Research Article

Evaluating the Efficacy of Lay Health Advisors for Increasing Risk-Appropriate Pap Test Screening: A Randomized Controlled Trial among Ohio Appalachian Women

Electra D. Paskett1,2,4, John M. McLaughlin1,2, Amy M. Lehman5, Mira L. Katz1,3, Cathy M. Tatum1, and Jill M. Oliver1

Abstract

Background: Cervical cancer is a significant health disparity among women in Ohio Appalachia. The goal of this study was to evaluate the efficacy of a lay health advisor (LHA) intervention for improving Papanicolaou (Pap) testing rates, to reduce cervical cancer, among women in need of screening.

Methods: Women from 14 Ohio Appalachian clinics in need of a Pap test were randomized to receive either usual care or an LHA intervention over a 10-month period. The intervention consisted of two in-person visits with an LHA, two phone calls, and four postcards. Both self-report and medical record review (MRR) data (primary outcome) were analyzed.

Results: Of the 286 women, 145 and 141 were randomized to intervention and usual care arms, respectively. According to MRR, more women in the LHA arm had a Pap test by the end of the study compared with those randomized to usual care (51.1% vs. 42.0%; OR = 1.44, 95% CI: 0.89–2.33; P = 0.135). Results of self-report were more pronounced (71.3% vs. 54.2%; OR = 2.10, 95% CI: 1.22–3.61; P = 0.008).

Conclusions: An LHA intervention showed some improvement in the receipt of Pap tests among Ohio Appalachian women in need of screening. Although biases inherent in using self-reports of screening are well known, this study also identified biases in using MRR data in clinics located in underserved areas.

Impact: LHA interventions show promise for improving screening behaviors among nonadherent women from underserved populations. Cancer Epidemiol Biomarkers Prev; 20(5); 835–43. ©2011 AACR.

Introduction

Rates of cervical cancer incidence have decreased roughly 75% since the introduction of the Papanicolaou (Pap) test in 1950 (1). Although persistent infection with human papillomavirus (HPV) causes the majority of cervical cancer today, remaining morbidity and mortality caused by cervical cancer is almost entirely the result of nonparticipation in screening and the absence of proper and timely follow-up for abnormalities diagnosed by screening (2–7). Thus, efforts to reduce the costs, both human and economic, of cervical cancer should focus on increasing adherence to recommended cervical cancer screening guidelines and ensuring compliance with treatment among women with abnormal findings, especially among women at higher risk for developing cervical cancer.

Women in Appalachia comprise a U.S. population that is at notably at higher risk for developing and dying of cervical cancer. Rates of cervical cancer incidence and mortality are 12% and 21% higher, respectively, in Appalachian Ohio counties than non-Appalachian counties in Ohio (8). Many factors indicative of women living in this geographic region may contribute to cervical cancer disparities, including unique values, beliefs, and attitudes about cervical cancer, the social environment [limited health care access and public transportation, low socioeconomic status (SES)], higher prevalence of HPV, provider–patient communication issues (including lack of recommendation for screening), psychosocial factors (fear of cancer, stress), behavioral factors (tobacco use, risky sexual activity), and lower rates of Pap test completion (8–12). Innovative strategies to reach underserved populations that address these multiple levels should be tested in Appalachian populations.

Lay health advisors (abbreviated LHA and synonymously referred to as promotoras, community health workers, natural helpers, or patient navigators) have emerged as a viable way to promote the uptake of proper

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risk-appropriate screening and facilitate proper postdiagnostic follow-up in vulnerable populations (13–24). Risk-appropriate cervical cancer screening (annually vs. every 2–3 years) is based on a woman’s risk (high vs. low) of developing cervical cancer as determined by the presence of risk factors (e.g., history of sexually transmitted disease, smoking). In the current complex and fragmented health care system, LHAs, especially in underserved populations, can serve as a bridge between the formal health care system and the community-based system of care and support. Utilizing LHAs has been previously effective in lowering rates of infant mortality and low birth weight, increasing childhood immunization, helping patients control hypertension, promoting smoking cessation, helping individuals with HIV (human immunodeficiency virus) infection or mental illness find needed services, increasing the use of screening tests for breast, cervical, prostate, and colorectal cancer, and promoting the use of genetic counseling, preventive, and primary care services in various settings (13, 14, 16–41). LHAs typically are trusted individuals from the same community as participants and, in the context of cervical cancer, have been trained to educate women about cervical health and the importance of having a routine Pap test (15, 16, 25, 33, 42). In addition to providing education, LHAs provide advice and advocacy, tangible aid, and emotional and logistical support women may need to act on what they have been taught about screening. Working with health care practitioners, LHAs address contextual multilevel barriers to cancer screening and abnormal Pap test follow-up, enhance access to screening, and reinforce tailored messages about risk-appropriate screening guidelines (15, 16, 25, 32, 33, 42).

