Evaluation of an Electronic Health Record Intervention to Decrease Over-screening in Women Beyond the Screening Age Limits or Post-hysterectomy

A thesis submitted to the faculty of the University of Minnesota by

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ABSTRACT

Background: The current (2012) national cervical cancer screening guidelines seek to balance the benefits of cervical cancer prevention with the risks of harm that can occur as a result of over-screening. To minimize these risks, the guidelines recommend against cervical cancer screening in populations for whom risk of cervical cancer is low, defined as women <21 years of age, >65 years of age, or post-hysterectomy. However, survey studies have demonstrated that healthcare providers have been resistant to decreasing cervical cancer screening, which may diminish reductions in harm sought by the current guidelines.

Objectives: 1) To assess current Fairview Health Services and University of Minnesota Physicians healthcare provider adherence to the 2012 cervical cancer screening guidelines for women for whom screening is not recommended; and 2) To evaluate the effects of implementing improved clinical decision support functionality in the electronic health record to decrease cervical cancer screening in populations for whom screening is not recommended.

Methods: A retrospective cross-sectional chart review was performed at Fairview Health Services and University of Minnesota Physicians to determine current screening practices from 2012-2014. Tests were designated as indicated or non-indicated per the 2012 cervical cancer screening guidelines. Point estimates and descriptive statistics were calculated. Patient and provider characteristics were compared between indicated and non-indicated groups using chi-squared and

Wilcoxon Rank-sum tests. To test the effect of electronic health record clinical decision support, the proportion of guideline non-adherent Pap tests in women <21 or >65 years of age or post-hysterectomy were compared 4 months prior (April-August 2016) and 3 months after (August-October 2016) implementation of a decision support alert warning providers that a Pap test is not indicated. Providers could cancel the Pap test or override the alert and place the order. Provider characteristics and Pap test indications were summarized by pre- / post-intervention period using descriptive statistics. The ordering of non-indicated pap tests was compared by intervention period and provider level characteristics, using generalized estimating equation models.

Results: A total of 3,920 Pap tests were ordered from 2012-2014. A total of 257 (51%; 95% CI 46.1-54.9%) of tests in the <21 group, 536 (40%; 95% CI 37.7-43.1%) in the >65 group and 605 (29%; 95% CI 27.1-31.0%) in the post-hysterectomy group were not guideline adherent. Implementation of the clinical decision support alert did not change the proportion of guideline non-adherent Pap tests ordered (OR 1.08, 95% CI 0.77-1.52), and the proportion of cancelled Pap test orders was similar at each time period (20% pre-intervention vs. 21% post-intervention).

Conclusions: For the populations of women for whom cervical cancer screening is not recommended, 35% of Pap tests performed in our health system were not guideline-adherent. An electronic health record clinical decision support alert did not change healthcare provider cervical cancer screening practices for

women who meet guideline criteria for screening cessation. This suggests that

screening in these populations occurs for reasons other than lack of knowledge

of the guidelines.

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LIST OF ABBREVIATIONS

ACOG, American College of Obstetrics and Gynecology

ACS, American Cancer Society

AIS, adenocarcinoma in situ

Am, American

ASCCP, American Society of Colposcopy and Cervical Pathology

ASCP, American Society of Clinical Pathology

ASCUS, atypical squamous cells of undetermined significance

BPA, best practice alert

CI, confidence interval

CIN, cervical intraepithelial neoplasia

CIS, carcinoma in situ

CNM, Certified Nurse Midwife

CPT, Common Procedural Terminology

DO, Doctor of Osteopathic Medicine

EHR, electronic health record

HPV, Human Papillomavirus

hyst, hysterectomy

IRB, institutional review board

MBBS, Bachelor of Medicine, Bachelor of Surgery

MD, Doctor of Medicine

OR, odds ratio

NP, Nurse Practitioner

PAC, Physician Assistant

PMB, postmenopausal bleeding

RHM, routine health maintenance

SD, standard deviation

USPSTF, United States Preventive Services Task Force

CHAPTER 1

Single Health System Adherence to the 2012 Cervical Cancer

Screening Guidelines at the Extremes of Age and Post-hysterectomy

Introduction

In 2012 the American Society for Colposcopy and Cervical Pathology (ASCCP), American Society for Clinical Pathology (ASCP), American Cancer Society (ACS) and the United States Preventive Services Task Force (USPSTF) published unified cervical cancer screening guidelines which sought to minimize the harms of over-screening while maintaining adequate detection of treatable cervical cancer precursors [1, 2]. The guidelines recommended against screening in average-risk women younger than 21 years, older than 65 years of age provided adequate previous screening and no history of high-grade dysplasia in the past 20 years, and post-hysterectomy with the cervix removed and no history of high-grade dysplasia in the past 20 years. For women for whom screening is still recommended, the guidelines lengthened the screening interval for all age groups (Table 1.1). These guidelines were developed based on an extensive systematic evidence review, and were endorsed by the American College of Obstetrics and Gynecology (ACOG) [3].

Table 1.1 2012 National Cervical Cancer Screening Guidelines

Screening Population	American Cancer Society, American Society of Colposcopy and Cervical Pathology, American Society of Clinical Pathologists, United States Preventive Services Task Force Recommendations[1]
Age <21 years	No screening
Age 21-29 years	Pap test alone (no HPV[2] test) every 3 years
Age 30-65 years	Pap + HPV co-test every 5 years (recommended by American Cancer Society, American Society of Colposcopy and Clinical Pathology, American Society of Clinical Pathology) OR Pap test alone every 3 years (considered acceptable by American Cancer Society, American Society of Colposcopy and Clinical Pathology, American Society of Clinical Pathology)
Age >65years	No screening if: - Adequate prior screening (3 consecutive negative Pap tests or 2 consecutive negative HPV results within 10 years, most recent test within 5 years of age 65 years) - No history of high-grade dysplasia[3] in the past 20 years
Post-hysterectomy	No screening if: - Cervix removed - No history of high-grade dysplasia in the past 20 years

[1] Recommendations apply only to average-risk women. Women who are immunocompromised or who were exposed to diethylstilbestrol require additional screening.
[2] HPV, Human Papillomavirus
[3] High-grade dysplasia includes cervical intraepithelial neoplasia (CIN) 2 or 3, carcinoma in situ (CIS), and adenocarcinoma in situ (AIS)

Although cervical cancer screening guidelines have recommended against

screening in women post-hysterectomy and age >65 years since 2003 and

against screening in women <21 years since 2009, survey studies have shown

that a majority of women younger than age 21 years, older than age 65 years and post-hysterectomy continue to undergo cytology screening [4, 5]. While these self-reported high rates of continued screening are concerning, provider and patient surveys are only a proxy for true practice patterns. This study was performed to obtain a more objective measure of the rates of non-indicated cervical cancer screening at the extremes of age and post-hysterectomy. The primary objective of this study was to determine the guideline non-indicated screening Pap test rates in women younger than age 21 years (<21), older than age 65 years (>65) or post-hysterectomy in a single large health system. The secondary objectives of this study were to describe patient and provider characteristics associated with performance of a non-indicated Pap test in populations for whom the guidelines recommend against screening and to describe temporal trends during the study period.

