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Performance of Implementing Guideline Driven Cervical Cancer Screening Measures in an Inner City Hospital System

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Abstract

Objective—In 2006, the American Society for Colposcopy and Cervical Pathology (ASCCP) updated evidence based guidelines recommending screening intervals for women with abnormal cervical cytology. In our low-income inner city population, we sought to improve performance by uniformly applying the guidelines to all patients. We report the prospective performance of a comprehensive tracking, evidence-based algorithmically driven call-back and appointment scheduling system for cervical cancer screening in a resource-limited inner city population.

Materials and Methods—Outreach efforts were formalized with algorithm-based protocols for triage to colposcopy, with universal adherence to evidence-based guidelines. During implementation from August 2006 through July 2008, we prospectively tracked performance using the electronic medical record with administrative and pathology reports to determine performance variables such as the total number of Pap tests, colposcopy visits, and the distribution of abnormal cytology and histology results, including all CIN 2,3 diagnoses.

Results—86,257 gynecologic visits and 41,527 Pap tests were performed system-wide during this period of widespread and uniform implementation of standard cervical cancer screening guidelines. The number of Pap tests performed per month varied little. The incidence of CIN 1 significantly decreased from 117/171 (68.4%) the first tracked month to 52/95 (54.7%) the last tracked month ($p=0.04$). The monthly incidence rate of CIN 2,3, including incident cervical cancers did not change. The total number of colposcopy visits declined, resulting in a 50% decrease in costs related to colposcopy services and approximately a 12% decrease in costs related to excisional biopsies.

Conclusions—Adherence to cervical cancer screening guidelines reduced the number of unnecessary colposcopies without increasing numbers of potentially missed CIN 2,3 lesions, including cervical cancer. Uniform implementation of administrative-based performance initiatives for cervical cancer screening minimizes differences in provider practices and maximizes performance of screening while containing cervical cancer screening costs.

Keywords

Pap smear; cytology; histology; colposcopy; follow-up

Introduction

A successful cervical cancer screening program includes performing Pap tests at regular intervals, recalling those with abnormal results for further evaluation such as repeat cytology, HPV testing or colposcopy with biopsy, and finally, assuring patient compliance. A systematic review of follow-up care after abnormal cervical, breast, and colon cancer screening showed that fewer than 75% of women received timely intervention and that the delay from index Pap to colposcopy can be as long as 3–4 months. Delays in follow up then increase the number of patients who ultimately fail to return for recommended care (1–3).

A better understanding of the natural history of cervical intraepithelial neoplasia (CIN) has resulted in the generation and regular updating of guidelines using uniform cytologic and histologic diagnostic categories. The 2006 American Society for Colposcopy and Cervical Pathology (ASCCP) Guidelines for the Management of Women with Abnormal Cervical Cytology and Cervical Cancer Precursors were developed at a consensus process comprised of 146 experts representing 29 organizations and professional societies (4). These guidelines have been re-affirmed by a number of organizations, including the American College of Obstetricians and Gynecologists ACOG (5).

Public hospitals, driven by performance and quality measures, have less financial incentive to increase the frequency of visits or procedures as service costs are often fixed regardless of patient volume. In 2006, soon after the ASCCP guidelines were revised, our institutional leadership recognized the need to: (1) adhere to evidence-based guidelines, (2) improve patient outreach for abnormal cytology results, and (3) verify that patients actually present for appropriate evaluation. To overcome provider and patient barriers to instituting guideline driven cervical cancer screening, we formalized a patient outreach system to centrally review all cytology and histology results and standardize the approach to management of all women with abnormal cytology. In this report, we describe the administrative algorithms and performance of this system as it was implemented in an urban, largely underinsured, high-risk population.

Materials and Methods

Institutional Review Board (IRB) approval was obtained to collect HIPAA-identified information from the North Bronx Health Network (NBHN) hospital records. Between August 2006 and July 2008, we tracked all Pap tests performed within our network.

The 2006 ASCCP guidelines for the management of abnormal cytology and cervical cancer precursors were posted in the clinical areas. Providers reviewed the algorithms and agreed to adhere to the recommendations. Administrative protocols, written in table format to be easily understood by all support staff, provided the time frame for scheduling follow-up appointments for further clinical evaluation and management of abnormal cytology and histology results. The electronic medical record (EMR), pathology, and administrative databases were linked with multiple safety alerts and cross-checks, to prospectively track all data and ensure that no results were missed by human error and to note when patients failed to show for scheduled appointments.

