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# Effectiveness of a Primary Care Practice Intervention for Increasing Colorectal Cancer Screening in Appalachian Kentucky

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# Abstract

**Objective**—This report describes findings from a randomized controlled trial of an intervention to increase colorectal cancer (CRC) screening in primary care practices in Appalachian Kentucky.

**Methods**—Sixty-six primary care practices were randomized to early or delayed intervention groups. The intervention was provided at practices using academic detailing, a method of education where providers receive information on a specific topic through personal contact. Data were collected in cross-sectional surveys of medical records at baseline and six months post-intervention.

The authors declare that there are no conflicts of interest.

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**Conflict of interest statement** 

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**Results**—A total of 3844 medical records were reviewed at baseline and 3751 at the six-month follow-up. At baselines, colonoscopy was recommended more frequently (43.4%) than any other screening modality, followed by fecal occult blood testing (18.0%), flexible sigmoidoscopy (0.4%), and double-contrast barium enema (0.3%). Rates of documented screening results were higher for all practices at the six-month follow-up for colonoscopy (31.8% vs 29.6%) and fecal occult blood testing (12.2% vs 11.2%). For early intervention practices that recommended screening, colonoscopy rates increased by 15.7% at six months compared to an increase of 2.4% in the delayed intervention practices (p=.01).

**Conclusions**—Using academic detailing to reach rural primary care providers with a CRC screening intervention was associated with an increase in colonoscopy.

#### Keywords

Colorectal cancer screening; randomized controlled trial; primary care; Appalachia

# INTRODUCTION

Appalachia has long been a region associated with significant health disparities (Lengerich et al., 2006). Fifty-four of the 120 counties in Kentucky are designated as Appalachian and the socioeconomic indicators for these counties are considerably lower than those for Kentucky as a whole, and the overall health outcomes are decidedly poorer (Friedell et al., 2010). Appalachian populations experience some of the highest cancer mortality rates in the nation, and lack of cancer screening has been identified as one of the most significant contributing factors (Shell and Tudiver, 2004). Research suggests that only 44% of rural, Appalachians in Kentucky obtained seek colorectal cancer (CRC) screening guidelines (Kelly et al., 2007). To reduce the burden of cancer in Appalachia, barriers to cancer screening must be identified and best practices to address such barriers must be developed (Scarinci et al., 2010). The purpose of this report is to describe findings from a randomized controlled trial designed to increase CRC screening by providing an intervention to primary health providers in Appalachian Kentucky.

While access to CRC screening in Appalachian Kentucky has increased over time, mortality rates have remained higher than the non-Appalachian areas of the state and screening rates remain low (Davis et al., 2006). Limited access to health care, limited financial resources, and lack of educational attainment are recognized barriers to obtaining healthcare overall and CRC screening in particular for Appalachian populations (Lengerich et al., 2006; Kelly et al., 2007; Scarinci et al., 2010). Personal barriers to colorectal screening include fear, embarrassment, financial issues, lack of ability to recognize need, and inadequate health literacy skills, among others (Kelly et al., 2007; Davis et al., 2001; Curry et al., 2011). One of the most important barriers that stands out from the personal barriers to CRC screening is lack of provider recommendation, a barrier which is out of control of patients who are in need of the screening (Kelly et al., 2007; Curry et al., 2011). Receiving a recommendation for screening from a physician has been identified as a primary predictor of patient compliance with screening recommendations (Curry et al., 2011). Yet, even physicians and medical staff report that procedural issues are a barrier to recommending screening to patients (Kelly et al., 2007).

To improve CRC screening in this high risk population, an intervention focusing on primary health care providers was developed. The decision to focus on primary health care providers instead of patients or the general public arose from results of interactions with a wide array of partners including community members, representatives from worksites, school personnel, public health department workers, CRC survivors, and health care providers (Hatcher et al., 2011). The input from these partners strongly suggested that efforts to

increase screening should begin with health care providers because their recommendation is one of the key reasons that patients obtain screening (Klabunde et al., 2005:Wee et al., 2005; Brenes and Paskett, 2000; Wackerbarth et al., 2007)). This project was reviewed and approved by the Institutional Review Board of the University of Kentucky and is registered with the National Cancer Institute # NCI-2013-00753.