Methods

This retrospective cross-sectional study was approved by the University of Minnesota Institutional Review Board. The electronic health record was queried using Common Procedural Terminology (CPT) codes for all Pap tests performed between September 1, 2012 (6 months after publication of the American Society of Colposcopy and Cervical Pathology, American Society for Clinical Pathology and American Cancer Society guidelines) and August 31, 2014 within University of Minnesota Physicians and Fairview Health Services, a large nonprofit health

center in Minnesota which partners with 2,500 physicians and has over 56 primary care clinics [6]. The health system includes academic and community clinics in urban, suburban and rural locations. The dataset included the following information: 1) patient demographics: patient age at the time of Pap test, patient race; 2) Encounter information: clinic location and specialty; 3) Provider information: provider name and degree (Medical Doctor or Doctor of Osteopathy, Nurse Practitioner, Physician Assistant, Certified Nurse Midwife, other). The dataset was then further queried to identify the three following groups of patients: 1) younger than 21 years of age (<21); 2) older than 65 years of age (>65); 3) post-hysterectomy. For patients undergoing more than one Pap test during the study period, only the first Pap test was included in the data analysis. A random number generator (www.randomizer.org/form.htm) was used to randomly select 30% of charts within each of the three screening groups for a manual chart review. For each group, if >10% of reviewed Pap tests were categorized as indicated based on patient risk factors and/or previous Pap test results, then all charts in that group were manually reviewed.

For the manual chart reviews, encounter notes, previous Pap and Human Papillomavirus test results and patient medical and surgical histories were reviewed to determine the indication for the Pap test. For the <21 group, indicated reasons for Pap testing included: 1) immunosuppression, including transplant clearance; 2) follow-up of a previous abnormal Pap test; 3) age 21 years within 6 months of Pap test. Although screening women age 20.5 years is

not specifically indicated by the guidelines, we assumed that providers were providing necessary preventive healthcare due to worry that these women may not return to clinic for several years, and thus these Pap tests were analyzed as indicated. For the >65 group, indicated reasons for screening included: 1) history of high-grade dysplasia within the past 20 years; 2) inadequate previous screening (adequate previous screening defined per the guidelines as at least three documented normal Pap tests or two normal co-tests within the past 10 years with at least one test within 5 years of age 65 years); 3) immunosuppression; 4) in-utero diethylstilbestrol exposure; 5) cancer surveillance (cervical, vulvar, vaginal, anal, endometrial, ovarian cancer surveillance). For the post-hysterectomy group, indicated screening included: 1) supracervical hysterectomy (a supracervical hysterectomy was assumed unless removal of the cervix was documented in the surgical history, clinic or operative notes or vaginal cytology was specified on the Pap order); 2) history of high-grade dysplasia within the past 20 years; 3) immunosuppression; 4) diethylstilbestrol exposure; 5) cancer surveillance. Although vaginal cytology is no longer recommended for endometrial cancer surveillance, it was not removed from the National Comprehensive Cancer Network surveillance guidelines until 2015 and thus was categorized as indicated for the study period. During the study period national cancer surveillance guidelines did not recommend vaginal cytology for ovarian cancer surveillance, however, since this was recommended by most of the local gynecologic oncologists during the study period, Pap tests

performed for this reason were coded as indicated. For encounter notes detailing the reason for cervical cancer screening, the stated reason was used as the indication, unless a more guideline-adherent reason also existed. For example, if the clinic note documented that screening was performed in a woman >65 per patient request, but review of her labs and previous clinic notes did not document three normal Pap tests within 10 years, inadequate previous screening was listed as the indication for screening. For women <21 years of age who were presenting for prenatal care or their postpartum visit with no other indicated reason for Pap testing, "pregnancy" was listed as the reason for screening unless the patient was within 6 months of her 21st birthday. For charts in which the reason for Pap testing was not stated and an indicated reason was not discovered during chart review, "routine health maintenance" was assigned by the investigators as the indication for screening (Figure 1).
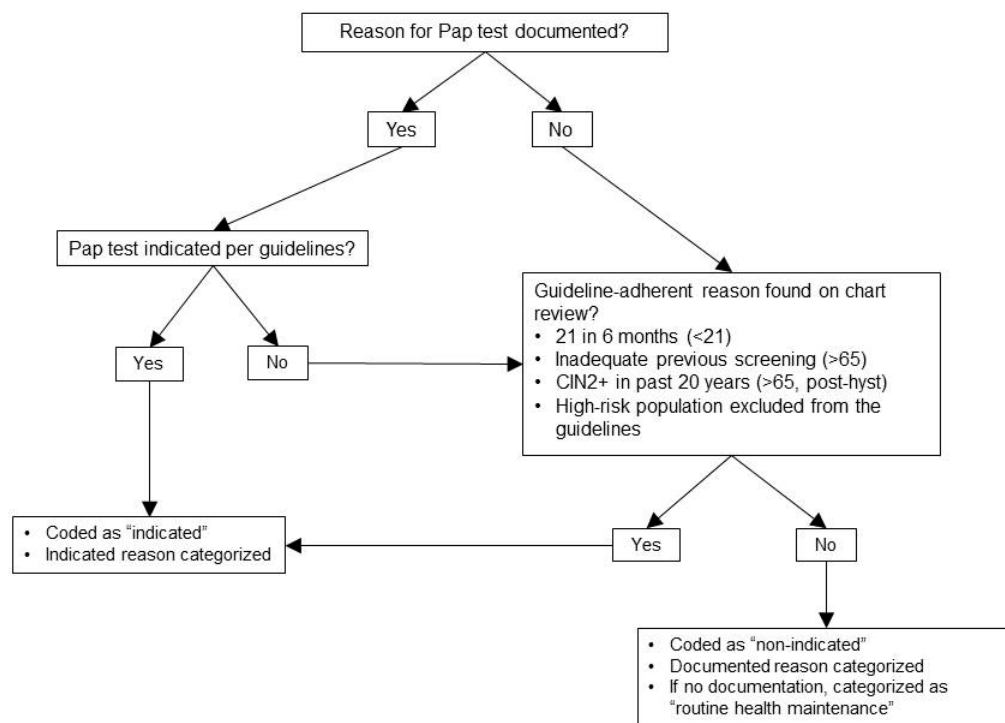
Figure 1. Flowchart describing the designation of Pap tests as indicated or non-indicated. Documented reasons were used unless a non-documented but indicated reason for a Pap test was discovered on chart review. Pap tests without a documented reason for which no guideline-adherent indication was found were categorized as "routine health maintenance."