Few of these prior studies have been conducted among Appalachian populations, and information about who benefits from LHA interventions and who is likely to be adherent to Pap testing guidelines in Appalachia is sparse. The primary objective of this study was to evaluate the efficacy of an LHA intervention program (vs. usual care) designed to increase adherence to risk-appropriate cervical cancer screening guidelines in Ohio Appalachia—a population at elevated risk for developing the disease (8). In addition, we examined other predictors of Pap test receipt.

Materials and Methods

Study population

The Community Awareness Resources and Education (CARE) initiative was conducted from March 2005 through February of 2009 as 1 of 8 Centers for Population Health and Health Disparities (P50) funded by the NIH, with the goal of addressing high cervical cancer incidence and mortality rates in Ohio Appalachia (43). All participants in this study (1 of 3 studies comprising the CARE initiative) were from 1 of 14 participating health clinics in Ohio Appalachia and were recruited in 2 phases. During the first phase (March 2005–June 2006), potential participants were asked to complete a baseline cross-sectional interview to determine eligibility for this study as well as 2 other components of the P50, and eligible participants were invited to participate. To increase efficiency, during the second phase (July 2006–February 2009), participants’ potential eligibility was determined first by telephone survey, and only participants who were potentially eligible for this study were asked to complete the baseline interview to determine final eligibility. Baseline interviews were completed in person unless the participant requested that the interview be completed by telephone.

To be eligible for the study, participants had to be female, 18 years or older, not pregnant, and a resident of Ohio Appalachia. At the time the study was conducted, Ohio Appalachia comprised 29 (33.0%) counties in the state. In addition, participants had to have been seen by a physician in the clinic from which they were selected within the previous 2 years and have no history of invasive cervical cancer or hysterectomy. Finally, to be eligible, participants had to be in need of a Pap test based on risk-appropriate guidelines described previously (43, 44). Specifically, women with any risk factors for cervical cancer [i.e., smoking, early age at first intercourse, 5 or more sexual partners in a lifetime, or having a personal history or partner with a history of HPV or a sexually transmitted infection (STI)] should have a Pap test annually whereas women with no identified risk factors should have a Pap test at least every 3 years. Although recommended screening guidelines (45) do not stratify by behavioral risk factors, previous research suggests that this may be important (43, 44). Informed consent procedures and study protocols were approved by the Institutional Review Boards of The Ohio State University and the University of Michigan.

Randomization and intervention design

Participants were randomized to either the LHA intervention group or the usual care control group via permuted block randomization that was stratified by clinic and administered through a central database system. Clinical research nurses who carried out the MRR, participant interviewers, and the primary investigators were blinded to the treatment arm assignment; however, the LHAs and participants unavoidably were not. After the baseline interview, women randomized to usual care received a letter from their physician and a National Cancer Institute (NCI) brochure that encouraged them to have a Pap test (46). The intervention design followed the framework set forth in the PRECEDE–PROCEED program planning model, which incorporates constructs of the Health Belief Model (e.g., perceived severity), Social Learning (Social Cognitive) Theory (e.g., expectancies; the values that a person places on an outcome), and a number of general models of health behavior (47, 48).
design of the educational program, namely, how messages were presented, was based primarily on Social Learning Theory (i.e., behavior is determined by expectancies and incentives; refs. 49, 50). In addition, the Transtheoretical Model (TTM) was used as a template to stage each participant’s readiness to change cervical cancer screening behaviors (51) and the Communication–Behavior Change model (e.g., addressing the personal relevance of the behavior by tailoring the message to a specific individual’s barriers) was used as a foundation for choosing what communication approach to take with individual women in the intervention group (52).