As per 2006 ASCCP guidelines, screening included Pap testing with HPV testing as a reflex test for atypical squamous cells of uncertain significance (ASCUS) results only (6). All Pap tests performed during this period used ThinPrep® (Hologic, Marlborough, MA) and all HPV testing was done using HC2 High-Risk HPV Test (Qiagen, Valencia, CA). Pap tests were performed by all primary care specialties including OB/GYN, family practice, and internal medicine providers. Additionally, referrals to NBHN colposcopy clinics come from

surrounding providers who serve low-income patients. HPV co-testing in women 30 and over is not reimbursed by Medicaid and therefore was not performed system wide. The number of referrals from outside clinics into our system for colposcopy varied little during this 24 month period of time. Additionally, the number of dedicated colposcopy sessions and providers did not fluctuate during the study interval.

All follow-up notifications of abnormal cytology and management of missed appointments were guided separately from point of care visits by the algorithm summarized in Figure 1. A provider in the Women's Health Department reviewed all abnormal cytology and histology results and instructed the administrative staff on arranging follow-up, strictly according to the algorithm summarized in Table 1.

From the EMR, we extracted the cytology and histology results, HPV testing results, appointment dates, and documentation of outreach attempts. The reports were linked behind a HIPAA firewall and merged for analysis. To avoid over-counting patients with more than one medical record number, patients' names and dates of birth were initially matched to the medical record numbers prior to database merger, at which point all data was de-identified.

Follow-up was tracked for each patient, starting with her first visit and tracking to the next visit, which could have been either a visit for a Pap and/or colposcopy assessment. The average time between these visits was calculated and presented in four 6-month blocks. All of the cytology and histology was counted, but the linking of the histology with the immediately preceding cytology was directly correlated by a pathologist. The diagnosis was classified based on the pathologist's correlation which was considered the final diagnosis for that patient. We tracked the patients prospectively for 24 months. The analysis of the interval number of weeks to return visit was extended to January 2009 to include those patients who had been initially referred to colposcopy during the last quartile of the study interval; however, new abnormal cytology results during this additional time period were censored. All data analyses in this study were performed using SAS version 9.2 (SAS Institute, Cary, NC).

Costs for the following current procedural terminology (CPT) codes: 1) Colposcopy with biopsy (57455), 2) Colposcopy with endocervical curettage (ECC) (57456), and 3) loop electrosurgical excision procedure (LEEP) (57461), were determined using the actual New York State Medicaid payment received for that time period since Medicaid was the insurance for the vast majority of those treated at NBHN who were insured. The average payment for a Thin Prep® Pap test was \$29. Colposcopy and biopsy was \$85.50. Colposcopy and ECC was \$90.82. LEEP/Cone biopsy was \$196.70 during the studied time period. The cost of HPV testing was \$60. The costs of these procedures were confirmed with other local hospital labs and were a reasonable approximation of cost and payment at NBHN. The cost analysis is the percent difference of the total cost for patients seen at the beginning of implementation of our system and at the end of the tracking period.

Results

Between August 1, 2006 and July 31, 2008, 86,257 gynecologic visits and 41,527 Pap tests were performed system-wide. There was a per-month median of 3647 (range 2968–4235) gynecologic visits, 1702 (range 1386–2301) Pap tests, 333 (range 222–474) abnormal Pap results, and 298 (range 197–415) colposcopy visits. The average age of women coming in for gynecologic visits was 32 years old (range 14–90). Of the total number of Pap tests, 7,813 (18.8%) were recorded as abnormal, confirmed by institutional pathologists. This rate is higher than the national average because all patients referred into the system for colposcopy had cytology rechecked by NBHN pathologists. The within institution

colposcopy referral abnormal Pap rate is less than 7%. Our study preceded the updates to the guidelines regarding screening in adolescents (1). In this time period, 1,341 women under the age of 21 had an abnormal Pap test.

While the month-by-month total number of gynecology visits during this time period varied little, incident number/month of LSIL decreased from a peak of 212 women in August 2006 to 112 women in July 2008. A similar, though not as substantial, decrease in absolute number/month for HSIL was noted with the frequency declining from 124 to 112 women. All other frequencies of less common cytologic diagnoses remained steady over this time period. (Figure 2).

