The Challenge of Follow-Up in a Low-Income Colposcopy Clinic: Characteristics Associated With Noncompliance in High-Risk Populations

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Abstract

Objective—The study aimed to identify sociodemographic and disease-specific factors associated with follow-up in an inner-city multiethnic colposcopy clinic.

Materials and Methods—All charts of patients referred to colposcopy clinic for abnormal cervical cytology and/or high-risk human papillomavirus infections to the University of California, Irvine, Colposcopy Clinic in Santa Ana from November 2006 to December 2007 were reviewed. Compliance was defined as at least 1 follow-up evaluation within 3 to 14 months from initial colposcopy appointment. To determine compliance, the following factors were evaluated in a multivariate analysis: race, age, spoken language, insurance status, annual income, marital status, referral cytology, histology, and pregnancy status.

Results—Among the 1,046 scheduled appointments, 50% were attended. Of the patients, 458 with a minimum of 14 months of follow-up were included. The mean (SD) age of these patients was 31.0(10.7) years. 58% were white and 55% spoke Spanish. A total of 248 patients (54%) had appropriately timed repeat testing, whereas 210 (46%) failed to return within 14 months. In univariate analysis, women who were referred from outside the clinic, single, younger than 40 years, and with self-pay or government-funded insurance were more likely to be noncompliant although this was not statistically significant. In multivariate analysis, referral from outside the clinic, self-pay, or government-funded insurance, Spanish-speaking, and single marital status were all significantly associated with non-compliance. Although cervical intraepithelial neoplasia 2 or 3 was not associated with noncompliance, 45% of women with cervical intraepithelial neoplasia 2 or 3 still did not comply with recommendations.

Conclusions—This inner-city clinic is perhaps successful at maintaining compliance for women at highest risk for cervical cancer when the triage originates from within the clinic and when the patient is married, English-speaking, and privately insured. However, reasons for those patients at highest risk for noncompliance in this clinic may need to be better characterized.

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Keywords

Despite improvements in our understanding of the progression of cervical intraepithelial neoplasia (CIN) to invasive cancer, cervical cancer is the leading cause of cancer deaths in women of developing nations [1–3]. Although the overall incidence in the United States has decreased dramatically over the years, patients who belong to a certain minority and/or low-income populations remain at high risk for cervical cancer. This may be due to a lack of access to health care and/or a lack of compliance once access has been granted. Disparities are known to exist among the US population in relation to incidence rates of cervical cancer, including racial and ethnic disparities [1, 4], especially in African American and Latina women [5]; age [6]; and socioeconomic status such as income, health care access, and education level [7, 8]. There are also discrepancies in prevention, screening, and treatment [1, 9]. Thus, an effort should be made to design and implement effective intervention strategies to improve compliance among high-risk patients.

Originating from a high-risk human papillomavirus (HPV) infection, invasive cervical cancer may take years to tens of years to progress, with potential opportunities to identify and treat CIN accordingly [10]. For women with persistently abnormal Pap test results, follow-up is based on the American Society for Colposcopy and Cervical Pathology (ASCCP) 2006 Consensus Guidelines, including screening via Pap test, then colposcopy-directed biopsy and/or elimination of cancer precursors through excisional procedures and continued surveillance and follow-up of care [11, 12]. This requires multiple visits to the doctor to avoid missed disease. Thus, noncompliance with any of these procedures may increase the risk of advanced CIN and/or the development of invasive cervical cancer [13–15]. Although research has revealed that progression to invasive cervical cancer or even the most severe CIN (CIN 3) does not occur in most HPV-infected women owing to regression of the infection [16–18], visits to the gynecologist are still necessary to detect advanced CIN and/or changes in cervical cells. It is likely that uninsured patients who do go on to develop a preventable disease like cervical cancer cause significant drain of public resources. This could include such expenses as radical surgery/chemoradiation (if curable) or possibly multiple emergency room visits, imaging, and palliative therapies (if incurable). Funding colposcopy clinics in areas of high-risk patients (i.e., areas of patients with low socioeconomic status) may help to offset the cost of caring for even one patient that develops advanced disease that would otherwise have been preventable. Furthermore, even though one may argue that most cases of CIN 1 and CIN 2 regress spontaneously, ultimately, some develop a worse preinvasive disease necessitating excisional procedures that may affect a patient's fertility and pregnancy outcomes, which are also likely impacting cost [19].

