The Journal of Emergency Medicine, Vol. 57, No. 6, pp. 836–843, 2019

0736-4679/$ - see front matter

https://doi.org/10.1016/j.jemermed.2019.07.021

Selected Topics: Oncological Emergencies

AN INTERVENTION TO INCREASE UPTAKE OF CERVICAL CANCER SCREENING AMONG EMERGENCY DEPARTMENT PATIENTS: RESULTS OF A RANDOMIZED PILOT STUDY

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☐ **Abstract—Background: Emergency departments (EDs) have the potential to promote critical public and preventive health interventions. Cervical cancer (CC) screening has been a cornerstone of preventive health efforts for decades. Approximately 20% of U.S. women are not adherent with CC screening guidelines—considerably below the U.S. Federal Government's target. ED patients are disproportionately nonadherent with CC screening guidelines. The ED, therefore, is an optimal setting to target women with an intervention that promotes CC screening. Objectives: To assess the feasibility and potential efficacy of an intervention, grounded in behavioral change theory, to promote uptake of CC screening among ED patients. Methods: Design: Randomized clinical trial pilot study; Patients: Women aged 21–65 years that were identified in the ED to be nonadherent with CC screening recommendations; Setting: Single center urban academic ED. Results: Among enrolled participants, 355 (79%) were determined to be adherent with screening recommendations and 95 (21%) were determined to be either nonadherent or have uncertain adherence. Among the nonadherent/uncertain group, 47 were randomized to the control condition (referral only) and 48 were randomized to the intervention condition. Thirty-six percent of participants in the control condition received or scheduled screening during the follow-up period. In the intervention condition, 43% received or scheduled screening during the follow-up period—a 19% relative improvement over the control condition. Conclusion: This pilot study demonstrates feasibility and preliminary efficacy of a behavioral intervention to increase uptake of CC screening among ED patients.** © 2019 Elsevier Inc. All rights reserved.

☐ **Keywords—cervical cancer; emergency medicine; theory of planned behavior; short message service**

INTRODUCTION

Emergency departments (ED) provide a unique opportunity to advance preventive health efforts among a broad cross-section of the population, as nearly 40 ED visits per year are made for every 100 persons in the country (1). For many patients, an ED visit involves periods of waiting (due to patient volume and time needed for diagnostic test results) during which preventive health needs can be assessed and intervened upon. Moreover, as EDs often function as a health care safety net, ED patients are disproportionately vulnerable to barriers to accessing recommended preventive health services. For these reasons, EDs have long been viewed as having the potential to deliver critical public and preventive health care, and a number of past efforts have demonstrated feasibility and success in this area. ED-based interventions addressing such issues as smoking cessation, alcohol-related problems, substance abuse, and human immunodeficiency virus (HIV) testing have proven feasible and successful (2–8). Although it would be impractical to conduct

RECEIVED: 31 May 2019; FINAL SUBMISSION RECEIVED: 16 July 2019;
ACCEPTED: 29 July 2019

recommended cancer screenings in the ED, an ED visit does present the opportunity to identify if a patient is adherent with recommended cancer screening, and if not, provide a referral and facilitate the needed testing.

Cervical cancer (CC) is among the most preventable forms of cancer. Screening for CC aims to identify treatable precancerous lesions prior to the development of invasive CC, which, without screening, is often first detected at a stage when palliation is all that can be offered. Still, approximately 20% of U.S. women aged 21–65 years are not adherent with U.S. Preventive Services Task Force (USPSTF) CC screening guidelines—considerably below the U.S. Federal Government's *Healthy People 2020* target of 93% adherence (9–11). The USPSTF recommends that women aged 21–65 years receive a Papanicolaou (Pap) test every 3 years, extendable to every 5 years for women aged 30–65 years with negative human papillomavirus cotesting. The Centers for Disease Control and Prevention found the very lowest rates of adherence to CC screening guidelines to be among women that use the ED as their usual source of care (9). The ED setting, therefore, provides an optimal opportunity to target women with an intervention that promotes CC screening.