# METHODS

The intervention for primary health care providers was developed for delivery by academic detailing. Academic detailing is a highly adaptable method of education where physicians are instructed through personal contact with an individual or group focused on a specific topic (Soumerai and Avorn, 1990; Albert et al., 2004; Gorin et al, 2006). This method was selected because of the rural locations of the primary health care providers and their limited time for continuing education. The intervention included four modules that addressed the following topics: screening efficacy, clinical performance measures, patient counseling, and creating a screening-friendly practice environment. The screening efficacy module covered the burden of CRC, risk factors, and the advantages of possible screening modalities (hs-FOBT, FS, DCBE, and colonoscopy). The clinical performance measures module presented information on methods used to collect performance data and why practices would choose to measure clinical performance. The patient counseling module discussed the relative effectiveness of different communication strategies on adherence to screening and strategies to overcome patient fears and perceived barriers to screening. The screening-friendly practice environment module presented tools to identify patients who need screening and how to encourage patients to follow-up with recommended screening. The modules were produced as powerpoint presentations and were pilot tested in 12 primary care practices in the study area prior to implementation of the study. Three individuals were recruited and trained in academic detailing to present the modules and answer questions. The modules were then presented in face-to-face visits at the practices. Individuals who knew the local community well and were familiar with primary care practices were selected to deliver the intervention.

#### **Evaluation Design**

A repeated cross-sectional group-randomized or 'cluster-randomized' design was adopted, where the units of randomization were the primary care practices, and the units of analysis, which were nested within the practices, were the medical records that were to be abstracted by our trained reviewers. A total of 66 practices were enrolled and 33 were assigned at random to an 'early' intervention group. The remaining 33 practices were assigned to a 'delayed' intervention group. Baseline medical record review was completed for all practices prior to randomization and then the 'early' group received the academic detailing intervention. The 'delayed' group received no treatment. Six months after the intervention was delivered, medical record reviews were repeated at each practice. Shortly after the sixmonth record review, the 'delayed' group practices were offered the academic detailing intervention.

#### Practice recruitment and enrollment

Primary care practices including general practice, family practice, and general internal medicine were eligible to participate in the project. Potential practices were identified in collaboration with regional Area Health Education Centers (AHEC) serving the study area. The AHECs provide continuing medical education and student placement services and have up-to-date information on medical practices in their catchment areas. Eligible practices had to have been in operation for at least one year, been seeing patients on a regular basis, and not planning on moving or closing for at least two years. All of the practices on the lists

were then contacted by telephone, eligibility criteria were confirmed, the project was described and enrollment was offered. Practices who agreed to consider participation were visited by AHEC staff where additional information about the project was provided, informed consent was obtained, and a survey of the practice was conducted.

#### **Measurement and Data Collection**

Medical record reviewers, who were trained abstractors from the academic institution conducting the project, visited the practices and collected data by abstracting medical records for patients age 50 and older without a previous diagnosis of CRC or Irritable Bowel Syndrome and who had been seen in the practice in the previous 60 days for a non-acute reason. Patients presenting with rectal bleeding were excluded. Documentation of physician recommendations for patients to obtain screening, as well as documentation of results, was obtained for FOBT, FS, DCBE, and colonoscopy. Records were selected for review using sequential lists of patients seen in the practice and continued until reviews of 60 records at each practice were completed.

#### **Research Design**

This repeated cross-sectional group-randomized intervention project was designed to provide at least 80% power to detect absolute differences in screening recommendations (having at least one of the four screening modalities recommended in the medical record) at the six-month interval of 10–15%. To achieve this design objective, 66 practices were to be enrolled, and no less than 60 patient medical records were to be reviewed from each practice at three points in time; baseline (upon randomization), six months after the intervention, and 18 months after the intervention. The 'intervention' effect comparison was conducted based on record review results collected six months after the intervention was delivered. Given that this was a group-randomized design where the practice represents the cluster and each record nested within time period represents the cluster elements (and unit of analysis), intraclass correlations become relevant and were accounted for both in the design (ICC values that ranged from 0.10 to 0.15 were assumed and used in the power calculations) and the statistical analysis ultimately performed (in this case, the ICC values were estimated using each outcome).

#### **Statistical Methods**

Estimates of the effects of the intervention were constructed from a statistical model employing logistic regression for repeated cross-sectional binary outcomes and using generalized estimating equations (GEEs) to obtain estimated intervention effect p-values (Ukoumunne and Thompson 2001). An exchangeable correlation was modeled between the response at baseline and the six month follow-up. The underlying model that was estimated for each outcome is given by

$$\log it(\pi_{jkt}) = \mu + \alpha G_k + \gamma X_t + \delta (GX)_{kt} + \beta_1 R_0 + \beta_2 R_1$$

