obtained from 150 female volunteers at Duke University Medical Center in North Carolina.(15) These women had higher mean utilities for atypical squamous cells of undetermined significance (ASCUS, 0.94) than for low-grade or high-grade squamous intraepithelial lesion (LSIL/HSIL) and CIN 1(0.91 for both); the mean utility for CIN 2/3 was 0.87. Finally, in a study of utilities for ovarian cancer diagnosis and treatment among 13 ovarian cancer patients and 37 female members of the general public, also conducted at Duke University, the mean time tradeoff utility scores for screening tests ranged from 0.83 to 0.90, while the mean scores for cancer states ranged from 0.81 (for newly diagnosed early ovarian cancer to 0.16 for end stage cancer.(22)

Several limitations of our study warrant discussion. FIrst, not all women in the sample had experienced all the surveillance and treatment options they were rating, although many had undergone one or more of the procedures we described and all had received abnormal Pap test results in the past two years. To assess whether undergoing any specific procedure was related to utilities assigned to the various scenarios, we compared the utility values of women who reported having undergone a LEEP procedure to those who did not, and found only one significant difference: women who had undergone a LEEP procedure had a higher mean utility for invasive cancer than women who had not had a LEEP (0.89 vs. 0.68, p-value for Mann-Whitney U test=0.0499). Importantly, there were no significant associations between having had a LEEP and the utility scores reported for normal Pap with and without negative HPV.

Second, given the need to limit the outcomes and the information provided to the participants to a manageable amount, we decided to only include two cancer states (very early (microinvasive) and early or late stage invasive cancer), and we focused on the procedures and treatments associated with these states without providing information on

their prognosis. Because the perceived prognosis may play a significant role in the utility of a cancer treatment or surveillance scenario, omitting this information may have artificially improve the utility associated with the invasive cancer scenario and the scenario concerning surveillance of invasive cancer.

Additionally, although we were able to recruit a sociodemographically diverse sample with a wide range of experience with the components of the various screening strategies, the participants were recruited from a single geographic area, limiting the generalizability of our findings. Moreover, the educational attainment of our participants was relatively high, with nearly half of the women (48%) reporting college degrees. 14% of the participants had difficulty with the preference assessments, most of whom had completed the interview in Spanish, did not have a college degree, and/or had household incomes of less than $50,000. Although time tradeoff utilities have been obtained from sociodemographically diverse populations in other contexts,(16,23) this finding underscores the difficulty that some groups, particularly those with lower educational attainment, may have in providing this type of preference data and specific challenges confronting efforts to engage women with less education in informed decision making. Finally, the small sample size limited our ability to analyze the factors that underlie some of the variations in preferences we observed.

Despite these limitations, we believe that our study has important implications for clinical guidelines and practice given that differing strategies based on Pap and HPV tests yielded such different utility values. Future comparative effectiveness analyses should consider using these values to assess what the quality-of-life impact of implementing these management strategies may be, in addition to their impact on cervical cancer incidence and overall life expectancy.

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APPENDIX: PROCEDURE AND OUTCOME DESCRIPTIONS

PROCEDURE DESCRIPTIONS (presented prior to utility assessment exercises)

Pap Smear Test

Why is it done?

- A Pap smear is done to look for abnormal cells on the cervix (the opening from the vagina into the uterus) that could become cancer.

What is it like to have it done?

- The Pap test takes a few minutes.
- You will need to lie on your back with your legs apart while the doctor puts the speculum in your vagina and gently scrapes your cervix.
- It is generally not painful, but can be uncomfortable. Some women feel embarrassed.

What happens after the procedure?

- You can go back to all your usual activities as soon as the test is over.

- You may have very light spotting afterward.

How does it affect my health and quality of life?

- Women who receive normal results usually feel reassured.
- Women who receive abnormal results often worry about what the results mean.

HPV Test

Why is it done?

- An HPV test is done to determine if you have a sexually transmitted virus that could cause cervical cancer.

What is it like to have it done?

- The HPV test takes a few minutes.
- The HPV test is done on a sample of cells collected from your cervix.
- You will need to lie still on your back with your legs apart while the doctor puts the speculum in your vagina and places a brush or swab in your cervix.
- It is generally not painful, but can be uncomfortable. Some women feel embarrassed.

