

Variations in Practice Guideline Adherence for Abnormal Cervical Cytology in a County Healthcare System

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BACKGROUND: Reduction in cervical cancer incidence and mortality is not only dependant on promoting cervical cancer screening but also on providing appropriate follow-up and treatment of abnormal cervical cytology.

OBJECTIVES: The objective of this study was to determine variations in guideline adherence for women requiring abnormal cervical cytology follow-up.

SUBJECTS: Subjects of the study are women 18 years or older with an abnormal Pap test in 2000 within a large county healthcare system ($n=8,571$).

MEASUREMENTS: Guideline adherence was determined by the presence or absence of the appropriate follow-up procedure within an acceptable time interval for each degree of cytological abnormality. Patients with no follow-up studies were deemed to be lost to follow-up.

RESULTS: Of study subjects, 18.5% were lost to follow-up care. Of the remaining 6,987 women, 60.3% received optimal care, 9.4% received suboptimal care, and 30.3% received poor care. Follow-up rates were higher for patients with higher degree of cytological abnormality (OR, 1.29, 95% CI, 1.17–1.42), older patients (OR, 1.03, 95% CI, 1.02–1.030) and those receiving the index Pap test at a larger healthcare facility (OR, 1.13; 95% CI, 1.01–1.27). Receiving optimal care was positively correlated with higher degree of cytological abnormality ($p<.0001$) and larger facility size ($p=.002$). Regional variations in care demonstrated the largest cluster having the lowest lost to follow-up rate and the most optimal care.

CONCLUSIONS: A significant number of women with abnormal cervical cytology are receiving less than optimal care. Further studies are required to determine the specific healthcare delivery practices that need to be targeted to improve guideline adherence for follow-up of abnormal cytology.

KEY WORDS: cytology; quality of care; practice guidelines; cervical cancer.

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INTRODUCTION

The American Cancer Society has estimated that 9,710 cases of invasive cervical cancer were diagnosed, and 3,700 deaths were attributed to the disease in the USA in 2006.¹ Cervical cancer is considered a preventable disease if women are appropriately screened. Institution of cervical cancer screening programs using the Papanicolaou (Pap) test has decreased mortality from cervical cancer by 75–80% in the last 50 years²; however, cervical cancer remains an important cause of morbidity and mortality in underserved, high-risk populations including minorities,³ individuals with low-income,^{4–6} the uninsured^{4–6}, and the elderly.⁷ In Los Angeles County, these high-risk groups have significantly higher cervical cancer incidence and mortality rates compared with the national average.^{8,9}

Despite the promise of the new human papillomavirus (HPV) vaccine in the fight against cervical cancer, providing comprehensive cervical cancer screening with Pap tests and appropriate follow-up and treatment of positive screening examinations remains key in reducing incidence and mortality. Although 85–89% of female Los Angeles County Healthcare System (LACHS) users have received a Pap test within the last 3 years, it is not known if women with abnormal cytology have been appropriately evaluated and treated.¹⁰ Other studies have shown that lost to follow-up rates in women seen at inner-city, public healthcare facilities vary from 20 to 50%.^{11–15} Several interventional studies have been performed in the LACHS directed at reducing lost to follow-up rates; however, they did not address the quality of care that women received.^{11–13}

Of approximately 50 million women undergoing Pap testing each year, 3.5 million (7%) of the women will require additional follow-up and evaluation.¹⁶ Determining which of these women are at increased risk for cervical neoplasia, performing appropriate diagnostic evaluations, and providing definitive treatment for discovered disease remains an important aspect of cervical cancer prevention and early detection. Therefore, we performed this study with the objective of determining if practice guidelines established by the National Cancer Institute¹⁷ have been adhered to during follow-up of abnormal cervical cytology.