Participants in the intervention arm received 2 in-person visits, 2 telephone calls, and 4 postcards from an LHA over 10 months. In this study, LHAs were women indigenous to the Ohio Appalachian region and were between 40 and 50 years old, had no post-secondary education, and were trained to deliver the intervention and subsequently observed by study coordinators in the field. Within 4 weeks of randomization to the intervention group, LHAs visited women either in their home or at a convenient site in the community. During the first 45- to 60-minute visit, LHAs provided information designed to increase knowledge about cervical cancer, Pap test screening, and the importance of follow-up after an abnormal test. LHAs also assessed each woman’s personal risk of developing cervical cancer in her lifetime, obtained information on barriers to screening, and then provided individualized counseling for reported barriers to having a Pap test.

LHAs followed the initial visit with 2 telephone calls at 1 and 5 months later and a series of 4 postcards mailed at 2, 3, 6, and 7 months after the initial visit to provide continuous contact and screening reminders. Postcards were targeted to each participant, based upon their current stage of change in the TTM (51). The intervention period concluded with a second in-person visit approximately 10 months after the first. At the final visit, the LHA provided additional barriers counseling, if necessary, and encouraged the participant to continue to be proactive about her health care.

Measures

As part of the CARE initiative, baseline information was collected on the basis of the Social Determinants of Health model (53) and described social and cultural factors, material factors, health and health behaviors, psychological factors, and environmental factors related to cervical cancer screening behavior (43). For this intervention study, it was determined a priori that only variables describing age, race, marital status, employment status, occupation, education, annual household income, type of health insurance, and history of previous abnormal Pap tests would be examined for potential confounding or effect modification of the intervention effect. A measure of SES, loosely based on the Hollingshead scale (54), was calculated and was derived by combining information about occupation, education, and income. For analysis purposes, SES was grouped into 3 levels: SES scores of 0–1, 2–3, and 4–6 represent low-, middle-, and high-level SES, respectively (43).

The primary outcome in this study was whether or not a woman who was in need of a Pap test, based upon risk-appropriate guidelines, actually received one in the time between randomization and the 12-month follow-up interview based on information in the medical record. As a secondary outcome, self-report of receipt of Pap test was obtained in the follow-up survey conducted at the end of the study. To obtain medical record information, a form requesting patient information along with a copy of the medical record release form was faxed to the clinic listed by each participant. At least 3 attempts (calls or another fax) were made to obtain the information from the clinic.

Statistical analysis

On the basis of the previous research, we estimated that approximately 40% of women in the control group would be screened at follow-up and between 55% and 65% would be screened if they were in the intervention group. Anticipating a 30% attrition rate, 140 women were needed per treatment arm to detect a 20% difference in screening rates assuming a 2-sided \( \chi^2 \) test (1 df) for detecting differences in proportions in independent data with a type I error rate of 0.05. Descriptive statistics were used to provide overall characteristics by the treatment arm and to ensure balancing of covariates after randomization. Initial unadjusted likelihood ratio \( \chi^2 \) tests were used to compare differences in rates of Pap test utilization between the intervention and control groups at follow-up. Both the primary and secondary end points were tested at the 0.05 level of significance. Logistic regression models were constructed to evaluate the intervention effect (i.e., having had a Pap test during the study period) and to assess the confounding influences of clinic (random effect) and other prespecified, potentially confounding fixed-effects measured at baseline. Interaction effects were assessed to determine whether the effect of the intervention was moderated by specific characteristics of the women. Separate exploratory logistic regression models were constructed to identify significant predictors (among factors listed in Table 1) of obtaining a Pap test after controlling for the treatment arm. Differential loss to follow-up was assessed by comparing characteristics of participants who did not provide self-reported Pap test status with those who did. For logistic regression analyses, likelihood ratio \( \chi^2 \) tests were used to determine improved statistical fit. All statistical analyses were conducted using SAS version 9.2 (SAS Institute Inc.).