What happens after the procedure?

- You can go back to all your usual activities as soon as the test is over.
- You may have very light spotting afterward.

How does it affect my health and quality of life?

- Women who receive negative results usually feel reassured.
- Women who receive positive results for the first time often worry about what the results mean.
- Women who receive positive results more than once sometimes worry about why the virus is still there.
- Because it is a sexually transmitted disease, some women may also be concerned about how positive results could affect their relationships.

Colposcopy

Why is it done?

- A colposcopy is recommended when a Pap smear is abnormal.
- It is performed to look more closely at the cervix and perform biopsies if needed.

What is it like to have it done?

- A colposcopy feels like a very long Pap test (it takes 10 to 30 minutes).
- You will need to lie still on your back with your legs apart while the doctor puts the speculum in your vagina and applies vinegar to your cervix to help locate any problem areas.
- It is generally not painful, but can be uncomfortable. Some women feel embarrassed.

- If a problem area is seen, a biopsy will often need to be taken. Although some anesthetic may be used, mild to moderate cramping and sharp pain is often experienced.

What happens after the procedure?

- Most women do not experience discomfort after this procedure, although some may have some mild cramping, bleeding, or spotting if a biopsy sample is taken.
- After the procedure, your doctor will tell you not to use tampons, have sexual intercourse or put anything in your vagina for at least 1 week.
- After one week, you can go back to all your usual activities.

How does it affect my health and quality of life?

- Women who receive normal results usually feel reassured.
- Women who receive abnormal results usually worry about what the results mean, and often have to undergo another procedure to treat the abnormality.

LEEP (loop electrosurgical excision procedure)

Why is it done?

- A LEEP is a larger biopsy of the cervix using an electrified, hot wire.
- It may be recommended when colposcopy results show changes on your cervix that have a high likelihood of becoming cancer if untreated.
- A LEEP is sometimes done to determine the cause of an abnormal Pap smear when colposcopy results are not clear.

What is it like to have it done?

- The LEEP akes 20 to 30 minutes and is similar to a colposcopy.
- For this procedure, the doctor will inject some local anesthetic into your cervix.
- Over 90% of the time, the abnormal cells are permanently removed by the treatment.
- Most women have some cramping during the procedure. Some women feel embarrassed.

What happens before and after the procedure?

- Some women experience discomfort after this procedure.
- Many have cramping, bleeding, or spotting.
- After the procedure, your doctor will tell you not to use tampons, have sexual intercourse or put anything in your vagina for at least 2 weeks.

How does it affect my health and quality of life?

- Your doctor will probably recommend Pap smears every 4-6 months until they've been normal for several visits, then every year for a long time.
- You may worry about the abnormal changes coming back or about developing cancer later.
- Although having a LEEP does not appear to affect your ability to get pregnant, some women may have problems with premature labor and earlier delivery of their pregnancies.

Simple Hysterectomy for Very Early Cervical Cancer

Why is it done?

- If your LEEP or colposcopy show that you have very early cervical cancer or are at high risk of having cervical cancer, your doctor may recommend that you have a hysterectomy to remove your cervix and uterus.

What is it?

- A hysterectomy is a major surgical procedure in which the uterus and cervix are removed through either your vagina or an incision on the lower abdomen.

What happens before and after the procedure?

- This surgery is performed under general anesthesia.
- As with any major surgery there are risks of complications such as infection, organ injury, and bleeding.
- Having a hysterectomy usually means staying in the hospital for 2 or 3 days.
- You can usually return to your regular activities in about 6 weeks.

How does it affect my health and quality of life?

- After a hysterectomy your menstrual periods will stop forever and you won't be able to become pregnant.
- You will see your doctor every 4-6 months for the first few years, then every year afterwards.
- If you had a hysterectomy for early cervical cancer, you may worry about having cancer again or dying from cancer. Depression and anxiety are common feelings for women who have had cancer.
- Some women experience problems with sexual satisfaction after a hysterectomy.

Radical Hysterectomy for Invasive Cervical Cancer

Why is it done?

- If after your colposcopy you are found to have cervical cancer that has invaded more deeply into the cervix, your doctor may recommend that you have a radical hysterectomy to remove your cervix, uterus, ovaries, some lymph nodes and part of your vaginal canal.