Healthcare provider information, including gender and birthdate to calculate age in 2012, was obtained from the Minnesota Board of Medical Practice for physicians and physician assistants, and from the Minnesota Board of Nursing for nurse practitioners and certified nurse midwives. The zip codes for the clinics were documented, and clinic locations were dichotomized as less than or greater than 60 miles from Minneapolis to serve as a surrogate for urban/suburban (<60 miles) or rural (>60 miles) clinics.

The primary objective of the study was to determine the proportion of non-indicated screening Pap tests performed in women <21 and >65 years of age and post-hysterectomy. The secondary objectives were to describe patient and provider characteristics associated with screening in populations for whom the guidelines recommend against screening and to describe temporal trends during the study period. Point estimates and exact 95% confidence intervals (CI) for the proportion of non-indicated Pap tests were calculated for each screening group. Differences in the proportion of non-indicated Pap tests were compared within each screening scenario by patient race and year of test using chi-squared tests and age using Wilcoxon Rank-Sum tests. Descriptive statistics for provider level data were calculated, and adherence to guidelines by provider level characteristics, including age, gender, degree, specialty, clinic location, and frequency of Pap orders (dichotomized as <1 Pap per week or 1+ Pap per week), was compared using general estimating equation models to account for repeated measures for some providers assuming an exchangeable correlation structure. Multivariate models were considered for each screening group including both patient and provider level characteristics identified as potentially relevant based on the univariate analyses, including variables with p-values <0.10. Data were analyzed using SAS 9.4 (Cary, NC) and p-values <0.05 were considered statistically significant.

Results

Between September 1, 2012 and August 31, 2014, a total of 122,254 Pap tests were performed in 77,899 individual patients within the health system. Pap tests were performed in a total of 3,920 women <21 and >65 and post-hysterectomy (5% of the total population). During this time period, co-testing was not uniformly performed, but reflex Human Papillomavirus testing was performed as indicated per the American Society of Colposcopy and Cervical Pathology Management guidelines [7]; primary Human Papillomavirus testing was not performed during the study period. In the review of a random sample of 30% of the charts in each age group, 31% (n=62) in the <21, 51% (n=207) in the >65 and 48% (n=506) in the post-hysterectomy group were guideline-indicated Pap tests. Therefore, all charts within each group were manually reviewed.

A total of 509 women under age 21 years (1% of all patients) underwent at least one Pap test during the study period. Of those, 257 (50.5%; 95% CI 46.1-54.9%) of these Pap tests were not indicated per the 2012 guidelines; if patients within 6 months of their 21st birthdays had been coded as not indicated, then 94% of Pap tests in this age group would have been non-indicated. The reasons for the non-indicated tests included routine health maintenance (66%), pregnancy (27%), and patient request (7%). A majority of indicated Pap tests were performed in women who were within 6 months of their 21st birthday (89%), with a smaller number performed to follow-up abnormal Pap tests performed prior to 2012 (8%), due to immunocompromised status or transplant clearance (3%), or as a requirement to enroll in the military (0.4%). There was a difference

in median age between those for whom screening was indicated compared to

those for whom screening was not indicated (p<0.0001), likely due to inclusion of

all women within 6 months of their 21st birthday as indicated (Table 1.2). Patients

in this age group were seen by 219 providers; the median number of patients

seen by each provider was 1 (range: 1-19). Providers performing non-indicated

Pap tests were more likely to be older (p=0.01), male (p=0.0005), and to perform

Pap tests less than once per week (p=0.002). Compared to physicians, nurse

practitioners (p=0.05) and physician assistants (p=0.003) were less likely to

perform non-indicated Pap tests. However, in multivariate analysis, only

performing Pap tests less than once per week remained significant (p=0.003)

(Table 1.2).

Table 1.2. Results for age <21 years group

Patient characteristics				
	All (N=509)	**Pap Not Indicated (N=257)**	**Pap Indicated (N=252)**	**p-value[1]**
Patient Age, years median (range)	20 (14-20)	19 (14-20)	20 (18-20)	<0.0001
Race n (%)				0.58
African/African Am	54 (10.6)	31 (57.4)	23 (42.6)	
Am Indian/Alaskan	7 (1.4)	2 (28.6)	5 (71.4)	
Asian	16 (3.2)	6 (37.5)	10 (62.5)	
White	406 (79.8)	205 (50.5)	201 (49.5)	
No response	26 (5.1)	13 (50.0)	13 (50.0)	

Provider characteristics				
	Pap Not Indicated (N=257)	**Pap Indicated (N=252)**	Odds Ratio (95% CI)	p-value[2]
Provider Age, years mean ±SD	47.6±11.3	44.8±10.9	1.03 (1.01-1.05)[3]	0.01
Gender	**n (%)**	**n (%)**		
Female	181 (45.6)	217 (54.5)	1.00	
Male	76 (68.5)	35 (31.5)	2.44 (1.48-4.03)	0.0005
Provider Degree				
MD/DO	190 (57.6)	140 (42.4)	1.00	
NP	35 (41.7)	49 (58.3)	0.53 (0.29-0.99)	0.05
CNM	5 (27.8)	13 (72.2)	0.40 (0.14-1.14)	0.09
PAC	27 (35.1)	50 (64.9)	0.43 (0.24-0.75)	0.003
Specialty				
Family Medicine	192 (52.2)	176 (47.8)	1.00	
Internal Medicine	19 (43.2)	25 (56.8)	0.67 (0.35-1.26)	0.21
Obstetrics/Gynecology	43 (48.3)	46 (51.7)	0.72 (0.37-1.39)	0.32
Other	3 (37.5)	5 (62.5)	0.50 (0.10-2.44)	0.39