Of total gynecologic visits, colposcopy visits accounted for 8.58% of the visits in August 2006 and 7.66% of all gynecology visits by July 2008. As per the guidelines, patients being tracked for findings of LSIL or CIN 1 can have repeat cytology without biopsy at the subsequent visit if prior results were consistent with low grade disease (5). There was a decreasing frequency of colposcopy, cervical biopsies and endocervical curettage procedures over this time period (Figure 3). The number of excisional procedures did not significantly vary from month to month. 5,420 colposcopy related procedures were performed, of which 429 were LEEP or Cone procedures, 2,021 were cervical biopsies, and 2,970 were sampling of the endocervix. When stratified by histological diagnosis, the number of CIN 1 diagnosed in August 2006 significantly decreased from 117 out of a total of 171 (68.4%) biopsies performed to 52 out of 95 (54.7%). biopsies performed in July 2008. The month- to-month rate of new CIN 2,3 or invasive cervical cancers did not substantially change (see Figure 4, $p=0.04$).

While the overall decline in number of colposcopy visits appears small, despite being significant, a dramatic decrease in costs related to cervical cancer screening was calculated during this time period. Comparing the number of histological procedures performed in August 2006 to the number performed in July 2008, the total cost for colposcopy with cervical biopsy decreased by 50%. Similarly, based on the number of colposcopies performed in July of 2008 (54 colposcopies with ECC performed) compared to August 2006 (167 colposcopies with ECC performed), assuming a cost of \$85.50, total cost of colposcopy with ECC decreased by 46.71%. Utilizing an average cost of LEEP/Cone biopsy of \$90.82 and calculating the difference in number of procedures in July 2008 (15 LEEP/Cone biopsies) to August 2006 (17 LEEP/Cone biopsies), we found that the cost of LEEP/cone biopsies on average decreased by 11.76%. Using the national average cost for ThinPrep® Pap test, there was an average decrease of 20% in total cost of Pap tests during this study period. The cost decreases occurred while maintaining the same rates of detection of incident CIN 2,3 and invasive cervical cancers.

100% of patients who had an abnormal result were notified in accordance with the administrative protocols. The median time in weeks from an incident abnormal Pap result to the patient's return for the recommended colposcopy evaluation improved by 45% over this time period. This dramatic improvement in time to follow up was not due to more sessions or providers, but attributable to administrative improvements in patient contact, communication, and the triaging of higher priority lesions to earlier colposcopy visits. Referrals to colposcopy specialists from primary care providers was the predominant reason for longer follow-up appointment times from incident abnormal cytology to colposcopy.

Discussion

The results from the North Bronx Healthcare Network cervical cancer screening program illustrate that the systematic implementation improves performance and decreases healthcare

costs, without worsening prediction of CIN 2,3. These data are even more dramatic considering the patient population in which these algorithms and performance measures were introduced, an inner city mostly under- or uninsured population many of whom live below the poverty line. Clinician and patient biases were overcome by uniform application of the guidelines. A centralized tracking database and a notification system, interpreted at an administrative level, shortened the time to colposcopy appointment for a population with many obstacles to routine preventative healthcare. Our patient population, notably at high risk for HPV infection like most women living in poverty (7), face associated obstacles to healthcare such as maintaining a working phone number or a steady address, arranging transportation to and from doctor visits, and ensuring employment and financial stability. Each of these factors contributes to difficulties in tracking patients in low resource settings over time. If these measures can work in an underinsured population, universal adoption of guidelines for the management of women with abnormal cervical cytology and cervical cancer precursors should be achievable in communities and practice settings where women have ample access to healthcare.

The 2006 ASCCP guidelines for management of women with abnormal cervical cytology and cervical cancer precursors took a key step towards applying evidence to create a more efficient clinical practice. The recommendations not only account for the fact that most early and equivocal CIN resolves over time without treatment (8–10), but also recognize that excisional procedures contribute to morbidity, such as preterm labor, delivery of low birth weight infants and cervical insufficiency, in a reproductive-aged population (11–13). Other potential harms of over-testing in the absence of clinically significant disease include patient anxiety, life disruption for surveillance, and health care costs (14, 15). In our study, application of guidelines and prospective tracking confirmed we were able to shorten the interval time to follow up and decrease in the number of unnecessary biopsies and Pap tests for clinically insignificant disease.