Thus, the objective of this study was to describe non-compliance with triage of abnormal Pap smear results and colposcopy in an inner-city, primarily government-funded program. Through exploration of risk factors associated with better follow-up, the goal was to be able to better define the patients at highest risk for noncompliance.

Materials and Methods

Chart Review

After approval from the investigational review board was obtained, a retrospective chart review was conducted of all patients referred to the colposcopy clinic in the University of California (UC), Irvine, Family Health Center in Santa Ana for abnormal results for cervical cytology and/or high-risk HPV DNA infections from November 2006 to December 2007. The following data were retrieved from the medical record (clinic charts and/or electronic records) by a trained research assistant for 458 patients who attended the clinic: date of initial colposcopy visit; date of follow-up counseling; date of next screening/test (Pap smear or excision/ablation); and patient characteristics such as age, race, marital status, pregnancy, Spanish surname (ethnicity), socioeconomic aspects such as zip code (to use as a proxy for income), primary language, insurance coverage, referral type, housing (house versus apartment), and disease factors such as cytology and histology. Of note, several different types of referrals present to this colposcopy clinic as follows: general obstetrics/gynecology and family practice clinics within the clinic building or referrals outside the clinic including private physicians or other community clinics.

During colposcopy visits in this clinic, the patients are routinely given materials on HPV and colposcopy in English or Spanish as well as counseled by the covering physician. In addition, they are given a note with their date of suggested follow-up and are told to make an appointment at the front desk or are given a number to call. In this clinic, patients seen in the colposcopy clinic are routinely recorded in a colposcopy spreadsheet and monitored for follow-up appointments and tests. If patients do not show up for repeat appointments, they are called. If 3 telephone calls (to the patient and/or their emergency contacts) are unsuccessful or if the telephone number is incorrect, a certified letter is sent to the patient encouraging follow-up. These letters are available in Spanish. Once these patients become colposcopy clinic patients, they are not routinely sent back to the referring physician because the referring clinics and physicians have sent these patients to this central colposcopy clinic for a more comprehensive and specialized care.

Guidelines: Defining Compliance in the Cohort Under Investigation

Follow-up recommendations for pathological diagnoses of CIN 1 to 3 were defined by ASCCP guidelines [13]. According to these guidelines, those with a histological diagnosis of CIN 1—mild CIN or preinvasive precursor lesions that can progress to squamous carcinomas of the cervix (cervical cancer) [9]—should return for another Pap smear/HPV test to screen for recurrent abnormal results for cytology [12]. Another abnormal result for cytology and a test positive for HPV require another colposcopy visit and subsequent follow-up visits to ensure no further progression of the CIN [12]. For women with a histological diagnosis of CIN 2 or CIN 3, excision via loop electrosurgical excision procedure (LEEP) or ablation of the transformation zone may be done, then follow-up Pap tests and/or colposcopy or HPV test. Patients are counseled to return to the clinic 6 to 12 months from their initial colposcopy. However, to accommodate scheduling, transportation, and child care issues, the follow-up interval was widened to a more "real-world" schedule. Thus, *compliance* in this study indicated that the patient returned to the Family Health

Center for treatment or another diagnosis within 14 months (but longer than 2.5 months) from their initial appointment, and *noncompliance* was defined as no follow-up visit at all within 2.5 to 14 months from initial appointment. Those patients who may have followed up for LEEP results less than 2.5 months from their procedure were excluded because it was felt that, more importantly, these women should be following up for their repeat Pap test. Furthermore, long-term (longer than 2.5 months) follow-up was thought to be more critical in this patient population where retention is difficult. Of the patients, 26 with less than 14 months of follow-up available were excluded. A total of 458 patients with follow-up time 12 to 28 months (median = 22 months) were included.