What is it?

- A radical hysterectomy is a major surgical procedure in which the cervix, uterus, ovaries, and top third of the vaginal canal are removed through an incision on the lower abdomen.

What happens before and after the procedure?

- This surgery is performed under general anesthesia.
- As with any major surgery there are risks of complications such as infection, organ injury, and bleeding.
- Having a hysterectomy usually means staying in the hospital for 2 or 3 days.
- You can usually return to your regular activities in about 6 weeks.

How does it affect my health and quality of life?

- After a hysterectomy your menstrual periods will stop forever and you won't be able to become pregnant.
- You will see your doctor every 4-6 months for the first few years, then every year afterwards.
- After having the hysterectomy, you may worry about the cancer spreading or dying from cancer. Depression and anxiety are common feelings for women who have had cancer.
- Because part of the vagina is removed, more women experience problems with sexual satisfaction after a radical hysterectomy than after a simple hysterectomy. Women may also have long term problems with leg swelling, urinary problems, bowel problems, or nerve irritation.

Radiation with Chemotherapy for Invasive Cervical Cancer

Why is it done?

- If after your colposcopy you are found to have cervical cancer that has invaded more deeply into the cervix, you may be offered treatment with radiation therapy.

What is it?

- Radiation therapy may be done with radioactive implants or external beam radiation. It is usually given together with chemotherapy given through an IV.

What happens before and after the procedure?

- Radiation and chemotherapy involve many visits for treatment, but usually does not require hospitalization.
- The chemotherapy frequently causes nausea and vomiting and hair loss.
- It may be 6 weeks or longer before you can return to your usual activities

How does it affect my health and quality of life?.

- After radiation and chemotherapy your periods stop forever and you won't be able to become pregnant.
- You will see your doctor every 4-6 months for the first few years, then every year afterwards.
- After having radiation and chemotherapy, you may worry about the cancer spreading or dying from cancer. Depression and anxiety are common feelings for women who have had cancer.
- You may have long term problems with sexual satisfaction, urination, bowel function, or leg swelling.

OUTCOME DESCRIPTIONS FOR UTILITY ASSESSMENT

Top Anchor: Imaginary Ideal Situation

Here is the "Imaginary Ideal Situation" we would like you to use in comparison with the others.

- You've never had any abnormal cells on your cervix.
- You have whatever other medical conditions or health problems you may be experiencing.

- You never develop cervical cancer.

Scenarios Assessed

In each of the following scenarios, we will ask you to imagine that you have been treated in the past for abnormal cells on your cervix. When you think about these situations, please consider how anxious you think you might feel while waiting for results, how relieved you might feel if you received normal results, and how concerned you might feel if you received abnormal results. These situations describe 6 months of your life. Remember that you are always to image that you have been treated for abnormal cells on your cervix at some point in the past.

Six month periods with testing and/or treatment—1) Pap test only, normal results

- You have a screening Pap test.
- You receive normal test results in 1 to 2 weeks.
- You spend the remainder of the 6 months without any further testing.

2) Pap test only, abnormal findings, colposcopy, normal findings

- You have a Pap test
- You receive abnormal test results in 1 to 2 weeks.
- You have a colposcopy.
- You receive normal results in 1 to 2 weeks.
- You spend the remainder of the 6 months without any further testing.

3) Pap test, abnormal findings, colposcopy, CIN1

- You receive abnormal results from a Pap test and your colposcopy shows minor changes on your cervix.
- To re-check the abnormal cells, your doctor recommends you have another colposcopy in 6 months.
- You spend the remainder of the 6 months without any further testing.

4) Pap test, abnormal findings, colposcopy, CIN2 or 3, LEEP, no cancer

- You receive more abnormal results from the colposcopy.
- You have a LEEP to remove the abnormal cells.
- 1 to 2 weeks later you are told that you do not have cervical cancer.
- Although having a LEEP does not appear to affect your ability to get pregnant, some women who have more than one LEEP, or a LEEP where a large amount of cervical tissue is removed, may have problems with premature labor and delivery of their pregnancies.
- You spend the remainder of the 6 months without any further testing.