where  $\pi_{jkt}$  is the probability of observing any of the screening tests recommended or test result documented, (Y<sub>ijkt</sub>=1), on a medical record (most generally the i<sup>th</sup> record in the j<sup>th</sup> practice belonging to the k<sup>th</sup> intervention group (k=1 for delayed, k=2 for early intervention) at time x<sub>t</sub> (=0 at baseline, =1 at 6 months). G<sub>k</sub> is an indicator for whether the i<sup>th</sup> record reviewed in the j<sup>th</sup> practice was an early (=0) or delayed (=1) intervention practice. R<sub>0</sub> is an indicator for whether the i<sup>th</sup> record in practice j was reviewed at a practice in the Northeast AHEC region (=1) or not, and R<sub>1</sub> is defined similarly for Southeastern AHEC region (=1). This notation implies that a record was reviewed at a practice in the Southern AHEC region

when  $R_0=R_1=0$ . The intervention effect in (1) corresponds to the group by time interaction term. This effectively translates into assessing whether the change from baseline to six months differs between the two intervention groups. The associated resultant p-value of the estimate for this term provides the strength of any intervention effect. An analysis of variance method was used to estimate intra-class correlations induced by the next of records at varying time points within a practice (Hade et al., 2010). An a-priori two-sided significance level was set to 5% for all statistical hypotheses conducted.

# RESULTS

Of the 66 practices enrolled in the project, 52 (78.8%) were family practices, 10 (15.2%) were internal medicine and four (6.0%) classified themselves as both. Of the 66, 37 (56.9%) were group practices and the remaining were solo. Of the group practices, 20 (54.1%) had between two and four providers, and 17 (45.9%) had five or more.

Table 1 shows baseline and six month data. A total of 3844 medical records were reviewed in the baseline cross-sectional survey and 3751 were reviewed at the 6-month follow-up survey. At baseline, the mean ( $\pm$  sd) age of patients across all 3 AHECs was found to be  $64.8 \pm 10.2$  years of age. There was a slight drop in age at 6 months from 64.8 to 64.1 years of age. The gender distribution for patient records reviewed at baseline and at 6 months was quite similar (60.5% females at baseline and 60.1% at 6 months). The population of Appalachian Kentucky is over 95% Caucasian and as a result, race/ethnic data were not recorded. There were no significant differences in demographic characteristics between the intervention and delay groups at baseline, suggesting adequate randomization.

The medical record review data showed that at baseline primary care providers recommended colonoscopy more frequently (43.4%) than any other screening modality. The baseline rate of recommendation of FOBT (18.0%) was less than half of that for colonoscopy. FS (0.4%) and double-contrast barium enema (0.3%) were only rarely recommended. The same result was found at the six-month assessment, although there was a slight decrease in recommendations for all four screening modalities (see Table 1). At the six-month follow-up, documentation of screening recommendations was lower than baseline for colonoscopy (40.3%), FOBT (14.8%), FS (0.2%), and barium enema (0.0%). As far as results of the screening being documented in the medical record, FOBT increased slightly from baseline (11.2% to 12.2%), as did colonoscopy (29.6% to 31.8%). Screening results by FOBT were found in less than 20% of the medical records, and rates for FS and DCBE were very low. Colonoscopy was the screening method most commonly found, with about 40% of the medical records showing evidence of a recommendation and about 30% showing documentation of results. It is notable that rates of FOBT appear to decline over the course of the study.

Table 2 presents the results from analysis of change in screening rates from baseline to the six-month follow-up by study group. As Table 2 shows, the change in screening colonoscopy rates from baseline to the six-month follow-up increased by about 5% and there were no statistically significant differences in rates between the early intervention and delayed intervention practices for FOBT or colonoscopy. The literature strongly suggests that screening rates are related to provider recommendation, and patients report that provider recommendation is very important in their decision to obtain screening (Tarasenko et al., 2011). Accordingly, additional analyses were conducted to assess the likelihood that screening results were documented when a provider recommendation, the rates of colonoscopy results being documented in the medical records at the six-month assessment were 15.7% higher in the early intervention compared to a 2.4% increase in the delayed

intervention practices (p=.01). No intervention effect was found for FOBT. Finally, analyses were performed to assess intervention effect for any of the screening tests included in this study, i.e. FOBT, FS, DCBE, or Colonoscopy. The dependent variables for these analyses were 'any screening recommended,' and 'any screening result documented.' No significant intervention effects were found.

The analyses reported above were conducted with consideration of the possible effect of clustering. Table 4a provides estimates for intra-class correlation corresponding to models fit to obtain the p-values for intervention effects on the four primary outcomes. The rho values ranged from 0.10 for colonoscopy results documented to 0.61 for FOBT results documented. Similarly, Table 4b provides ICCs for the outcomes of FOBT screening and colonoscopy screening documentation conditioned on provider recommendation for such action.