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METHODS

Setting

Women in this study were patients from more than 90% of the facilities in the Los Angeles County Healthcare System in 2000: four hospitals, all six comprehensive health centers (CHCs), and 21 personal health centers (PHCs). One hospital, four PHCs, and a rehabilitation center were excluded because of remote location and a lack of a centralized cytology lab for data collection. The participating study sites accounted for more than 95% of the Pap tests taken in the county healthcare system in 2000.

Facilities were categorized into three groups based on their size. Personal health centers, serving as primary care clinics in the healthcare system, performed cervical cancer screening only. Comprehensive health centers (mid-sized clinics) and the medical centers (hospital level centers) served as referral centers for further evaluation of abnormal cervical cytology. Facility type is used to denote the size of the facility.

The facilities were organized into regionalized systems of care with each of 4 clusters consisting of a medical center serving as the tertiary care level facility, 1 to 3 CHCs, and several PHCs. Regional cluster is used as a measure of the existing clustering of facilities into these independent systems of care. The study protocol with a waiver of informed consent was approved by the institutional review board at each institution.

Sample

Women 18 years and older were eligible for the study if they had an abnormal cytology between January 1st and December 31, 2000 at one of the study sites. An abnormal cytology was defined per Bethesda System terminology¹⁸ as: squamous cell carcinoma, adenocarcinoma, high-grade squamous intraepithelial lesion (HSIL), atypical glandular cells of undetermined significance (AGUS), low-grade squamous intraepithelial lesion (LSIL), atypical squamous cells of undetermined significance (ASCUS), or unsatisfactory. Pap tests reported as "satisfactory but limited by" were not included. All cytology being performed in the study sites were traditional Pap tests. Liquid-based cytology and HPV testing was not performed during the study period.

Data Collection

Records of approximately 82,000 Pap tests from 3 laboratories used by the study sites were reviewed to identify eligible patients. Computer-assisted cross-referencing ensured that each woman was counted only once with the first abnormal

cytology in the year representing the index case. Cytology and histology records from January 1, 2000 to December 31, 2002 were searched to identify all pathology follow-up evaluations performed on the women in the study cohort. Cytology data were obtained from the same laboratories, and histology data were obtained from the computerized database at each medical center that stores results for procedures conducted at the medical center and the associated CHCs. Information on colposcopies was not available. To overcome this, the responsible clinical provider from each healthcare facility was interviewed to determine standard clinical practices in each setting. This found that 92% of clinicians routinely performed endocervical curettage, thereby generating a histology specimen at every colposcopy.

Patient identifiers, including name, date of birth, and medical record number, were used to match the follow-up studies with the index case. All three identifiers matched in more than 95% of cases. For remaining studies, they were determined to be from the same patient if at least 2 of the three identifiers matched. Two trained research staff performed the data abstraction, and all pathology reports were over read by the primary author.

Measures of Follow-up and Appropriateness

The main objective of the study was to determine the quality of care provided to women with abnormal Pap tests. The quality of care was evaluated using 3 measures: (1) Presence or absence of *any* follow-up care defined as the patient having at least 1 additional cytology or histology specimen during the follow-up period. (2) Provision of the appropriate follow-up cytology or histology specimen relative to the index Pap test result as outlined in published practice guidelines.¹⁷ (3) Timeliness of follow-up measured as the time from the index Pap test to the appropriate follow-up study based on published practice guidelines when available or on expert opinion obtained from a panel of 5 physicians with expertise in the management of abnormal cytology.

Appropriateness of care was categorized into 3 levels based on the timeliness and type of follow-up procedures performed for each degree of Pap test abnormality as outlined in Table 1. Optimal care denoted that the correct procedure had been performed within an acceptable time interval. Suboptimal care indicated that the correct procedure was performed so practice guidelines were followed, but with significant delay in timing. Poor care denoted that either an inadequate procedure was performed, indicating practice guidelines were not followed, or

Table 1. Diagnostic Evaluation Protocol for Determining Appropriateness of Care for Women with Abnormal Cervical Cytology*