Statistics

Univariate statistical analyses were performed using Pearson χ^2 and *t* tests to measure for differences between groups defined by compliance (yes or no) in sociodemographic and clinical characteristics. Multivariate analysis was conducted using stepwise logistic regression. Variables entered into the multivariate model included age, race, marital status, language spoken, Spanish surname, histology, income, pregnancy status, insurance, and referral source. Variables that met significance criteria to enter with $p < .15$ were kept in the final model.

Results

Follow-up Rates

The total number of scheduled colposcopy appointments from November 2006 to December 2007 was 1,046. The number of appointments attended by patients was 523 with a no-show rate of 50% (523/1,046). Of the 458 patients who attended their first appointment, many required multiple subsequent visits. Of the patients, 54% (248/458) who attended their first appointment returned for follow-up and thus were considered compliant, as defined previously. Of the compliant subjects, 49% (121/248) returned for follow-up in less than 6 months (2.5–6 months), 34% (85/248) returned in 6–9 months, 14% (35/248) returned in 9–12 months, and 3% (7/248) returned in 12–14 months.

The noncompliant group (210/458) consisted of 188 who did not return at all in the specified time, 11 who returned in more than 14 months, and 11 who attended clinic in less than 2.5 months later but failed to return for follow-up. From the compliant group, the mean (SD) time to follow-up appointment was 194 (73) days or roughly 6.5 months, in line with ASCCP recommendations of 6 to 12 months for follow-up Pap smear and/or colposcopy.

The patient characteristics of this population can be seen in Table 1. Differences were small and, for the most part, did not reach statistical significance. Mean (SE) age was 31.7 (0.7) years for the compliant group versus 30.8 (0.7) years for the noncompliant group ($p = .36$). Women younger than 40 years were more likely to be non-compliant than did older women; however, differences were not significant (47% vs 39%, $p = .13$). Married women were more likely to follow up than did unmarried women although this was not statistically significant (59% vs 52%, $p = .19$). In addition, data suggest that women who were uninsured or had limited insurance coverage were more likely to be noncompliant compared with those

with any insurance (55% vs 44%, *p* = .07). Referrals from within the clinic were more likely to be compliant than those referred from outside sources (*p*=.045). However, of the 234 patients with colposcopy referral from within the clinic, 93 (40%) were also noncompliant with follow-up.

Of the 458 patients who attended their first appointment, 294 (68%) were diagnosed with CIN 1 or had normal result for histological diagnosis and 129 (44%) did not follow up. A total of 139 (32%) were diagnosed with CIN 2 or 3, and 62 (45%) of these patients did not follow up. Of the 25 patients with unknown histology, 19 (76%) were noncompliant. In univariate analysis, histological diagnosis of CIN 2 or 3 did not predict compliance. Of note, 54% of patients with CIN 2 or 3 had been referred from outside clinics. When looking at only those patients who were referred from within the clinic, 66% of those patients with CIN 2 or 3 had confirmed follow-up. If those patients referred from outside the clinic are excluded, the only significant predictor of compliance with recommended follow-up is marital status.

Of the 139 subjects with CIN 2 or 3, 46 (33%) had a LEEP at the first visit. Of these, 52% were compliant and 48% were noncompliant. Among those who did not have a LEEP at visit 1 (93/139), 57% were compliant and 43% were noncompliant. However, noteworthy is the 45% of women with CIN 2 or 3 that are still noncompliant (similar with the 44% of patients with CIN 1 who are noncompliant.)

Significant independent predictors of compliance in stepwise multivariate logistic regression analysis include marital status (married vs not married, odds ratio [OR] = 1.91, *p* = .013), referral from within UC, Irvine (OR = 2.02, *p* = .001), and having some kind of insurance (other than self-pay or outpatient limited insurance) (OR for self-pay or O/P limited = 0.53, *p* = .030) (Table 2). Spanish speakers had nonsignificantly lower compliance after adjusting for other variables (OR = 0.65, *p* = .07).