#### DISCUSSION

The results from evaluation of this project demonstrated an intervention effect that is encouraging for cancer prevention and control. From medical record review data, a statistically significant increase in completion of screening colonoscopy was found at the six-month post-intervention assessment of patients of practices that received the intervention. This result was limited to situations where a recommendation to obtain screening was documented, however, and it was not found when the recommendation to obtain screening was not documented. Across all screening modalities, the intervention practices increased rates of documented results from 62.9% to 79.7%, while the delayed intervention practice increased rates from 61.7% to 71.2% (p=0.06). This finding is consistent with numerous reports in the literature indicating that provider recommendation is one of the most important elements in encouraging patients to obtain screening (Blackley et al., 2012; Davis et al., 2006; Davis et al., 2001; Curry et al., 2011). It is significant that this intervention effect was observed in patients who live in a rural, medically underserved area, as this indicates promise that this established technique may be effective for increasing screening for the most vulnerable populations.

The primary care practices that participated in this project were located in Appalachian Kentucky, a rural area with a population that experiences pronounced cancer health disparities. Unemployment in the population is high, levels of educational attainment are low, and health insurance coverage is limited, as is access to health care. To obtain colonoscopy, the patients had to overcome substantial barriers such as cost and travel which suggests that the recommendations of the providers were taken seriously, and that primary physicians can directly influence the preventive health behaviors of their patients in these underserved communities. The intervention addressed the topic of patient counseling, so it is possible that this instruction helped the providers to deliver clearer messages recommending screening.

This project assessed screening by FOBT, FS, double contrast barium enema (DCBE), and colonoscopy, all of which were recommended screening modalities when the project began in 2004. We had intended to include all screening tests in evaluating the effectiveness of the intervention but, as Table 1 shows, FS and DCBE were only used rarely, which led us to focus our attention on FOBT and colonoscopy. We had anticipated that the rates for FOBT would be substantial because of its low cost and ease of use. Particularly in rural populations where access to colonoscopy is limited, we anticipated that FOBT would be used widely. It was a surprise to see that FOBT rates were low and remained relatively constant through the six-month assessment across all practices. However, as Table 3 shows, the rates for FOBT being completed increased substantially during the project when the test was recommended

by health care providers, but this change occurred in both study groups indicating a possible secular trend and probably not an intervention effect. For colonoscopy, on the other hand, receipt of the intervention among practices that recommended colonoscopy was associated with a substantial increase in screening. The results from this investigation suggest that interventions to increase screening for colorectal cancer in rural primary care practices may benefit from beginning by intervening with with the goal of increasing the rate at which health care providers recommend screening. Our data indicate that when screening was recommended, the academic detailing intervention was effective in increasing screening. It is curious that the intervention did not appear to increase recommendations for screening, but this may be a reflection of low rates of recording recommendations for screening in the medical record. It is possible that providers were more likely to document screening test results than to document their recommendation to obtain screening. Additional research is needed to continue exploration of methods to increase screening for colorectal cancer. This research should focus on screening modalities as well as outreach methods. FOBT was the stool blood test used by the practices enrolled in this study. In recent years, many providers have changed to the FIT test. This screening test has several advantages over the FOBT and has been used successfully in at least one study in Appalachia (Curry et. al. 2011). Research is also needed to improve understanding of the potential for different outreach strategies. A report by Gupta and colleagues showed that an intervention delivered by mail was associated with a tripling of FIT testing among uninsured patients of a large safety net health system (Gupta et al., 2013).

This study demonstrated that an intervention delivered to primary care practices in rural Appalachia was effective in increasing colonoscopy. The fact that the intervention was effective in a population with severe cancer health disparities underscores its importance and potential to greatly effect change. The intervention was delivered using academic detailing, and while there is evidence that academic detailing can be used to increase cancer screening in urban environments (Sheinfield-Gorin et al., 2006), to our knowledge there are no reports of its effectiveness with rural populations, thus indicating the importance of the results of this current study.

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# Highlights

- Randomized controlled trial in rural primary care practices
- Sixty-six primary care practices, 33 intervention, 33 control
- Data from 3844 medical records at baseline and 3751 at the six-month follow-up
- Colonoscopy rates were higher at the six-month follow-up (31.8% vs 29.6%)
- Colonoscopy increased (p<.01) for intervention practices that recommended screening

#### Table 1

Colorectal screening recommended and completed (medical record results documented) at baseline and 6months by Study Group, Kentucky, U.S.A., 2005–2009