Clinic within 60 miles of Minneapolis					
	Yes	236 (49.6)	240 (50.4)	1.00	
	No	21 (63.6)	12 (36.4)	1.71 (0.69-4.24)	0.25
Frequency of Pap Orders					
	1+ Pap per week	194 (47.1)	218 (52.9)	1.00	
	<1 Pap per week	63 (65.0)	34 (35.1)	2.20 (1.34-3.61)	0.002
Multivariate Model[2,4]					
Provider age				1.02 (1.00-1.04)[c]	0.06
Gender					
	Female			1.00	
	Male			1.28 (0.72-2.28)	0.40
Provider Degree					
	MD/DO			1.00	
	NP			0.54 (0.28-1.03)	0.06
	CNM			0.37 (0.13-1.07)	0.06
	PAC			0.53 (0.28-1.00)	0.05
Frequency of Pap Orders					
	1+ Pap per week			1.00	
	<1 Pap per week			2.27 (1.33-3.86)	0.003

Abbreviations: *Am, American; MD, Medical Doctor; DO, Doctor of Osteopathy; NP, Nurse Practitioner; CNM, Certified Nurse Midwife; PAC, Physician Assistant*

[1]Categorical variables: Fisher's Exact test; continuous variables: Wilcoxon rank-sum test
[2]General estimating equation model
[3]Per 1 year increase in age
[4]Adjusted for provider age, gender, degree, and frequency of Pap test orders; effective sample size: N=197.

A total of 1,327 women older than age 65 years (2% of all patients) underwent at least one Pap test during the study period. Of these, 536 (40.4%; 95% CI 37.7-43.1%) were not indicated. The most common reason for non-indicated Pap tests was routine health maintenance (88%). Other reasons for non-indicated Pap tests were patient request (7%), follow-up of previous abnormal Pap tests for which the guidelines do not recommend follow-up (e.g. follow-up of an ASCUS Pap test 10 years prior with subsequent normal Pap tests; 5%), and history of high-grade cervical dysplasia more than 20 years prior with subsequent normal screening (0.6%). The most common reasons for indicated cervical cancer screening in this age group were inadequate previous screening (56%), followed by guideline-adherent follow-up of an abnormal cervical cancer screening test (18%). Other reasons for indicated Pap testing were cancer surveillance (11%), evaluation of post-menopausal bleeding or abnormal exam findings (10%), high-grade dysplasia within the past 20 years (3%), immunocompromised state or transplant clearance (1%), diethylstilbestrol exposure (0.1%), and to meet a requirement for a research study (0.1%). In this group, white women were more likely to receive non-indicated screening (p=0.007) (Table 1.3). Patients in this age group were seen by 317 providers; the median number of patients seen by each provider was 2 (range: 1-52). Providers performing non-indicated Pap tests in this group were more likely to be older (p=0.008), male (p=0.02), in specialties other than gynecology (p=0.04) and to work within 60 miles of Minneapolis (p=0.002). In multivariate analysis, male

gender (p=0.01), specialty (p=0.02) and clinic location (p=0.001) remained

significant (Table 1.3).

Table 1.3. Results for age >65 years group

Patient characteristics				
	All (N=1327)	**Pap Not Indicated (N=536)**	**Pap Indicated (N=791)**	**p-value[1]**
Patient Age, years median (range)	69 (65-95)	68 (66-88)	69 (65-95)	0.25
Race n (%)				0.007
African/African Am	33 (2.5)	6 (18.2)	27 (81.8)	
Am Indian/Alaskan	5 (0.4)	0 (0.0)	5 (100.0)	
Asian	26 (2.0)	7 (26.9)	19 (73.1)	
White	1239 (93.4)	516 (41.7)	723 (58.4)	
No response	24 (1.8)	7 (29.2)	17 (70.8)	

Provider characteristics				
	Pap Not Indicated (N=536)	**Pap Indicated (N=791)**	**Odds Ratio (95% CI)**	**p-value[2]**
Provider Age, years mean ±SD	51.5±11.9	48.8±11.3	1.02 (1.00-1.03)[3]	0.008
Gender				
Female	351 (37.5)	585 (62.5)	1.00	
Male	185 (47.3)	206 (52.7)	1.53 (1.07-2.18)	0.02
Provider Degree				
MD/DO	476 (41.6)	669 (58.4)	1.00	
NP	40 (34.5)	76 (65.5)	0.76 (0.48-1.20)	0.24
CNM	1 (9.1)	10 (90.9)	0.22 (0.03-1.75)	0.15
PAC	19 (34.6)	36 (65.5)	0.90 (0.45-1.79)	0.76
Specialty				
Family Medicine	334 (41.8)	466 (58.3)	1.00	
Internal Medicine	70 (42.2)	96 (57.8)	1.06 (0.67-1.68)	0.79
Obstetrics/Gynecology	128 (37.1)	217 (62.9)	0.66 (0.44-0.99)	0.04

Clinic within 60 miles of Minneapolis

Yes	532 (42.8)	711 (57.2)	1.00	
No	4 (4.8)	80 (95.2)	0.13 (0.04-0.46)	0.002

Frequency of Pap Orders

1+ Pap per week	428 (41.2)	611 (58.8)	1.00	
<1 Pap per week	108 (37.5)	180 (62.5)	0.91 (0.65-1.29)	0.61

Multivariate Model[2,4]

Gender

Female	1.00	
Male	1.73 (1.14-2.61)	0.01

Specialty

Family Medicine	1.00	
Internal Medicine	1.13 (0.68-1.85)	0.64
Obstetrics/Gynecology	0.62 (0.42-0.92)	0.02

Clinic Location

<60 miles from Minneapolis	1.00	
>60 miles from Minneapolis	0.12 (0.03-0.44)	0.001

Abbreviations: Am, American; MD, Medical Doctor; DO, Doctor of Osteopathy; NP, Nurse Practitioner; CNM,Certified Nurse Midwife; PAC, Physician Assistant

[1]Categorical variables: Fisher's Exact test; continuous variables: Wilcoxon rank-sum test
[2]General estimating equation model
[3]Per 1 year increase in age
[4]Adjusted for provider age, gender, degree, and frequency of Pap test orders; effective sample size: N=290.