Discussion

The UC, Irvine, Family Health Center is Orange County's "only Federally Qualified Health Center, a facility that ensures the people living in medically underserved areas have access to health care" [20]. In 2007, the percentage of individuals living below the poverty line in Santa Ana was 17.1%, compared with 12.4% of individuals in the rest of California [21]. Because many patients in Orange County are underinsured, government-funded screening programs exist for those below the federal poverty level. However, obstacles might exist for women attending this clinic, especially with regard to transportation, child care, self-pay costs, education level and health care knowledge, or employment constraints. For these reasons, the women attending this clinic are potentially at higher risk for noncompliance with cervical cancer screening and diagnostic programs. Thus, the aim of this study was to investigate patient compliance with cervical cancer prevention and treatment programs by determining factors that influence follow-up after colposcopy.

In this study, various factors that may predict compliance of women attending the UC, Irvine, Family Health Center colposcopy clinic were explored. For example, women who are

married were more compliant. Previous findings also show that noncompliance of women with cervical neoplasia is associated with unmarried status [22–24]. Note that the unmarried women in this study were more likely to be younger (younger than 40 years), to be uninsured (self-pay/medical limited), to be referred from outside clinics, to be non-Hispanic (based on language and surname), to have lower income, and to have CIN 2 or 3.

In multivariable analysis, those women who were referred from outside clinics were more likely to be noncompliant. This may be because their follow-up cannot be guaranteed; they may be seen for follow-up with their referring clinic or physician. Because the clinic team has difficulty locating these women, the compliance with follow-up may be difficult to document.

At this colposcopy clinic, there is an intensive tracking program to maintain follow-up including counseling, mailing the results, telephone calls, and certified letters. These data demonstrate some success in maintaining follow-up for women referred from within the primary care given at the clinic.

Furthermore, it seems as though, compared with patients with lower grade lesions, those with higher grade lesions are more likely to follow up, which again may point to the success of the follow-up program. Yet, one cannot ignore the still striking report that 45% of these women lack documented follow-up. This means that, despite the counseling and tracking efforts, some women just do not return. Multiple socioeconomic factors were explored in an attempt to better define this noncompliant group, and patient characteristics associated with noncompliance were insurance status, referral source, marital status, and language spoken. Perhaps, it is these women that should be identified through more intense screening at the initial Pap smear or colposcopy visit. This could include ways to alleviate stress, ways to improve personal responsibilities and educational or literacy level, and general quality-of-life interventions aimed at improving compliance in these women at higher risk at the initiation of the colposcopy follow-up period.

Another way to look at the situation of improving colposcopy compliance is to improve this conventional method of doing biopsies to decrease the need for multiple, and even unnecessary, colposcopy [13]. The primary goal of colposcopy is to look for high-risk features, especially CIN 3 or the most advanced CIN. Yet, even colposcopy can miss significant lesions in a single visit, requiring additional colposcopies. In a review by Chase et al. [25], improving current colposcopic techniques, such as taking multiple biopsies to reach more accurate histology, and discovering new markers, such as HPV gene methylation [26], which may predict high-risk premalignant diseases in a less painful way might be more effective for cervical cancer screening/prevention and the future of follow-up procedures and compliancy [27]. Along with better education and awareness of cancer, improving colposcopy procedures and techniques to try to reduce anxiety and pain, to obtain more accurate histology, and even to lower costs may bring about a more accurate triage of patients and lead to a more efficient care of those at a higher risk for cervical cancer. Furthermore, a "see and treat" or visual inspection with acetic acid approach at the time of colposcopy may be appropriate and is acceptable under ASCCP guidelines especially in a

setting of poor follow-up [28]. It is hoped that these strategies, once improved, level some of the discrepancies in cervical cancer rates, local and worldwide.