A health promotion effort delivered at a single point of contact during an ED visit has intrinsic limitations in its potential to impact health-related behavior. An approach that reinforces a preventive health effort at one or more time points after an ED visit may increase the likelihood of successfully catalyzing behavioral change. Short message service (SMS) on mobile phones, also known as text messaging, is a low-cost, scalable, and effective means of delivering health behavior interventions and could be used to reinforce health messages initially delivered in the acute context of the ED (12–26). Evidence-based SMS interventions for health behavior include smoking cessation, primary care attendance, breast cancer screening, and sun safety, among others (20,22,23,27–31).

We conducted a randomized clinical trial pilot to assess the feasibility and preliminary efficacy of an SMS-based behavioral intervention to promote uptake of CC screening among women aged 21–65 years that were identified in the ED to be nonadherent with USPSTF CC screening recommendations.

MATERIALS AND METHODS

Design, Setting, Population

We enrolled 450 study participants into a randomized controlled clinical trial pilot (ClinicalTrials.gov #NCT03483610) over a period of 8 weeks (June–August, 2018). All enrollment occurred at a large (approximately 118,000 annual patient visits), urban, academic ED. Eligible patients were female, ages 21–65 years, and demonstrating decisional capacity to consent to participate. Women with past hysterectomy with cervical removal, known infection with HIV (as screening recommendations for women with HIV differ from the general population), inability to consent (e.g., lacking decisional capacity, intoxicated, or in distress), non-English speaking, or not having a text-capable mobile phone were excluded. We approached 502 eligible patients to achieve our enrollment target of 450, resulting in an overall enrollment rate of 90%. The primary reason for declining to enroll was lack of interest. The first step of our approach was to identify whether the participant was adherent with USPSTF screening guidelines. The second step of our approach was to randomize nonadherent participants and participants with uncertain adherence to one of the two treatment conditions: 1) referral only (control) or, 2) referral and an SMS-based behavioral intervention aimed at generating intention to get screened. Follow-up by telephone at 150 days was conducted to assess the primary outcome of scheduling/obtaining CC screening. Randomization was performed using the REDCap survey instrument with a one-to-one ratio (32).

Study Procedures and Intervention

Enrollment was conducted by research staff using the electronic medical record system to identify potentially eligible ED patients. A convenience sample was used and screening for eligibility was conducted 16 h/day, 7 days/week. Eligible women were approached, read a brief script describing the study, and invited to enroll. Consent documentation was completed for all enrollees. Research staff used a REDCap questionnaire to collect demographic data and to determine adherence with USPSTF CC screening guidelines (32). This study was approved by the University of Rochester's Research Subject Review Board. The randomization and follow-up processes are illustrated in Figure 1. Among enrolled participants, 355 (79%) were determined to be adherent with USPSTF screening recommendations and their participation in the study ended. Among 95 (21%) enrolled participants that were determined to be either nonadherent or have uncertain adherence, 47 were randomized to the control condition and 48 were randomized to the intervention condition. Participants assigned to the control condition were notified of their screening status and referred to their usual provider of women's health care (if they reported having one) or to our medical system's Women's Health Practice (which provides CC screening with no out-of-pocket costs) to obtain screening or to clarify their screening status (if uncertain). Participants randomized to the intervention condition were similarly notified of their screening status and referred. In addition,

participants in the intervention condition received a total of three text messages delivered at 30-day intervals over a period of 90 days after enrollment.

Each text message included content related to one of the three elements of the Theory of Planned Behavior (TPB) aimed at developing intention to get screened (33). The TPB is one of the most extensively utilized behavioral change theories in preventive medicine—it states that the strongest predictor of engaging in a specific behavior is the intention to engage in the behavior. Intention is viewed as the direct result of 1) an individual's favorable or unfavorable attitudes toward the behavior, 2) subjective normative beliefs about the behavior, and 3) perceived control over whether or not he/she can perform the behavior. Text messages also included a reminder to schedule screening and contact information for the participant's usual provider of women's health care or our medical system's Women's Health Practice. Details of the text messages are presented in Table 1. All randomized enrollees received a follow-up call at 150 days to determine if they scheduled or underwent CC screening (primary outcome) and to collect additional qualitative feedback regarding barriers to care and perceptions of the study interventions.

Data Analysis

Participant demographic and behavioral characteristics are presented with frequencies and percentages or with means and standard deviations. Comparisons between groups were performed using χ^2 tests for independence and independent measures *t*-tests.