A total of 2,084 women had at least one Pap test post-hysterectomy (3% of all patients). Of these, 605 (29.0%; 95% CI 27.1-31.0%) were not indicated per the guidelines. The most common reason for non-indicated Pap tests was routine health maintenance (87%), with a much smaller proportion performed for non-indicated follow-up of abnormal Pap tests in the distant past (6%), patient request (4%), history of high-grade dysplasia more than 20 years prior (3%), and cancer surveillance in cancers without a Pap test indication, such as non-genital melanoma (0.7%).   The most common reasons for indicated Pap tests were cancer surveillance (45%) and supracervical hysterectomy (37%). Other indications were history of high-grade dysplasia within the past 20 years (11%), guideline-adherent follow-up of an abnormal Pap test (3%), evaluation of vaginal bleeding or an abnormal exam finding (3%), and diethylstilbestrol exposure, immunocompromised state or transplant clearance, patient request (each <1%). There were no differences patient characteristics between those who had indicated versus non-indicated testing (Table 1.4). Patients in this group were seen by 362 providers; the median number of patients seen by each provider was 3 (range: 1-122). Gynecologists were less likely than primary care providers to order non-indicated Pap tests (p=0.003); no other provider characteristics were associated with the ordering of non-indicated tests (Table 1.4).

Table 1.4. Results for post-hysterectomy group

Patient characteristics				
	All (N=2084)	**Pap Not Indicated (N=605)**	**Pap Indicated (N=1479)**	**p-value[1]**
Patient Age, years median (range)	54 (24-89)	55 (28-88)	54 (24-89)	0.12
Race n (%)				0.64
African/African Am	95 (4.6)	31 (32.6)	64 (67.4)	
Am Indian/Alaskan	24 (1.2)	4 (16.7)	20 (83.3)	
Asian/Pacific Islander	40 (1.9)	13 (32.5)	27 (67.5)	
White	1854 (89.0)	539 (29.1)	1315 (70.9)	
No response	71 (3.4)	18 (25.4)	53 (74.7)	

Provider characteristics				
	Pap Not Indicated (N=605)	**Pap Indicated (N=1479)**	**Odds Ratio (95% CI)**	**p-value[2]**
Provider Age, years mean ±SD	47.2±11.7	45.8±10.5	1.00 (0.99-1.02)[3]	0.50
Gender	n (%)	n (%)		
Female	449 (26.9)	1219 (73.1)	1.00	
Male	156 (37.5)	260 (62.5)	1.25 (0.89-1.74)	0.20
Provider Degree				
MD/DO	433 (31.2)	953 (68.8)	1.00	
NP	91 (18.9)	391 (81.1)	1.16 (0.77-1.74)	0.49
CNM	3 (18.8)	13 (81.3)	0.75 (0.18-3.10)	0.70
PAC	78 (39.0)	122 (61.0)	1.35 (0.90-2.03)	0.15
Specialty				
Family Medicine	397 (38.4)	638 (61.6)	1.00	
Internal Medicine	63 (37.1)	107 (62.9)	0.91 (0.60-1.39)	0.67
Obstetrics/Gynecology	130 (28.6)	324 (71.4)	0.61 (0.44-0.85)	0.003
Other	15 (3.5)	410 (96.5)	0.07 (0.04-0.15)	<0.001

Clinic within 60 miles of Minneapolis

Yes	582 (28.9)	1435 (71.2)	1.00	
No	23 (34.3)	44 (65.7)	1.24 (0.64-2.40)	0.53

Frequency of Pap Orders

1+ Pap per week	513 (29.2)	1243 (70.8)	1.00	
<1 Pap per week	92 (28.1)	236 (72.0)	1.05 (0.76-1.44)	0.78

Abbreviations: *Am, American; MD, Medical Doctor; DO, Doctor of Osteopathy; NP, Nurse Practitioner; CNM, Certified Nurse Midwife; PAC, Physician Assistant*
[1]Categorical variables: Fisher's Exact test; continuous variables: Wilcoxon rank-sum test
[2]General estimating equation model
[3]Per 1 year increase in age

Between 2012 and 2014, the total number of Pap tests ordered per month decreased in all 3 groups. However, temporal trends in the proportion of non-indicated Pap tests ordered each year varied by group. In the <21 group, there was a decline in the proportion of non-indicated Pap tests over the study time period (p=0.006). In contrast, there was an increase in the proportion of non-indicated tests ordered in the post-hysterectomy group during the same time period (p=0.04). The proportion of non-indicated Pap tests in the >65 group remained relatively stable over time (p=0.91).

Discussion

Cervical cancer screening at the extremes of age and post-hysterectomy was performed in 35% patients in our health system despite recommendations against screening for more than a decade. The proportion of non-indicated Pap tests appeared to increase in the post-hysterectomy group despite a temporal decrease in the total number of Pap tests and a concomitant decrease in the proportion of non-indicated tests in the <21 years age group. There were no common patient or provider characteristics associated with excess screening across all groups. Non-indicated screening is likely due to confusion about the guidelines and patient and provider worry that omitting screening will increase the cervical cancer incidence.

Our results build on those of previous survey studies showing that women at low risk for developing cervical cancer continue to undergo screening. A

claims database study showed that 57% of women younger than age 21 years had Pap tests performed [4], and a 2010 study using data from the National Health Interview Survey showed that 58.4% of women >65 years of age and 34.1% of women post-hysterectomy continued Pap testing [5].

Lack of knowledge of the guidelines is one reason for non-adherence [8]. Unified guidelines were created in 2012 [1-3], but the guidelines are complex and have changed frequently [9, 10]. Our chart review showed that providers often did not differentiate between abnormal cytology and a histologic diagnosis of dysplasia. Furthermore, the coupling of Pap tests with prenatal care increased screening in women <21 years of age.