Results

Study participants

Figure 1 displays the number of women selected, assessed for eligibility, accrued, randomized, and...
assessed for the primary outcome. The main reasons women were ineligible were currently pregnant (76%), not speaking English (54%), not an active patient at the clinic (55%), and not living in Appalachia (12%). (Note: Participants at screening could be ineligible for more than one reason.) After the baseline interview, the most common reason for ineligibility (145 of 423) was not needing a Pap test. The overall response rate was 81.9% (286 of 349 eligible women). Of the 286 women who met all eligibility criteria and consented, 145 were randomized to the LHA intervention and 141 were allocated to usual care. Six women were later found to be ineligible after randomization and were not included in the analysis.

Baseline characteristics of the intervention and usual care groups are shown in Table 1. The mean age of the participants was 43.7 years, and nearly all of the participants (95.4%) were white, which is typical of the Ohio Appalachian area. Most had household incomes of less than $50,000 (74.7%) and were either married or part of a couple (63.4%). A majority of participants had some type of health care coverage (82.4%), and more than half of the population (52.1%) had completed at least some college. Approximately a quarter of the participants (27.6%) had a history of an abnormal Pap test, and more than a third (36.4%) had CES-D scores of 16 or more, indicative of clinical depression. Although a notably higher proportion of participants in the intervention group had a history of abnormal Pap tests, there were no statistically significant differences in baseline characteristics between the intervention and usual care groups at $P < 0.05$.

### Pap test screening rates at study completion

MRR data pertaining to Pap test status at the end of the study were available for 270 (96.4%) participants. Four and 6 participants were missing MRR data from the intervention and control groups, respectively. No significant differences in baseline characteristics were found between women with and without MRR data. At follow-up, 47 women were missing data about self-reported Pap test status. Those without self-reported Pap test status were significantly younger (35.3 vs. 45.5 years, $P < 0.0001$) and more likely to have a history of abnormal Pap test (42.6% vs. 24.6%, $P = 0.012$). Participants with and without self-reported Pap test status were similar across other measured demographic factors. A larger proportion of participants from the intervention group did not provide Pap test information at the follow-up survey, although this difference was not statistically significant (19.6% vs. 13.9%, $P = 0.201$).

Table 2 shows the proportion of women who at study completion had a Pap test according to MRR and self-reported having had a Pap test by study arm. According to MRR, a greater proportion of women in the intervention group had a Pap test at study completion than women in the control group (51.1% vs. 42.0%, $P = 0.135$). Overall, a notably larger proportion of participants self-reported having had a Pap test by the end of the study than was confirmed by MRR (62.7% vs. 46.7%, respectively). Like MRR, however, a greater proportion of participants self-reported having had a Pap test by the end of the study in the intervention group than those

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**Table 1. Baseline participant demographics by treatment arm (N = 280)**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control (n = 137)</th>
<th>Intervention (n = 143)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, y</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–30</td>
<td>27 (19.7)</td>
<td>41 (28.7)</td>
</tr>
<tr>
<td>31–50</td>
<td>63 (46.0)</td>
<td>58 (40.5)</td>
</tr>
<tr>
<td>≥51</td>
<td>47 (34.3)</td>
<td>44 (30.8)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>131 (95.6)</td>
<td>136 (95.1)</td>
</tr>
<tr>
<td>Nonwhite</td>
<td>6 (4.4)</td>
<td>7 (4.9)</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never married</td>
<td>15 (11.0)</td>
<td>14 (9.8)</td>
</tr>
<tr>
<td>Married/member of couple</td>
<td>80 (58.8)</td>
<td>97 (67.8)</td>
</tr>
<tr>
<td>Divorced/widowed/separated</td>
<td>41 (30.2)</td>
<td>32 (22.4)</td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full- or part-time</td>
<td>77 (56.2)</td>
<td>89 (62.2)</td>
</tr>
<tr>
<td>Unemployed or disabled</td>
<td>19 (13.9)</td>
<td>25 (17.5)</td>
</tr>
<tr>
<td>Other</td>
<td>41 (29.9)</td>
<td>29 (20.3)</td>
</tr>
<tr>
<td><strong>Health insurance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>82 (59.9)</td>
<td>81 (57.1)</td>
</tr>
<tr>
<td>Medicare and/or Medicaid only</td>
<td>36 (26.3)</td>
<td>31 (21.8)</td>
</tr>
<tr>
<td>No coverage</td>
<td>19 (13.8)</td>
<td>30 (21.1)</td>
</tr>
<tr>
<td><strong>Annual household income</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$0–$20,000</td>
<td>49 (38.9)</td>
<td>49 (36.3)</td>
</tr>
<tr>
<td>$20,001–$50,000</td>
<td>43 (33.3)</td>
<td>55 (40.7)</td>
</tr>
<tr>
<td>≥$50,000</td>
<td>35 (27.8)</td>
<td>31 (23.0)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>10 (7.3)</td>
<td>10 (7.0)</td>
</tr>
<tr>
<td>High school graduate/GED</td>
<td>55 (40.1)</td>
<td>59 (41.3)</td>
</tr>
<tr>
<td>At least some college</td>
<td>72 (52.6)</td>
<td>74 (51.7)</td>
</tr>
<tr>
<td><strong>SES</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–1</td>
<td>30 (22.2)</td>
<td>28 (19.9)</td>
</tr>
<tr>
<td>2–3</td>
<td>63 (46.7)</td>
<td>64 (45.4)</td>
</tr>
<tr>
<td>4–6</td>
<td>42 (31.1)</td>
<td>49 (34.7)</td>
</tr>
<tr>
<td><strong>Previous abnormal Pap test</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>30 (22.6)</td>
<td>46 (32.4)</td>
</tr>
<tr>
<td>No</td>
<td>103 (77.4)</td>
<td>96 (67.6)</td>
</tr>
<tr>
<td><strong>CES-D</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;16</td>
<td>86 (63.7)</td>
<td>89 (63.6)</td>
</tr>
<tr>
<td>≤16</td>
<td>49 (36.3)</td>
<td>51 (36.4)</td>
</tr>
</tbody>
</table>