As Behbakht et al. [9] described, disparities in cervical cancer rates exist essentially because of cultural, cognitive, and financial barriers. Various cultures and religions have different beliefs and attitudes about cancer and thus affect their outlook on risk factors and approaches on screening, prevention, and treatment [29–31]. In addition, women who lack the health literacy and awareness of cervical cancer and its features, such as the purpose of a Pap smear and when to receive it [32]; of risk factors of the sexually transmitted HPV and its link to invasive cervical cancer [33]; and about prevention and treatment of cancer progression and how preventable cervical cancer can be [33] are less likely to seek medical attention [7, 34]. This health illiteracy may also be a result of financial barriers that make it harder to access education [7]. Lack of finances also affects transportation, child care, and health care coverage [7]. These large-scale underlying factors for disparities in cervical cancer rates can be applied to small-scale situations such as the one analyzed by this study. A prospective study based on focus group data would be helpful to elucidate further other barriers to compliance, for example, car ownership, number of bus transfers required to get to a clinic, number of children living in the patient's home versus biological children, child care, income, employment status, family support, stability of the patient's current housing, educational level, and health literacy. Unfortunately, it could be possible that, as long as poverty and inadequate insurance and education persist in an inadequate health care system, follow-up issues and ultimately less-than-adequate cervical cancer prevention programs in groups at high risk will persist especially because this same group is the least likely to receive HPV vaccination.

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Table 1

Patient Characteristics

	Compliant—return 2.5–14 mo		Noncompliant—no return		Total	χ^2
	n	**%**	**n**	**%**	**n**	**p**
Age, y						
40	195	53	176	47	371	.159
>40	53	61	34	39	87	
Race						
White	149	57	114	43	263	.211
Other	99	51	96	49	198	
Language						
Spanish	102	55	92	45	194	.563
Other	146	56	118	44	264	
Surname						
Spanish	145	55	120	45	265	.775
Other	103	53	90	47	193	
Income						
$50,000	170	52	155	48	335	.154
>$50,000	77	60	52	40	129	
Marital status						
Married	75	59	52	41	127	.192
Other	173	52	158	48	331	
Pregnant						
Yes	36	47	40	52	76	.194
No	212	55	170	43	382	
Cytology						
HSIL	42	55	34	45	76	.909
LSIL/ASCUS	204	55	170	45	374	
Histology						
CIN 2 or 3/CIS	77	55	62	45	139	.887
CIN 1/normal	165	56	129	44	294	

| | Compliant—return 2.5–14 mo | | Noncompliant—no return | | Total | χ² |
	n	%	*n*	%	*n*	*p*
Unknown (excluded)	6	24	19	76	25	
Insurance						
Government-funded insurance for women less than 60	180	55	147	45	327	.127
Government-funded and privately-funded insurance for women over 60	34	62	21	38	55	
Self-pay or outpatient limited insurance	34	45	42	55	76	
Referred from						
UCI-FHC/UCIMC	141	60	93	40	234	.045
Planned parenthood	32	43	43	57	75	
Community clinic	12	36	21	64	33	
Private physician	20	50	20	50	40	

HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; ASCUS, atypical squamous cells of undetermined significance; CIN, cervical intraepithelial neoplasia; UCI-FHC, University of California, Irvine, Family Health Center; UCIMC, University of California, Irvine Medical Center.

Table 2

Predictors of Compliance—Multivariate Analysis (Revised)

Parameter	Coefficient	OR	Lower 95% CI	Upper 95% CI	p
Referral: UCI (1) versus other (0)	0.705	2.02	1.32	3.09	.001
Marital status: married (1) versus not married (0)	0.646	1.91	1.15	3.16	.013
Insurance: self or O/P limited (1) versus other insurance (0)	−0.644	0.53	0.29	0.94	.030
Language: Spanish (1) versus other (0)	−0.425	0.65	0.41	1.04	.070

OR, odds ratio; CI, confidence interval.