Pap test result	Optimal care	Suboptimal care	Poor care
SCC and adenocarcinoma [†]	Histology specimen within 1 mo	Histology specimen within 1–3 mo	Histology specimen >3 mo or only cytology specimen
HSIL and AGUS [†]	Histology specimen within 3 mo	Histology specimen within 3–6 mo	Histology specimen >6 mo or only cytology specimen
LSIL and ASCUS [‡]	Histology specimen within 6 mo or serial Pap tests every 3–6 mo times 2	Histology specimen within 6–9 mo or serial Pap tests 6–9 mo apart times 2	Histology specimen >9 mo or serial Pap tests <3 mo or >9 mo apart
Unsatisfactory	Pap test or histology specimen within 12 mo	Pap test or histology specimen within 12–18 mo	Pap test or histology specimen >18 mo

*Based on guidelines published by National Cancer Institute and expert opinion

[†]For adenocarcinoma and AGUS, endometrial biopsies were considered acceptable histology follow-up.

[‡]If either follow-up Pap test was abnormal, histological evidence of colposcopy was expected.

the time to care was unacceptable. Patients that had no follow-up studies were deemed to be lost to follow-up and put into a fourth category.

Statistical Analysis

The analysis included all the women in the cohort. Descriptive statistics were used to examine the association between independent variables and the outcomes of interest. Independent variables included degree of cytological abnormality, patient's age, and measures of facility organization (facility size and regional clustering). Initial associations were examined for the overall sample and then separately for the subgroups of women with each degree of Pap test abnormality, facility size, and regional cluster using the chi-square test for homogeneity.

Dichotomous logistic regression was used to examine the factors independently associated with lost to follow-up care, and an ordinal logistic regression model was used to examine the factors associated with the appropriateness of follow-up care. As the regional cluster was an issue in the estimation of the regression models, it was accounted for by the use of the Huber "correction" approach incorporated into the STATA (version 8) statistical package (College Station, Texas, 2004). Also, because the model of the appropriateness of follow-up care excluded women who were lost to follow-up, it was necessary to account for potential bias in this analysis. A probability weighting scheme was incorporated, where the weights were calculated as the reciprocal of the probability of follow-up, which was derived from a logistic regression model for all women in the sample using available demographic variables.

RESULTS

Characteristics of Cohort

The characteristics of the study cohort which included 8,571 women who met eligibility criteria are displayed in Table 2. Mean age of the women was 39.2 years (SD 13.3 years). More than 50% of the cohort had an index Pap test result of ASCUS,

Table 2. Characteristics of the Study Population

	Study cohort, n (%)
Total patients	8,571
Age (y)—mean±SD; range	39.2±13.3 (18–90)
Index Pap test result	
Carcinoma	34 (0.4)
HSIL	479 (5.6)
AGUS	699 (8.2)
LSIL	1,478 (17.2)
ASCUS	4,671 (54.5)
Unsatisfactory	1,210 (14.1)
Facility size	
Medical center/hospital (n=4)	4,221 (49.3)
Mid-size clinic (CHC; n=6)	2,538 (29.6)
Small clinic (PHC; n=21)	1,812 (21.1)
Regional cluster	
1 (n=9)	4,381 (51.1)
2 (n=8)	1,394 (16.3)
3 (n=5)	1,469 (17.1)
4 (n=9)	1,327 (15.5)

and 17.2% of cases were LSIL. Of the patients, 14.2% had a high-grade Pap test abnormality (cancer, HSIL, or AGUS), and 14.1% of cases were identified as being unsatisfactory.

Close to half of the cases with an abnormal index Pap test originated in medical centers, whereas 29.6% cases came from CHCs and 21.1% from PHCs. Regional cluster 1 was the largest system of care accounting for 50% of the index Pap tests, and the remaining three clusters were fairly evenly divided with 15.5 to 17.1% of the cases each.