RESULTS

Enrollment data for this study have been previously disseminated in abstract form and are presented in detail in Table 2 (34). Table 2 also details comparisons between participants deemed adherent or nonadherent/uncertain with USPSTF screening guidelines at baseline. The strongest predictors of adherence were having a regular provider of women's health care, using birth control pills/injection/intrauterine device, and having private insurance. Factors associated with nonadherence upon enrollment included Hispanic ethnicity, lack of health insurance, lack of a normal provider of women's health care, and cigarette smoking. When examined as an ordinal variable, a higher education level was associated with adherence (Spearman $r = 0.13$; $p = 0.008$). Race, age, and body mass index were not found to be associated with adherence.

We successfully contacted 68% of participants, although 11 (12%) declined to complete the follow-up interview. The results from those retained in this pilot study are promising. Among all study participants surveyed at follow-up, 39% received or scheduled a CC screening (Table 3), far greater than would be anticipated in the absence of screening or intervention. In

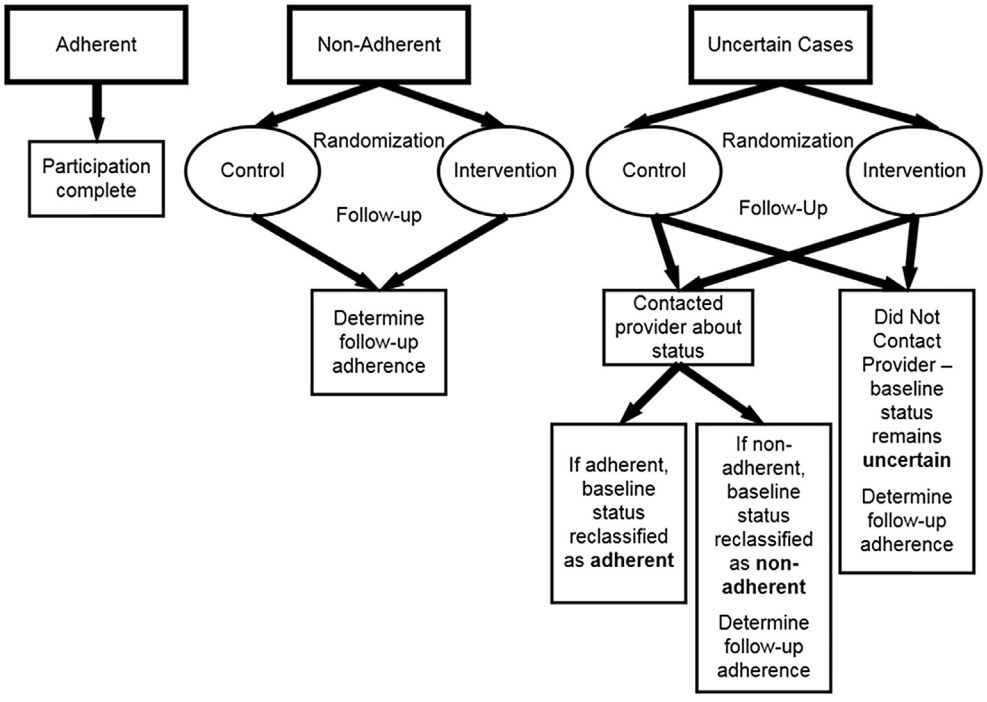

Figure 1. Randomization and follow-up processes.

Table 1. Theory of Planned Behavior (TPB) Text Messages Sent to Intervention Group

Element of the TPB	TPB Portion of Text	Scheduling Portion of Text
Attitudes about screening	"Regular screening for cervical cancer is an extremely effective way to prevent cancer or identify early stages of cancer that can be effectively treated"	Schedule cervical screening by calling your usual women's health provider or with University of Rochester's Women's Health Practice at University of Rochester
Subjective norms about screening	"Over 80% of women across the country stay up-to-date with cervical cancer screening guidelines"	Same as above
Perceived behavioral control over obtaining screening	"Pap tests are available, without cost to you, at your women's health provider or at the University of Rochester's Women's Health Practice"	Same as above

the control condition, 36% received or scheduled screening during the follow-up period. In the intervention condition, 43% received or scheduled screening during the follow-up period—a 7% absolute improvement and a 19% relative improvement over the control condition. Given the small sample size in this pilot, this difference was not statistically significant ($p = 0.643$). This effect was likely somewhat attenuated by higher levels (i.e., Cohen's d $\geq$ 0.20) of several perceived barriers to care in the intervention condition compared with the control condition (i.e., transportation issues, beliefs that doctors are unresponsive to their concerns, embarrassment regarding a potential illness, confusion trying to schedule appointments, and