5) Colposcopy, very early cancer, hysterectomy

- You have a colposcopy.
- You are diagnosed with very early cervical cancer.
- You have a simple hysterectomy.

- Most women who have had cervical cancer experience anxiety and worry about dying and some experience depression.
- Some women have some problems with sexual satisfaction.
- A hysterectomy means that you will not be able to have children.

6) Colposcopy, invasive cancer, hysterectomy or radiation and chemotherapy

- You have a colposcopy.
- You are diagnosed with invasive cervical cancer.
- You have a radical hysterectomy or radiation and chemotherapy.
- Most women who have had cervical cancer experience anxiety and worry about dying and some experience depression.
- Many women who have one of these treatments will have problems with sexual satisfaction.
- You will not be able to have children.
- If you have radiation and chemotherapy you may also have problems with urination, bowel function, nausea and vomiting.

7) Pap test, normal results, HPV test, negative results

- You have a Pap test and an HPV test.
- You receive normal results for the Pap test and negative results for the HPV test in 1 to 2 weeks, meaning that the virus that can cause cervical cancer is not present on your cervix.
- You spend the remainder of the 6 months without any further testing.

8) Pap test, normal results, HPV test, positive results, colposcopy, normal results

- You have a Pap test and an HPV test but, this time, your Pap is normal but you receive positive HPV test results, meaning that the virus that can cause cervical cancer is present.
- You have a colposcopy.
- You receive normal results in 1 to 2 weeks.
- You spend the remainder of the 6 months without any further testing.

Six month periods with no testing or treatment—9) General

- You do not have any testing during the 6 month period you are imagining.
- You may experience some anxiety about having been treated for abnormal cells on your cervix in the past.
- You may be relieved to not have to think about whether there are abnormal cells on your cervix.

10) Prior very early (micorinvasive) cervical cancer diagnosis and treatment (IA1)

- You have been diagnosed with very early cervical cancer in the past and that you had a simple hysterectomy.
- You may be relieved that your cancer was caught and that you were able to get treatment.

- You may be worried about your cancer returning.
- You may have problems with sexual satisfaction.
- You will not be able to have any more children.

11) Prior early or late stage invasive cervical cancer diagnosis and treatment (IA2 or greater)

- You have been diagnosed with invasive cervical cancer in the past and that you had a radical hysterectomy or radiation and chemotherapy to treat it.
- You may be relieved that your cancer was caught and that you were able to get treatment.
- You may be worried about your cancer returning.
- You may have problems with urination, bowel function or leg swelling.
- Many women have problems with sexual satisfaction.
- You will not be able to have any more children.
- You may be worried about other cancers.

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Table 1

Characteristics of study population

	Entire sample (N = 76)		Sample included in the analysis (N = 65)	
Sociodemographics	**n**	**%**	**n**	**%**
Race/ethnicity				
White	31	41	29	45
Latina/Hispanic	27	36	19	29
African American/Black	11	14	11	17
Asian/Pacific Islander	3	4	3	5
Multiethnic/other	4	5	3	5
Completed interview in Spanish	26	34	17	26
Age (mean, SD)	38.4	11	38.8	11
< 25	6	8	5	8
25-29	18	24	15	23
30-39	17	22	14	22
40-49	22	29	19	29
50-64	13	17	12	18
Born in the United States	54	71	50	77
Educational attainment				
≤ High school graduate	18	24	11	17
Some college	21	28	20	31
College graduate	26	34	24	37
Graduate school	11	14	10	15
Income				
≤$25,000	22	29	14	22
$25,001-$50,000	27	36	25	38
$50,001-$100,000	17	22	17	26
> $100,000	7	9	7	11
Unsure	3	4	2	3
Married or living with partner	38	51	32	50
Insurance status				
Medi-Cal	14	18	11	17
Kaiser	18	24	17	26
Other private insurance or HMO	23	30	23	35
Medicare	2	3	2	3
Other	6	8	4	6
Unsure	3	4	3	5
None	13	17	8	12
Prior tests or treatments for dysplasia				
Colposcopy	68	89	60	92
LEEP	19	25	17	26
Cryotherapy	8	11	8	13

	Entire sample (N = 76)		Sample included in the analysis (N = 65)	
Cone biopsy	5	7	4	6
Hysterectomy	0	0	0	0
Positive HPV test*	34	46	29	46
Health-related quality of life †	48.3	11.5	49.2	11.0
PCS (SF-12; mean, SD)				
MCS (SF-12; mean, SD)	45.8	10.4	46.0	10.8
Cancer worry (mean, SD)‡	5.6	2.5	5.4	2.0

SD, standard deviation; HMO, health maintenance organization; LEEP, loop electrosurgical excision procedure; HPV, human papillomavirus; SF, short-form; PCS, Physical Component Summary; MCS, Mental Component Summary. All numbers are n (%) unless otherwise noted.