Variations in Lost to Follow-Up Care

Overall, 1,584 (18.5%) patients in the cohort were lost to follow-up care, defined as not having any follow-up cytology or histology specimens within the county's healthcare system in the course of the 3 study years. Lost to follow-up rates declined with increasing patient age and increasing severity of index Pap test result (Table 3). All patients with Pap tests suspicious for carcinoma received follow-up. The highest lost to follow-up rate was at the small clinics (PHCs; 23.1%) and in cases of LSIL and ASCUS ($p<.01$). Regional cluster variations indicated highest lost to follow-up in cluster 4 and lowest lost to follow-up in cluster 1.

Logistic regression analysis examining the factors predicting lost to follow-up found patients with higher grade abnormalities were less likely to be lost to follow-up (OR, 1.29; 95% CI, 1.17–1.42), as were older patients (OR, 1.03; 95% CI, 1.02–1.03) and patients with an index Pap test obtained at larger facilities (OR, 1.13; 95% CI, 1.01–1.27).

Variations in Appropriateness of Follow-Up Care

Of the 6,987 patients that returned for follow-up care, 4,216 (60.3%) had optimal care, 655 (9.4%) had suboptimal care, and 2,116 (30.3%) had poor care (Table 4). Poor care was most frequently observed for the low-grade Pap test abnormalities, LSIL (28.4%) and ASCUS (41.2%). LSIL and ASCUS cases were further examined to determine how patients with serial Pap test follow-up compared with those that received colposcopy with biopsy or endocervical curettage. It was found that for both LSIL and ASCUS cases, those receiving histological follow-up had higher rates of optimal follow-up, 95.8% ($n=672$) and 92.3% ($n=1,381$) respectively, compared with cytological follow-up, 5.9% ($n=305$) and 9.7% ($n=1,581$) respectively.

Analysis by facility characteristics found that the medical centers had a higher rate of appropriate care (68.6%) compared to CHCs (47.4%) and PHCs (44.3%; Table 4). Regional variations indicated that cluster 1 had the most optimal follow-up care (70.1%) and cluster 2 the least (31%). Further analysis of cluster 2 determined that suboptimal care was provided more frequently at the PHCs and CHC.

Appropriateness of follow-up care was significantly predicted by the degree of Pap test abnormality ($p<.0001$) and the facility size ($p=.002$); but not by patient's age. Women with a higher degree of Pap test abnormality had a higher probability of receiving optimal care (98.3% for cancer vs. 61.5% for ASCUS at medical centers), and women receiving care at larger facilities had higher probabilities of receiving optimal care (i.e., of women with HSIL, 92.5% received optimal care at medical centers vs. 78.5% of women at CHCs and only 54.3% of women at PHCs).

Table 3. Lost to Follow-Up Care for Women with Abnormal Cervical Cytology (n=8,571)

	Lost to follow-up N (%)	Returned for any follow-up N (%)	P value*	Adjusted odds ratio† (95% CI)
Overall	1,584 (18.5)	6,987 (81.5)	<0.0001	
Age			<0.0001	1.03 (1.02–1.03)‡
<30 years	647 (27.6)	1,698 (72.4)		
30–50 years	661 (15.6)	3,576 (84.4)		
>50 years	271 (13.7)	1,713 (86.3)		
Index Pap test result			<0.001	1.29 (1.17–1.42)§
Carcinoma	0 (0.0)	34 (100.0)		
HSIL	41 (8.6)	438 (91.4)		
AGUS	76 (10.9)	623 (89.1)		
LSIL	277 (18.7)	1,201 (81.3)		
ASCUS	934 (20.0)	3,737 (80.0)		
Unsatisfactory	256 (21.2)	954 (78.8)		
Facility size			<0.001	1.13 (1.01–1.27)¶
Medical center/hospital	757 (17.9)	3,464 (82.1)		
Mid-size clinic (CHC)	409 (16.1)	2,129 (83.9)		
Small clinic (PHC)	418 (23.1)	1,394 (76.9)		
Regional cluster			<0.001	
1	670 (15.3)	3,711 (84.7)		
2	272 (19.5)	1,122 (80.5)		
3	318 (21.7)	1,151 (78.3)		
4	324 (24.4)	1,003 (75.6)		