	Base	line	6-Month F	follow-up
	Intervention	Delay	Intervention	Delay
	(Mean±sd)	(Mean±sd)	(Mean±sd)	(Mean±sd)
Number of office visits in past year	$6.5\pm4.6$	$6.3\pm4.5$	$7.3\pm5.4$	$6.7\pm4.7$
Age	$65.6\pm10.5$	$64.1\pm9.7$	$64.7\pm9.9$	$63.5\pm9.7$
	N (%)	N (%)	N (%)	N (%)
Gender				
Female	1141 (60.5)	1173 (60.5)	1077 (58.5)	1178 (61.7)
Male	746 (39.5)	767 (39.5)	765 (41.5)	731 (38.3)
FOBT Recommended*	322 (17.2)	365 (18.8)	249 (13.6)	305 (16.0)
FOBT Results documented*	248 (13.2)	177 (9.2)	225 (12.2)	230 (12.1)
Flexible Sig Recommended	6 (0.3)	9 (0.5)	2 (0.1)	5 (0.3)
Flexible Sig Results documented	7 (0.4)	4 (0.2)	2 (0.1)	6 (0.3)
Colonoscopy Recommended	805 (42.6)	858 (44.1)	735 (39.9)	774 (40.6)
Colonoscopy Results documented	542 (28.7)	592 (30.4)	621 (33.7)	570 (29.9)
DCBE Recommended	6 (0.3)	5 (0.3)	1 (0.1)	0 (0.0)
DCBE Results documented	5 (0.3)	5 (0.3)	2 (0.1)	0 (0.0)
Any Screening Recommended	914 (48.3)	967 (49.6)	833 (45.2)	863 (45.2)
Any Results Documented	710 (37.5)	702 (36.0)	732 (39.7)	691 (36.2)

\*Recommendations and documented results were reported independently.

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# Table 2

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	Baseline Six Months	Change from Baseline	p-value <sup>I</sup>
Early Intervention	17.2% 13.6%	↓ 3.6%	0.7192
Delayed Intervention	18.8% 16.0%	¢ 2.8%	
Early Intervention	13.2% 12.2%	$\downarrow 1.0\%$	0.4631
Delayed Intervention	9.2% 12.1%	↑ 2.9%	
Early Intervention	42.6% 39.9%	¢ 2.7%	0.9011
Delayed Intervention	44.1% 40.6%	¢ 3.5%	
Early Intervention	28.7% 33.7%	$\uparrow 5.0\%$	0.0969
Delayed Intervention	30.4% 29.9%	$\downarrow 0.5\%$	
Early Intervention	48.3% 45.2%	¢ 3.1%	0.8386
Delayed Intervention	49.6% 45.2%	4.4%	
Early Intervention	37.5% 39.7%	$\uparrow 2.2\%$	0.7438
Delayed Intervention	36.0% 36.2%	$\uparrow 0.2\%$	

I p-value corresponding to Intervention by time interaction term found in equation (1).

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# Table 3

Change in Screening Rates baseline to 6-month assessment, by study group when provider recommended screening, Kentucky, U.S.A., 2005–2009

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Screening	Study Group Baseline	Basel		6-month	dn-wollof ı	6-month follow-up Change from baseline to 6-month follow-up p-value	p-value
		× N	N* % Yes N*	*z	% Yes		
FOBT results documented	Early	317	317 38.2	249	79.5	41.3%	.82
	Delayed	359	359 29.5	304	75.7	46.2	
Colonoscopy results documented Early	Early	804	59.0	735	74.7	15.7	.01
	Delayed	856	856 61.0	773	63.4	2.4	
Any Screening 06completed	Early	914	914 62.9	833	79.6	16.7	.06
	Delayed	967 61.7	61.7	863	71.2	9.5	

\* N is the number of observations where screening was recommended and a screening result was not missing

#### Table 4a

Estimated Intra-Class Correlations by Screening Modality, Kentucky, U.S.A., 2005–2009

	Intra-Class Correla	ntion (ICC) Estimate <sup>1</sup>
	Baseline	Six Month
FOBT recommended	0.2893	.2680
FOBT results documented	0.6131	.2112
Colonoscopy recommended	0.1658	.1979
Colonoscopy results documented	0.1010	.1336

 $^{I}$ ICCs obtained from 'reduced' models using equation (1) fit to each of the screening modalities

#### Table 4b

Estimated Intra-Class Correlations by Screening Modality Conditioned on Screening Being Recommended, Kentucky, U.S.A., 2005–2009

	Intra-Class Correla	ation (ICC) Estimate <sup>1</sup>
	Baseline	Six Month
FOBT results documented	.6779	.2795
Colonoscopy results documented	.1048	.0801

 $^{I}\mathrm{ICCs}$  obtained from 'reduced' models using equation (1) fit to each of the screening modalities