*Not all variables sum to N = 280 because of missing data.*

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receiving usual care (71.3% vs. 54.2%, \(P = 0.008\)). This difference, however, might be a reflection of the missing data from women who did not complete the follow-up interview.

Logistic regression modeling showed that over the course of the study, participants receiving the LHA intervention were 1.44 (95% CI: 0.89–2.33; \(P = 0.135\)) times as likely to have had a Pap test based on MRR. According to participant self-report, those in the intervention group were 2.10 (95% CI: 1.22–3.61; \(P = 0.008\)) times as likely to report having had a Pap test during the study period (Table 3). There was no evidence of confounding or effect modification by any of the pre-specified variables collected at baseline for either reporting type; therefore, we report crude results. In addition, results of exploratory analyses suggested that

Figure 1. Study flow of participants from sampling to analysis, CONSORT diagram. *For phase II, women were screened for eligibility and recruited directly into this study. A total of 571 women participated in a cross-sectional study; of these, 164 were then eligible for this study.

Table 2. Pap test status by the treatment arm and the report type

<table>
<thead>
<tr>
<th>Pap test status</th>
<th>MRR ((N = 270^a))</th>
<th>Self-report ((N = 233^b))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control</td>
<td>Intervention</td>
</tr>
<tr>
<td>Pap not within last 12 mo</td>
<td>76 (58.0)</td>
<td>68 (48.9)</td>
</tr>
<tr>
<td>Pap within last 12 mo</td>
<td>55 (42.0)</td>
<td>71 (51.1)</td>
</tr>
</tbody>
</table>

\(^a\)Ten women did not have MRR data about Pap test status.
\(^b\)Forty-seven women did not complete the final interview and did not have data about self-reported Pap test status.
after controlling for the intervention effect, women who reported having had a Pap test in the past 3 years were more than twice as likely (OR \(= 2.13, 95\% \text{ CI: 1.09–4.16}; P = 0.028\)) to receive a Pap test based on MRR by the end of the study. According to self-report, women who reported having had sex before age 18 or having had a previous sexual partner with an STI were 2.92 (95\% CI: 1.53–5.55) and 2.85 (1.23–6.60) times as likely to have a Pap test during the study period, respectively. No significant interactions with the treatment arm were found.

**Agreement between MRR and self-report**

Overall agreement between MRR and self-report data was good (74.4\%; \(\kappa = 0.728\)), and agreement was similar between the intervention and control groups (74.8\% vs. 74.1\%; Table 4). The largest discrepancy was in the control group, wherein 34.4\% of participants who reported having had a Pap test based on MRR within the study period did not compare with 30.4\% of the participants in the intervention group. Among women who reported not having had a Pap test, only a minority of women in both intervention (12.5\%) and control (15.7\%) groups actually did according to MRR.