*We only asked participants whether or not they had had a positive HPV test.

†Scale ranges from 1 to 100, with higher scores denoting better physical and mental health.

‡Scale adapted from four-item Cancer Worry Scale developed by Lerman et al.(10) For each item, scores range from 4 to 16, with higher scores denoting more worry.

Table 2

Utilities* for outcomes of alternative surveillance strategies after treatment of high-grade cervical neoplasia

Scenario	n†	Mean	SD	Median	25%ile	75%ile
Scenarios describing events taking place within the 6-month period being assessed.						
Undergo Pap test, receive normal results	64	.989	.026	1.000	1.000	1.000
Undergo Pap and HPV tests, receive normal Pap and negative HPV results	64	.953	.176	1.000	.999	1.000
Undergo Pap test, receive abnormal results; undergo colposcopy, receive normal results	65	.927	.236	1.000	.977	1.000
Undergo Pap and HPV tests, receive normal Pap and positive HPV results	65	.909	.239	1.000	.958	1.000
Undergo Pap test, receive abnormal results; undergo colposcopy, minor changes (CIN 1); repeat colposcopy in 6 months	59	.897	.272	.998	.950	1.000
Undergo Pap test, receive abnormal results; undergo colposcopy, receive abnormal results (CIN 2/3); undergo LEEP, no cancer	65	.806	.358	.996	.889	1.000
Undergo colposcopy, results show very early (microinvasive) cancer; undergo a simple hysterectomy	59	.724	.385	.950	.528	.995
Undergo colposcopy, results show invasive cancer; undergo a radical hysterectomy or radiation and chemotherapy	59	.666	.415	.940	.078	.981
Scenarios with no screening or treatment during the 6-month period being assessed.						
Prior treatment for CIN 2/3; no cervical cancer testing	64	.835	.334	.984	.920	1.000
Diagnosed with early stage cervical cancer and treated with a simple hysterectomy *at some point in the past*	59	.816	.321	.972	.854	1.000
Diagnosed with invasive cervical cancer and treated with a radical hysterectomy or radiation and chemotherapy *at some point in the past*	59	.754	.350	.943	.679	.985

CIN; cervical intraepithelial neoplasia; SD, standard deviation; Pap, Papanicolaou; HPV, human papillomavirus; LEEP, loop electrosurgical excision procedure.

*Utilities were measured using the time tradeoff method and range from 0 = dead to 1=ideal health.

†Some participants did not rate all scenarios.

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Table 3

Unadjusted and adjusted associations between sociodemographic and other characteristics and having higher utilities for normal PAP plus negative HPV testing scenario versus a normal PAP only scenario

	Unadjusted OR			Adjusted OR		
	Odds Ratio	**95% CI**	**p-value**	**Odds Ratio**	**95% CI**	**p-value**
Ethnicity						
Latina	0.58	0.11-3.03	0.51	0.41	0.06-3.03	0.38
Other	1.00			1.00		
Race						
African American	0.48	0.05-4.21	0.50	0.61	0.04-9.36	0.72
Other	1.00			1.00		
Education						
Not a college graduate	0.45	0.10-1.91	0.27	0.68	0.10-4.62	0.69
College graduate	1.00			1.00		
Age						
≤ 39 years	1.21	0.31-4.67	0.78	1.61	0.37-7.12	0.53
> 39 years	1.00			1.00		
SF-12 MCS (centered on mean)*	0.95	0.89-1.01	0.08	0.94	0.88-1.004	0.06

OR, odds ratio; CI, confidence interval; SF, short form; MCS, mental component summary.

*Odds ratio for every one-point increase on the100-point MCS scale.