* χ^2 test for homogeneity

†Adjusted for age, degree of Pap test abnormality, facility size and clustering by facility location

‡Older age, $p < .0001$ §Higher degree of Pap test abnormality, $p < .0001$ ¶Larger facility size, $p = .032$

DISCUSSION

Our work provides insight into the quality of care being provided to women with abnormal cervical cytology. Although screening rates for cervical cancer remain high,¹⁹ appropriate diagnostic evaluation of abnormal screening tests and therapeutic intervention for pre-invasive neoplasia is necessary to reduce cervical cancer incidence and mortality. Our study

suggests that compared to historical controls,^{11–13} lost to follow-up rates have declined in this county healthcare system. However, for those that did return for follow-up care, a substantial proportion of women are receiving less than optimal follow-up care as defined by practice guidelines.

A majority of the patients with less than optimal care fell within the poor care category and not suboptimal care, pointing to the lack of provider adherence to practice guide-

Table 4. Appropriateness of Care for Women Returning for Follow-Up of Abnormal Cervical Cytology (n=6,987)

	Optimal care N (%)	Suboptimal care N (%)	Poor care N (%)	P value*
Overall	4,216 (60.3)	655 (9.4)	2,116 (30.3)	<.0001
Age				.13
<30 years	1,007 (59.3)	140 (8.2)	551 (32.5)	
30–50 years	2,175 (60.8)	344 (9.6)	1,057 (29.6)	
>50 years	1,034 (60.4)	171 (9.9)	508 (29.7)	
Index Pap test result				<.0001
Carcinoma	34 (100.0)	0 (0.0)	0 (0.0)	
HSIL	352 (80.4)	34 (7.8)	52 (11.8)	
AGUS	399 (64.0)	88 (14.1)	136 (21.9)	
LSIL	789 (65.7)	71 (5.9)	341 (28.4)	
ASCUS	1,766 (47.3)	431 (11.5)	1,540 (41.2)	
Unsatisfactory	876 (91.8)	31 (3.3)	47 (4.9)	
Facility Size				<.0001
Medical Center/Hospital	2,375 (68.6)	226 (6.5)	863 (24.9)	
Mid-size clinic (CHC)	1,223 (57.4)	229 (10.8)	677 (31.8)	
Small clinic (PHC)	618 (44.3)	200 (14.4)	576 (41.3)	
Regional cluster				<.0001
1	2,600 (70.1)	263 (7.1)	848 (22.8)	
2	348 (31.0)	171 (15.2)	603 (53.8)	
3	678 (58.9)	125 (10.9)	348 (30.2)	
4	590 (58.8)	96 (9.6)	317 (31.6)	

* χ^2 test for homogeneity

lines as a prominent feature of care. Patient and clinic factors could account for delays in the timeliness of care received (suboptimal care); however, lack of provider knowledge of practice guidelines would account for incorrect procedures being performed during follow-up (poor care). Our findings point to a need for increased provider education regarding the appropriate evidence-based follow-up for women with abnormal cervical cytology.

In our study, women with high-grade Pap test abnormalities had better follow-up care than women with low-grade abnormalities with the exception of AGUS. This is consistent with findings from another study conducted within a largely suburban patient population where only 36% of women with an AGUS cytology result received appropriate and thorough evaluation.²⁰ AGUS has often been misunderstood to represent a low-grade cervical abnormality with uncertain significance similar to ASCUS^{21,22}; however, invasive cancers are found in more than 5%, and high-grade pre-invasive disease is found in 14% of women with AGUS,²³ which puts these patients at a significantly higher risk if they do not receive a timely and thorough evaluation.