Some providers distrust the guidelines. In a 2016 California survey, 35% of primary care and 59% of gynecologists did not feel that the current guidelines were clinically appropriate [11]; interestingly gynecologists had lower rates of non-indicated screening in our study . Some respondents to the California survey felt that the guidelines were created to save money and that decreasing screening would result in an increased incidence of cervical cancer. Other providers continue screening to meet patient expectations during health maintenance visits, and many providers do not have adequate time to explain the guideline changes to patients [11]. Lastly, some providers acknowledged financial incentive to continuing cervical cancer screening [11].

In this study, the increase in the proportion of non-indicated Pap tests in the post-hysterectomy group may be due to a change in the total number of Pap

tests performed rather than a true increase in the performance of non-indicated tests. During the study period the total number of Pap tests performed in the post-hysterectomy group declined by 56% while the number of non-indicated Pap tests only decreased by 46%. This may reflect adoption of the guidelines by some while those who intentionally disregarded the guidelines continued to screen.

The strengths of this study are the large number of patients from a large health system which includes urban, suburban and rural sites and both academic and community clinics. All charts were manually reviewed; an electronic health record query alone would have inaccurately doubled the number of non-indicated Pap tests in women <21 and >65 years old, and tripled the number in post-hysterectomy patients. Nonetheless, our study provides a conservative estimate of the number of non-indicated Pap tests, and the true number may be much higher. The primary limitation of our study is the fact that we could only compare the number of non-indicated Pap tests to the total number of Pap tests performed within each screening group; ideally we would have compared the number of Pap tests performed to the total number of women seen within the health system in each group, however we were unable to query the data in this way. This study was performed within a single health system, so our results may not be generalizable to other health systems. Other limitations of the study are those inherent to a retrospective chart review. Data collection was limited by the quality of documentation and we only had access to records within our electronic

health record It is possible that patients had a Pap testing history outside of our system which likely resulted in an over-estimate in the number of women >65 years of age who continued screening due to inadequate previous testing.

The 2012 guidelines seek to maintain the benefits of screening while limiting potential harms, such as preterm delivery in future pregnancies following excisional procedures, increased risk of pelvic organ prolapse or urinary incontinence following hysterectomy, or vaginal stenosis following treatment of vaginal dysplasia [2]. Continued screening in populations at low risk for cervical cancer limits the protections sought by the current guidelines.

CHAPTER 2

Effect of an Electronic Health Record Clinical Decision Support Alert to Decrease Cervical Cancer Screening in Women Beyond the Screening Age Limits or Post-hysterectomy

Introduction

Lack of knowledge of the complex guidelines is a major barrier to guideline adherence [8, 11]. Since 2009, the U.S. Department of Health and Human Services has promoted usage of electronic health system clinical decision support to encourage the practice of evidence-based medicine [12]. The objective of this study was to test the effect of an electronic health record (EHR) clinical decision support alert to decrease cervical cancer over-screening in women <21 or >65 years of age, or post-hysterectomy.

Methods

This quality improvement initiative and study were implemented at Fairview Health Systems and University of Minnesota Physicians. The University of Minnesota Medical Center is one division of Fairview Health System, a large non-profit health center in Minnesota. The Fairview Health System is composed of greater than 56 primary care clinics in urban, suburban, and rural locations [6]. University of Minnesota Physicians is the non-profit multi-specialty group practice for the University of Minnesota Medical School faculty, many of whom provide clinical services at the University of Minnesota Medical Center and other Fairview

Health System clinics [13]. University of Minnesota Physicians collaborates with Fairview Health System to provide care to patients throughout Minnesota. The groups share a common electronic health record (EHR), thus changes can be implemented at University of Minnesota Physician clinics and Fairview Health System Clinics simultaneously. Prior to this EHR intervention, there was no clinical decision support for cervical cancer screening in the system; clinical decision support was in place for other healthcare interventions.

A Best Practice Alert (BPA) was designed by the study investigators in collaboration with several physician informaticists and information technology professionals. The alert was then reviewed and approved by the health system Clinical Decision Support and Ambulatory Informatics Committees. The BPA was implemented in the Epic EHR and deployed first in a pilot clinic to test acceptability, and subsequently deployed to all clinics within the healthcare system, including community and academic-based practice plan clinics (Fairview Health Services and University of Minnesota Physician, respectively). For 4 months (January 19-May 17, 2016), the BPA fired silently in the background: the EHR tracked every time an order was entered for a screening Pap test in a woman <21 years of age, >65 years of age, or post-hysterectomy (provided the hysterectomy was documented in the surgical history universal field and thus identified by the EHR), but the EHR user would not see the alert. For the following 3 months (May 18-August 17, 2016) the BPA was live and actively working: the BPA was made visible to the user whenever a screening Pap test

was ordered for a woman <21 years of age, >65 years of age, or post-hysterectomy. The BPA informed the user that screening Pap tests are not indicated in this group. The BPA linked to the American Society of Colposcopy and Cervical Pathology (ASCCP) guidelines for reference [2], and the provider was given 2 options: 1) cancel the Pap test order, or 2) override the BPA and order the Pap test. Providers who overrode the BPA were asked but not required to state a reason. Options included: 1) immunocompromised; 2) history of diethylstilbestrol exposure; 3) history of high-grade dysplasia; 4) follow-up of previous abnormal cervical cancer screening; 5) inadequate previous screening; 6) cancer surveillance; 7) other. Two months prior to the BPA going live information about the BPA was included in the monthly health system newsletter. Additionally, the month the BPA went live an 8-minute webinar detailing the changes to the cervical cancer screening orders was sent to all health system providers for optional review.

This study was designated a retrospective cohort study of a quality improvement intervention by the University of Minnesota IRB. Thus, implementation of the clinical decision support alert was considered IRB-exempt, but IRB approval was obtained for a retrospective data review. The effect of the BPA was measured by comparing cervical cancer screening practices in women <21 or >65, or post-hysterectomy before and after the BPA was visible to EHR users. An electronic health record analytics platform (Logicstream, Minneapolis, MN) captured each encounter when a guideline non-adherent test was ordered,

both during the pre-intervention and post-intervention periods. A manual chart review of all identified encounters was then performed to determine the reason for the Pap test, whether or not ordering was congruent with the 2012 cervical cancer screening guidelines and the action on the Pap test (i.e. continuation or cancellation of the order). For women >65 years of age whose chart review did not document adequate previous screening either through review of laboratory results or documentation in the provider's note, the Pap test was coded as guideline-adherent due to inadequate previous screening. For women <21 years of age but within 6 months of their 21st birthday, Pap tests were coded as indicated. Pap tests for which we could find no guideline-adherent reason were coded as non-adherent, performed for "routine healthcare maintenance." Pap test orders which were placed without a Pap specimen subsequently sent to cytology were coded as cancelled. To better understand workflow, the staff who entered the order (e.g. provider, nurse, medical assistant, other) as well as the encounter provider (physician, nurse practitioner, certified nurse midwife, physician assistant) were recorded. Healthcare provider data were collected from the Minnesota Board of Medical Practice and the Medical Board of Nursing to determine if provider gender or age in 2012 was associated with guideline adherence. Lastly, zip codes of the clinics were collected to determine if rural (defined as >30 miles outside of the Minneapolis-St. Paul metro area) or urban location was associated with guideline-adherence.