**Discussion**

Cervical cancer is largely preventable through Pap testing, with prompt and proper follow-up for abnormal results. Not all women, however, receive Pap tests at appropriate intervals, and Appalachia Ohio is an area where women are particularly at risk for Pap test non-adherence (8). In this randomized trial, we tested the efficacy of an LHA intervention designed to increase the uptake of Pap test screening among women in need of the test who were recruited from 14 separate health clinics in Ohio Appalachia. The LHA intervention was hypothesized to promote Pap test screening by improving knowledge, reducing barriers, and increasing positive beliefs about screening. The impact of the intervention on knowledge, barriers, and beliefs is the topic of another article; however, evidence from previous studies of LHA interventions documents this process (40, 41).

Overall, the results show an increase in screening among women who received the LHA intervention,

### Table 3. ORs and 95% CIs for receiving Pap tests within the 12-month follow-up period for participants in the intervention group by report type

<table>
<thead>
<tr>
<th></th>
<th>MRR (n = 270(^a))</th>
<th></th>
<th>Self-report (n = 233(^a))</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR (95% CI)</td>
<td>P</td>
<td>OR (95% CI)</td>
<td>P</td>
</tr>
<tr>
<td>Model 1(^c)</td>
<td>1.44 (0.89–2.33)</td>
<td>0.135</td>
<td>2.10 (1.22–3.61)</td>
</tr>
<tr>
<td>Model 2(^d)</td>
<td>1.46 (0.90–2.36)</td>
<td>0.129</td>
<td>2.18 (1.25–3.79)</td>
</tr>
<tr>
<td>Model 3(^e)</td>
<td>1.37 (0.81–2.31)</td>
<td>0.237</td>
<td>1.98 (1.16–3.99)</td>
</tr>
</tbody>
</table>

\(^a\)Ten women did not have MRR data about Pap test status.

\(^b\)Forty-seven women did not complete the final interview and did not have data about self-reported Pap test status.

\(^c\)Model 1 is the crude model and includes only the treatment effect in the model.

\(^d\)Model 2 includes clinic as a random effect.

\(^e\)Model 3 includes clinic as a random effect and age, race, marital status, previous history of abnormal Pap test, employment status, health insurance status, and SES as fixed effects.

### Table 4. Agreement between MRR and self-report methods of assessing Pap test uptake (N = 223\(^b\))

<table>
<thead>
<tr>
<th>Treatment arm</th>
<th>Control (n = 112)</th>
<th>Intervention (n = 111)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRR</td>
<td>Self-report</td>
<td></td>
</tr>
<tr>
<td>Pap not within last 12 mo</td>
<td>Pap within last 12 mo</td>
<td>Pap not within last 12 mo</td>
</tr>
<tr>
<td>Pap within last 12 mo</td>
<td>Pap not within last 12 mo</td>
<td>Pap within last 12 mo</td>
</tr>
</tbody>
</table>

\(^b\)Forty-seven women did not complete the final interview and did not have data about self-reported Pap test status; 10 other women did not have data about MRR.
although results from MRR and self-report differed in effect size and the level of statistical significance of the intervention effect. Participants in the intervention group were more than twice as likely to report having had a Pap test within the study period \( (P = 0.008) \). However, according to MRR, although a higher proportion of participants in the intervention group received a Pap test, the difference between the 2 arms was not significant \( (P = 0.135) \). The effect size for our LHA intervention was similar to that reported by several previous studies using MRR \( (17) \); however, other studies have shown an even larger intervention effect \( (19, 22, 33, 40, 41) \). Perhaps the lack of statistical significance for the intervention effect based on MRR in our analysis stemmed also from our definition of usual care. We defined usual care as receiving an NCI brochure and a letter from the participant’s physician. In reality, however, usual care may include neither, and we may have “watered down” our intervention effect by defining usual care in such a manner.