Table 2. Baseline Demographic Characteristics and Group Comparisons

	Overall	Adherent (n = 355)	Nonadherent or Uncertain (n = 95)	*p* Value*
Race, n (%)				0.690†
White	259 (58)	206 (58)	53 (56)	
Black/African American	150 (33)	123 (35)	27 (28)	
Asian	11 (2)	7 (2)	4 (4)	
Native American	3 (1)	0 (0)	3 (3)	
Native Hawaiian/Pac Islander	1 (<1)	1 (<1)	0 (0)	
Multiracial	10 (2)	8 (2)	2 (2)	
Other/refused to answer	16 (4)	10 (3)	6 (6)	
Hispanic ethnicity, n (%)	48 (11)	31 (9)	17 (18)	0.010
Age in years, M ± SD	38.5 ± 12.1	38.6 ± 11.9	37.9 ± 12.6	0.621‡
Educational level, n (%)				0.103§
< High school	32 (7)	22 (6)	10 (11)	
HS degree or equivalent	150 (33)	113 (32)	37 (39)	
Some college	157 (35)	124 (35)	33 (35)	
4-year college degree	68 (15)	57 (16)	11 (12)	
Professional degree	43 (10)	39 (11)	4 (4)	
Insurance status,‖ n (%)				
None	18 (4)	10 (3)	8 (8)	0.013
Private	210 (47)	177 (50)	33 (35)	0.009
Medicaid	184 (41)	143 (40)	41 (43)	0.613
Medicare	44 (10)	33 (9)	11 (12)	0.506
Other	24 (5)	20 (6)	4 (4)	0.583
Smoker, n (%)	117 (26)	83	34	0.014
Methods of contraception, n (%)¶				
None	169 (38)	135 (38)	34 (36)	0.689
Condoms	84 (19)	67 (19)	17 (18)	0.828
BC pills/injection/IUD	117 (26)	101 (28)	16 (17)	0.022
Body mass index,‡ M ± SD	31.6 ± 9.4	31.2 ± 8.5	33.1 ± 12.1	0.168

BC = birth control; HS = high school; IUD = intrauterine device.
* Value based on Pearson chi-squared tests for independence.
† Analyzed as White vs. non-White due to small cell sizes.
‡ Value based on independent measures *t*-tests.
§ When examined as an ordinal variable, Spearman correlation = 0.13, $p = 0.008$.
‖ Categories are not mutually exclusive, as patient can have more than one type. Comparisons made between those who endorse this type of insurance vs those who do not.
¶ Categories are not mutually exclusive, as patient can use more than one form. Comparisons made between those who endorse this form of contraception vs those who do not.

Table 3. Pilot Study Results

	Control (n = 28)	Intervention (n = 21)	*p* Value*
Received CC screening since enrollment	7 (25%)	7 (33%)	0.523
Scheduled CC screening since enrollment	3 (11%)	2 (10%)	0.890
Received or scheduled CC screening since enrollment	10 (36%)	9 (43%)	0.643
Experienced problems scheduling or keeping appointment for CC screening	3 (11%)	3 (14%)	0.706

CC = cervical cancer.
Fifty four participants completed follow-up survey; 5 were determined adherent and re-classified as such.
* Value based on Pearson chi-squared tests for independence.

difficulty understanding written medical information). These types of preexisting differences are common in small, pilot trials and are very unlikely to be observed in subsequent larger efficacy trials.

DISCUSSION

The ED offers significant promise as a setting to advance preventive health efforts, and several successful initiatives have been deployed in this arena (2–8). From the patient perspective, there seems to be wide receptivity to ED-based preventive health interventions (35). ED directors are also in favor of ED-based preventive health services that don't increase patient length of stay or take clinician time away from other patients (36). In recognition that ED patients are disproportionately likely to be nonadherent with USPSTF CC screening guidelines, we conducted this pilot study to assess the feasibility and potential efficacy of an SMS intervention aimed at increasing CC screening uptake among ED patients found to be nonadherent with USPSTF screening recommendations.