Provider characteristics and Pap test indications were summarized by pre-
or post-intervention period using descriptive statistics. The ordering of guideline

non-adherent Pap tests was compared by intervention period and provider level

characteristics, including age, gender, specialty, and clinic location using

generalized estimating equation models to account for repeated measures for

some providers assuming an exchangeable correlation structure. Odds ratios

and 95% confidence intervals are presented. Analyses were conducted in SAS

9.4 (Cary, NC) and p-values of <0.05 were considered statistically significant.

Results

In the pre-intervention period, there were 388 (average 97 per month) Pap

tests ordered, compared to 313 (average 104 per month) Pap tests in the post-

intervention period. Of these, 240 (62%) were guideline non-adherent in the pre-

intervention period, and 198 (63%) were guideline non-adherent in the post-

intervention period. There were no differences in provider characteristics (age,

gender, provider degree, specialty), staff who entered the order, or location of the

clinic (Table 2.1).

Table 2.1. Provider characteristics

	Pre-Intervention (N=388)		Post-Intervention (N=313)	
	N	**Mean (SD)**	**N**	**Mean (SD)**
Provider Age, years	388	48.8 (12.9)	313	48.3 (13.1)
	N	**(%)**	**N**	**(%)**
Provider Gender				
Female	216	(55.7)	187	(59.7)
Male	172	(44.3)	126	(40.3)
Provider Degree				
MD/DO/MBBS	297	(76.6)	228	(72.8)
Nurse Practitioner	51	(13.1)	56	(17.9)
Certified Nurse Midwife	7	(1.8)	4	(1.3)
Physician Assistant	33	(8.5)	25	(8.0)
Specialty				
Family Medicine	141	(36.3)	97	(31.0)
Internal Medicine	37	(9.5)	41	(13.1)
Gynecology	209	(53.9)	173	(55.3)
Pediatrics	0	(0.0)	2	(0.6)
Other	1	(0.3)	0	(0.0)
Order Entered				
Provider[1]	150	(38.7)	112	(35.8)
Medical Assistant	202	(52.1)	176	(56.2)
Nurse	35	(9.0)	23	(7.4)
Unknown	1	(0.3)	2	(0.6)
Clinic within 30 miles of Minneapolis				
Yes	340	(87.6)	288	(92.0)
No	48	(12.4)	25	(8.0)

Abbreviations: MD, Doctor of Medicine; DO, Doctor of Osteopathic Medicine; MBBS, Bachelor of Medicine/Bachelor of Surgery.
[1]Provider refers to physician, nurse practitioner, certified nurse midwife, or physician assistant of record for the encounter during which cervical cancer screening was performed.

Post-intervention, there was no difference in the proportion of non-indicated Pap tests ordered in women <21 or >65 years of age, or post-hysterectomy (OR 1.08, 95% CI 0.77-1.52) (Table 6). There was also no

difference in the proportion of guideline non-adherent Pap tests orders which were ultimately cancelled (pre-intervention 20% vs. 21%) either due to patient or provider decision not to order a test after an EHR order was placed, or due to placement of orders prior to the patient encounter with subsequent cancellation of the order if the patient did not present to her clinic visit. A majority (51% pre- and post-intervention) were ordered for routine healthcare maintenance. There were more Pap tests ordered in women >65 years of age due to inadequate previous screening post-intervention (16% vs. 8%), and more Pap tests ordered for surveillance following high-grade dysplasia pre-intervention (5% vs. 3%). Other reasons for ordering Pap tests are detailed in Table 2.2.

Table 2.2. BPA Trigger and Action

	Pre-Intervention (N=388)		Post-Intervention (N=313)	
	N	**(%)**	**N**	**(%)**
Reason for Trigger				
<21 years	80	(20.6)	66	(21.1)
>65 years	196	(50.5)	170	(54.3)
>65 years+Post-hyst	68	(17.5)	52	(16.6)
Post-hyst	44	(11.3)	25	(8.0)
Pap was indicated				
No	240	(61.9)	198	(63.3)
Yes	148	(38.1)	115	(36.7)
Action Taken				
Cancelled	77	(19.9)	64	(20.5)
Ordered	311	(80.2)	249	(79.6)
Reason for Pap				
21 in <6 months	46	(11.9)	26	(8.3)
Abnormal exam	10	(2.6)	1	(0.3)
Cancer surveillance	20	(5.2)	21	(6.7)
Immunosuppressed	5	(1.3)	3	(1.0)
Inadequate screening[1]	32	(8.3)	50	(16.0)
PMB	22	(5.7)	7	(2.2)
Patient Request	10	(2.6)	16	(5.1)
Pregnant	4	(1.0)	2	(0.6)
RHM	198	(51.0)	161	(51.4)
Supracervical hyst	5	(1.3)	2	(0.6)
Abnormal follow-up	12	(3.1)	12	(3.8)
History of CIN2+[2]	20	(5.2)	9	(2.9)
Other	4	(1.0)	3	(1.0)

Abbreviations: BPA, Best Practice Alert; hyst, hysterectomy; PMB, postmenopausal bleeding; RHM, routine health maintenance
[1]Inadequate screening is defined by lack of at least 3 normal Pap tests or 2 negative Human Papillomavirus (HPV) tests within 10 years of age 65 years, with at least 1 test within 5 years of age 65 years.
[2]CIN2+ includes cervical intraepithelial neoplasia (CIN) grade 2 and 3, cervical carcinoma in situ (CIS), and adenocarcinoma in situ (AIS)

Multivariate analysis of provider characteristics associated with the

ordering of guideline non-adherent Pap tests showed that only male gender was

statistically significant (OR 2.30, 95% CI 1.36-3.89) (Table 2.3). There were no

differences in the proportion of guideline non-adherent Pap tests by specialty or

clinic location.