Despite adoption by all cervical cancer screening stake-holding organizations, many barriers still exist to the routine application of guidelines into clinical practice. Cited reasons include institutional barriers, lack of awareness by providers or resistance to catering to “cookbook” medicine, anecdotal cases of high-grade disease in young women, and a general underestimation of the harms of over-testing and frequent follow-up. With a pay for service model like that in the U.S., there are some financial incentives for over-screening and for scheduling procedure-based visits (16, 17). Results from a 2006/2007 Primary Care Provider Survey sponsored by the CDC reaffirmed that few providers follow guidelines as recommended, with many women being over-screened for cervical cancer in the U.S (18–19). These barriers are also patient-driven as many U.S. women are accustomed to requesting a Pap test as part of the annual visit and may not be agreeable to adopting longer screening intervals. The lay press often reports that decreased screening is a form of health care rationing. These provider- and patient-based barriers are difficult for many large practices and systems to overcome, resulting in inconsistent adoption of guidelines. We showed that creating a standard protocol that combined patient contact efforts with clinically relevant follow up recommendations from informed administrative staff and provider staff who consistently apply these principles improves patient care.

Though outside the scope of our study question, we found that the documentation of abnormal results in the patient record and subsequent communication with patients improved over this time period. The additional efforts by the central office to follow up on missed appointments increased compliance with return visits, providing timely, patient centered care. The type of model we described conforms with goals set forth by the Institution of Medicine which recommend improvements in the health system, including use

of evidenced based principles and providing timely and efficient care in a patient centered fashion (21).

There are limitations to our study. Although this study involved a large amount of data from a cohort over two years, the data is limited to cytology, histology, HPV results, and portions of the outreach effort that were tracked on administrative databases and the EMR. We captured those patients who had their care in our network, and did not account for patients who may have chosen to follow up elsewhere. However, we believe this number is small considering this is generally an underinsured population. Also, this study correlates cytology with histology and may have missed those patients with low-grade disease who presented for a colposcopy, but did not have a biopsy taken at that visit due to pregnancy or a negative finding by colposcopy likely due to regression.

The colposcopy providers in our study were receptive to following published guidelines and had no financial incentive to order more tests or see patients more frequently than the recommended intervals, nor was there pressure to contain costs. This population of providers may make generalizing our finding to other practices somewhat difficult. Posting the guidelines in an easy to follow format served as a reminder to consistently follow the standards. Further examination of provider reluctance to adopt guidelines may help to overcome barriers to regular use in other practice settings. Though we believe that removing the patient outreach efforts from point of care testing improves strict adherence, we recognize that the provider remains at the front line with regards to patient education and advice regarding treatment recommendations. This communication must be consistently relayed to the patient. Managed care organizations have had some success in promoting use of evidence-based guidelines by using reminder systems and pay-for-performance initiatives, though currently this may not translate to a private practice setting. With U.S. healthcare reform changes including further utilization of an EMR, improved tracking and performing testing outside recommended clinical guidelines might minimize over-testing and frequent follow-up. Future studies looking into alternative communication methods with patients and barriers to access of preventative care may further improve recall rates.

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Figure 1.

Algorithm used by the administrative staff in the follow up office to guide outreach efforts and timing of subsequent visit. All outreach was initially by phone and followed with a letter. When an appointment was missed, additional outreach was by phone followed by a letter. In cases where a certified letter was sent, a routine letter was also sent as some patients did not pick up certified letters.

Figure 2.

The overall number of gynecology visits varied little over this time period. However, the number of abnormal Pap tests with equivocal results such as LSIL and ASCUS decreased significantly over the 24 month study period. The number of HSIL and clinically significant lesions did not vary during this time period.

Figure 3.

There was a trending decrease in the number of colposcopy and biopsy procedures. The number of LEEP/Cone procedures did not vary during this time period.

Figure 4. Over time, the number of histologic findings of CIN 1 significantly decreased. There was little variation with regards to the other histologic categories of dysplasia.

Table 1

Repeat Pap testing with histology correlation: Administrative recommendations for extended follow-up after provider review.

Cytology Result	Histology Result	Next Appointment Clinic	Next Appointment Date
ASCUS -HPV Negative	CIN 1 or less	GYN OR PRENATAL	One Year
ASCUS-HPV Positive or LSIL	CIN 1 or less	COLPOSCOPY	Repeat cytology at 6 & 12 months
ASCUS, Cannot r/o HSIL HSIL AGUS SCC	CIN 1 or less	COLPOSCOPY	Provider review of clinical data
ASCUS-HPV Positive or LSIL ASCUS, Cannot r/o HSIL HSIL AGUS SCC	CIN 2,3	COLPOSCOPY Consultation and evaluation for excisional procedure	2 weeks