We identified substantial interval uptake of CC screening among study participants in both our control and intervention conditions (36% and 43%, respectively). This magnitude of uptake among the controls indicates some probable efficacy of the control condition. Our control condition included screening for adherence and referral for care. A control condition for which adherence with screening was assessed but not communicated to the patient, and without referral for nonadherent participants, would have been unethical. Thus, although the baseline level of CC screening uptake among nonadherent women during any given 150-day follow-up period is unknown, simply assessing adherence and referral for those identified as nonadherent/uncertain seems to catalyze uptake of CC screening.

Uptake among our intervention condition exceeded the control level by 19%, demonstrating potential efficacy for our intervention. SMS on mobile phones, also known as text messaging, is a low-cost, scalable, and effective means of delivering health behavior interventions (12–26). According to the Pew Research Center, the vast majority of Americans—95%—own a cell phone, and an estimated 98% of all cell phones have texting capabilities (17,37). Evidence-based SMS interventions for health behavior include smoking cessation, primary care attendance, breast cancer screening, and sun safety, among others (20,22,23,27–31). However, minimal research has been conducted applying SMS interventions to CC screening, and no prior research, apart from this study, has targeted a CC prevention intervention by leveraging the universal health care access setting of the ED.

In addition to demonstrating feasibility of recruitment and the potential for efficacy, the results of this study provide insight into several considerations for this type of intervention in the ED. One risk of assessing adherence with cancer screening guidelines using patient self-report is over-referral. In this study, the rate of over-referral (e.g., identifying adherent patients as nonadherent or uncertain) was low (7.4%), and the consequences of this potential problem were minimal. Our intervention consisted of a total of three SMS communications. There is not an evidence-based best practice regarding the optimal intensity (frequency and total number) of text messages to best impact behavioral change—subsequent research with greater intervention intensity may result in enhanced efficacy. Finally, the demonstrated feasibility of our approach in the ED has the potential to serve as a model for additional interventions aimed at increasing uptake of other important preventive health services such as colorectal and breast cancer screening.

Limitations

There are several important limitations of this work. Although our recruitment strategy was effective and efficient, and preliminary estimates of nonadherence were confirmed, additional steps will be required in future work to improve retention. Our sample size for this pilot study, although appropriate for establishing feasibility and estimating effect size for subsequent work, was not sufficient to demonstrate statistically significant differences between study conditions. Finally, our study sample was collected from a single ED, limiting the generalizability of our findings.

CONCLUSIONS

In summary, the results of this randomized clinical trial pilot demonstrate the feasibility and potential efficacy of an SMS-based intervention to increase uptake of CC screening among ED patients. We were able to reliably determine adherence with CC screening recommendations among female ED patients, ages 21–65 years, and to randomize nonadherent/uncertain women to the control and intervention study conditions. We found substantial uptake of CC screening among participants in both study conditions but the intervention condition demonstrated greater uptake, indicating preliminary efficacy of the intervention. A large-scale efficacy trial is forthcoming.

Acknowledgments—This project was supported by a pilot award from the University of Rochester's Clinical & Translational Sciences Institute (National Institutes of Health, United States Grant ID: UL1 TR002001) to DA.

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ARTICLE SUMMARY

1. Why is this topic important?

Emergency department (ED) patients are at disproportionate risk for nonadherence with cervical cancer screening recommendations. An ED intervention that increases uptake of cervical cancer screening has the potential to decrease the incidence of cervical cancer and save lives.

2. What does this study attempt to show?

This study presents the results of a randomized clinical trial pilot study that demonstrates the feasibility and preliminary efficacy of an intervention to increase the uptake of cervical cancer screening among ED patients.

3. What are the key findings?

Study participants in both the control and intervention conditions had significant uptake of cervical cancer screening during the 150-day follow-up period. The intervention condition had 19% greater uptake of cervical cancer screening relative to the control condition.

4. How is patient care impacted?

This pilot study demonstrates preliminary efficacy of a behavioral intervention to increase uptake of cervical cancer screening among ED patients. A large-scale efficacy trial is planned.