Table 2.3. Multivariate Generalized Estimating Equation Model: Effect of BPA and provider characteristics associated with ordering a guideline non-adherent Pap test

	Odds Ratio (95% CI)[1]	p-value[1]
BPA Alert		
No alert visualized	1.00	
BPA alert visualized	1.08 (0.77, 1.52)	0.64
Provider Age, per year increase	1.00 (0.98, 1.02)	0.76
Provider Gender		
Female	1.00	
Male	2.30 (1.36, 3.89)	0.002
Specialty		
Internal Medicine	1.00	
Family Medicine	0.98 (0.52, 1.87)	0.96
Gynecology	0.74 (0.38, 1.46)	0.39
Clinic within 30 miles of Minneapolis		
Yes	1.00	
No	1.17 (0.58, 2.34)	0.66

Abbreviations: BPA, Best Practice Alert
[1]Excluded pediatrics or "other" specialty due to small numbers

Overall, half (52%) of the guideline non-adherent Pap tests were ordered

by 11 providers. Of these, a single gynecology clinic and five providers were

responsible for ordering 45% of the 198 guideline non-adherent Pap tests in the

post-intervention period, with a single provider ordering 21% of the tests. The

remaining 94 guideline non-adherent Pap tests were ordered by 77 providers,

with 64 providers each ordering a single guideline non-adherent Pap test.

Discussion

Our study showed that an EHR clinical decision alert intended to decrease guideline non-adherent cervical cancer screening did not decrease screening in women beyond the screening age limits or post-hysterectomy. In contrast to the results of this study, a previous study of a similar electronic health record BPA to decrease guideline non-adherent screening in women <21 years of age showed a significant decrease in screening post-intervention [14]. The intervention in this study was implemented in 2011, two years after the guidelines recommended against screening in women <21 years of age regardless of age at sexual debut. At that time, a majority of over-screening may have occurred due to lack of knowledge of the guidelines. However, since our intervention was performed five years later, lack of knowledge may have been less of a factor. Providers also may be more likely to accept the guideline recommendation against screening in young women compared to older women, as was demonstrated in a study in 2010 showing a BPA changed provider practices in women <21 years of age but did not significantly impact the ordering of guideline non-adherent Pap tests in women >70 years of age [15]. Although we did not see a difference post-intervention in either group in our study, the number of tests ordered in women >65 years of age was more than double that of women <21 years of age in both the pre- and post-intervention periods.

Further review of our data revealed that a majority of guideline non-adherent Pap tests were ordered by a few healthcare providers. The reasons for over-screening among these 11 providers needs to be explored further, but these

data suggest that a focused educational intervention addressing individual provider concerns or misconceptions about screening may be more effective than a system-wide EHR intervention. Furthermore, despite accounting for providers who ordered >1 Pap test during the study period, male providers were more than twice as likely to order Pap tests beyond the screening age limits or post-hysterectomy, and provider gender remained statistically significant when controlling for provider age. Studies of provider adherence to previous versions of the cervical cancer screening guidelines have shown mixed results [16, 17]. A previous study which showed female providers were more likely to adhere to cervical cancer screening recommendations in women younger than 21 years of age and 30+ years of age found that provider-reported interest in women's health was a significant predictor of delaying screening in women younger than 21 years of age but not in women 30+ years of age [17]. It is also possible that female providers see a higher proportion of female patients, resulting in greater awareness of the guidelines. However, our previous study evaluating cervical cancer screening practices within our health system showed that less-frequent cervical cancer screening (defined as ordering <1 Pap test per week) was associated with over-screening only in women <21 years of age [8].

The strengths of our study are the implementation of a BPA which could be monitored prior to being visible to the user, thus allowing pre-intervention and post-intervention data to be collected in the same manner. The study was conducted over a short period of time, limiting temporal variation in provider

practice independent of clinical decision support. All of the data were manually

reviewed so that indicated Pap tests which triggered the best practice alert were

coded correctly, decreasing the risk of a type I error. Our study was limited by the

fact that we could only assess Pap tests which triggered the BPA. Thus, we

cannot estimate the effect of healthcare provider education through the BPA,

which would result in the provider not placing an order for a woman in the same

non-screening group in a future encounter. However, given the similar numbers

of Pap tests ordered pre- and post-intervention, it is unlikely that this had a

substantial effect on screening practices. The lack of a difference may also be

due to suboptimal timing of the BPA. The BPA triggered when the Pap test order

was placed, and providers may have been reluctant to cancel orders once the

Pap specimen had been obtained. Additionally, more than 60% of orders were

placed by staff other than the healthcare provider listed on the clinic encounter,

and the alert may never have been seen by the provider who ultimately makes

the cervical cancer screening decision. Although a manual chart review was

performed, our data collection was limited by the results available within our

electronic health record system and the providers' notes. However, coding of Pap

tests was performed in the same manner and by the same investigators in the

pre- and post-intervention period, and misclassification of the Pap tests as

indicated would only strengthen the negative results of our study. Lastly, since

the effect was measured by proportion of guideline non-adherent Pap tests, and

a majority of non-adherent Pap tests were ordered by a minority of providers, our

study was underpowered to detect practice changes for providers who ordered a smaller number of guideline non-adherent Pap tests at baseline.

In conclusion, this study showed that clinical decision support within the EHR did not improve adherence to national guidelines recommending against screening in women <21 years of age, >65 years of age, or post-hysterectomy. These results suggest continued over-screening in women beyond the screening age limits or post-hysterectomy is due to factors other than lack of knowledge of the guidelines at this time. However, this study did not test the impact of clinical decision support in women age 21-65 years of age where screening decisions are more difficult due to different recommended screening intervals depending on the method of screening (cytology alone vs. cytology + HPV co-testing) and previous screening results. Thus, electronic health record clinical decision support may be useful following the introduction of the next set of guidelines which are likely to become more complicated as additional methods of screening (primary cytology; primary HPV testing; co-testing), additional diagnostic tests (e.g. immunohistochemistry for the p16 tumor suppressor protein), and stratified screening recommendations by HPV vaccination status are incorporated.

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