Self-report bias in screening has been extensively studied and likely explains why the overall proportion of women who reported having had a Pap test during the study period was notably higher than that confirmed by MRR \( (55–60) \). However, self-report and MRR discordance between the intervention and control groups did not seem to be differential among those who had information for both report types. That is, a slightly higher proportion of women in the control group who did not have a Pap test according to MRR reported having had a Pap test. For self-report bias to explain the difference in magnitude and significance of the intervention effect between self-report and MRR data in this study, the opposite would have had to be true.

Therefore, we sought alternate explanations for the discordance of results in MRR and self-report. It is likely that women who did not complete the follow-up survey were less likely to have had a Pap test within the study period. This fact may be particularly important among the women in the intervention group who may have refused the follow-up survey because they did not want to indirectly disappoint the LHA who had spent time trying to assist them during the past year. Thus, social desirability bias may have been introduced into the self-report population and the self-reported intervention effect may have been artificially inflated.

Another possibility stems from the MRR of Pap test completion in the clinics in which this study was conducted. Although in most settings MRR is the gold standard, Ohio Appalachia represents a unique setting. Many clinics in our study had inadequate resources to maintain complete and up-to-date medical records. Most of the clinics lacked computerized records, and many were understaffed in administrative positions. Still another site was damaged by local flooding and reported losing a portion of their medical records in the natural disaster. Thus, there is the possibility that for some of the women who reported having had a Pap test, but for whom there was no medical record of the test, a Pap test was done but the record was lost or destroyed. In this scenario, the intervention effect in the MRR analysis could have been underestimated. The latter possibility should be considered in future studies that plan to use MRR as the gold standard in highly rural, understaffed, and underfunded clinics where lack of computerized medical record technology is prevalent.

Secondary outcomes showed that, based on MRR data, having a Pap test in the previous 3 years was the strongest predictor of obtaining a Pap test over the course of the intervention. This underscores the importance of promoting regular screening by health care providers to establish patterns of healthy behavior. In addition, based on self-report, women in this study with a history of risky sexual behavior (i.e., having had sex before age 18 or with a partner with an STI) were more likely to adhere to risk-appropriate screening guidelines, suggesting that providers may stress the importance of regular screening to high-risk women or that women who engage in risky sexual behavior may be more acutely aware of their cervical cancer risk. The finding that significant predictors of Pap adherence for MRR were dissimilar than those of self-report further highlights the need to examine outcomes of studies conducted in rural populations by using a variety of methods.

This study is not without limitations. Primarily, medical records in the Appalachian Ohio clinics included in our study may have been incomplete. Computerized medical records were used in only 2 \( (14.3\%) \) of the participating clinics, and other clinics reported having had problems finding or maintaining medical records for all of the women enrolled in our study. If records of Pap tests for participants were differentially lost, the effect of the intervention could have been dampened. In addition, we did not have follow-up survey data or MRR data for all women, which could have introduced bias, although we obtained this information for the great majority of participants. However, internal validity of this study was likely protected by randomization and statistical control for measured baseline demographics. Furthermore, results are not generalizable to populations outside Ohio Appalachia but only to the clinics who participated in our study.

Despite limitations, this study is one of the few LHA interventions conducted in Appalachia, an area that suffers from health disparities. Moreover, we recruited women from 14 clinics across 4 regions of Ohio Appalachia, representing the great variation in this area. In addition, we captured information on participant characteristics to assess factors associated with both the intervention and the outcome. Finally, this is one of few studies that compared MRR with self-reported Pap test receipt among an underserved population served by rural health clinics. Because Pap tests must be obtained from a health care provider, the use of medical records to verify receipt of Pap tests has traditionally been the gold standard for research. Data about Pap testing from Appalachian clinics have never been evaluated for use in...
research studies, nor compared with self-reported Pap test adherence.

Ultimately, results from our study suggest increased uptake in Pap testing among women who were randomized to receive an LHA intervention. Thus, the LHA intervention seems to be transferable to the Ohio Appalachian population in need of Pap testing; however, future studies should explore methods to strengthen Pap test uptake in the Ohio Appalachian region. Indeed, results of MRR, which is typically considered the gold standard, were not significant. Future studies should continue to assess the effect and cost-effectiveness of LHAs on uptake of cervical cancer screening in vulnerable populations, evaluate the effect of varying definitions of usual care, and examine the reliability of MRR in clinic populations with poor administrative oversight, funding, and access to computerized medical charting.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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