Furthermore, it is worth noting that in our study, unsatisfactory smears received, with the exception of cancer, the highest rate of appropriate follow-up at almost 92%, identifying another opportunity for provider education. While assessment of adequacy is an integral part of the overall evaluation of a cervical cytology smear, data show that there are often no significant differences in the incidence of squamous abnormalities following an unsatisfactory smear compared to a negative smear.^{24,25}

There was a large discrepancy in the appropriateness of care for low-grade cytological abnormalities (LSIL and ASCUS) that were managed through accelerated cytological evaluation rather than immediate colposcopy with histological evaluation. Although more than 70% of LSIL cases spontaneously revert to normal, about 30% of these patients will have CIN II/III or invasive cancer diagnosed at initial evaluation or during surveillance.^{26,27} Recent management guidelines (2001) recommend a more aggressive evaluation of women with LSIL diagnosis, with immediate colposcopy rather than serial cytology.¹⁶ Also, the addition of the category ASC-H in the 2001 Bethesda System serves to differentiate those cases of ASC that have a higher positive predictive value for histological abnormalities, triaging them to immediate colposcopy. Lastly, the introduction of HPV testing in the triage of women with ASCUS should serve as a significant factor in improving management of low-grade cytological abnormalities.

Although liquid-based cytology, reflex HPV testing for ASCUS, and combined HPV/cytology screening were not used during this study period, the results of this study remain valid. While these new screening and management modalities may shift patients between immediate colposcopy and accelerated or routine cytologic follow-up, the fundamental issue identified in this study remains unaltered: a deficiency in adherence to practice guidelines.

In our study, cases originating at larger medical centers received more optimal care than cases originating at small clinics. A study performed in this same population in 1990 also found that patients from PHCs were less likely to complete their follow-up care compared with patients from CHCs.²⁸ Potential explanations include that women with abnormal cervical cytology at a PHC must navigate several additional

medical facilities to receive complete evaluation for their abnormal Pap test. Both clinic and patient factors such as discrepancies in referral systems, delays in making appointments, and large travel distances would affect the success of these women receiving appropriate follow-up.

Regional variations, also apparent within this county healthcare system, could be explained by the geographic size of the cluster, availability or lack of a public transportation network, the socioeconomic and ethnic makeup of the patient population in that specific region, as well as the size, availability, and specialization of the medical teaching programs at specific facilities. Further studies are needed to determine which of these factors influence the quality of care being provided to women with abnormal cervical cytology.

As this study was conducted within a single healthcare system in Los Angeles County, the results may not be generalizable to healthcare systems in other regions or non-county healthcare systems within Los Angeles. In addition, the study results do not account for patient migration. As patients in the county healthcare system gain and lose health insurance, they may move in and out of the system, giving the appearance of incomplete care. However, if this were the sole reason, one would expect lack of follow-up to be randomly distributed across cytological abnormalities and not strongly inversely influenced by the degree of cytological abnormality.

Given that our study was conducted before the 2002 release of the updated management guidelines for abnormal cervical cytology, the criteria used in determining appropriateness of care were based on guidelines published in 1994. These guidelines provided instructions only on the procedures recommended during the management of abnormal Pap tests. The optimal time interval within which follow-up studies should have been done was determined by expert opinion. The validity of such criteria could be questioned; however, the experts enlisted strongly agreed that the criteria closely represented the standards of care at the time.

In conclusion, our study suggests that the overall quality of follow-up care being provided to women with abnormal Pap tests needs to be addressed. This need is not unique to this county's healthcare system, as attested by several other recent studies, which highlighted under-management of AGUS²⁰ or the lack of guideline adherence in women with ASCUS or LSIL.²⁹ Deficiencies identified in practice guideline adherence in our study serve as a basis to further define factors influencing the quality of care for women with abnormal Pap tests and for developing targeted interventions of specific healthcare delivery practices. In addition, studies examining appropriateness of treatment of cervical dysplasia and early cancer are warranted. Ultimately, improving the quality of care in a healthcare system serving a high-risk population will help decrease disparities in cervical cancer mortality.

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