Effectiveness of Interventions to Increase Colorectal Cancer Screening Among American Indians and Alaska Natives

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Introduction
Screening rates for colorectal cancer are low in many American Indian and Alaska Native (AI/AN) communities. Direct mailing of a fecal immunochemical test (FIT) kit can address patient and structural barriers to screening. Our objective was to determine if such an evidence-based intervention could increase colorectal cancer screening among AI/AN populations.

Methods
We recruited study participants from 3 tribally operated health care facilities and randomly assigned them to 1 of 3 study groups: 1) usual care, 2) mailing of FIT kits, and 3) mailing of FIT kits plus follow-up outreach by telephone and/or home visit from an American Indian Community Health Representative (CHR).

Results
Among participants who received usual care, 6.4% returned completed FIT kits. Among participants who were mailed FIT kits without outreach, 16.9% returned the kits — a significant increase over usual care (P < .01). Among participants who received mailed FIT kits plus CHR outreach, 18.8% returned kits, which was also a significant increase over usual care (P < .01) but not a significant increase compared with the mailed FIT kit–only group (P = .44). Of 165 participants who returned FIT kits during the study, 39 (23.6%) had a positive result and were referred for colonoscopy of which 23 (59.0%) completed the colonoscopy. Twelve participants who completed a colonoscopy had polyps, and 1 was diagnosed with colorectal cancer.

Conclusion
Direct mailing of FIT kits to eligible community members may be a useful, population-based strategy to increase colorectal cancer screening among AI/AN people.
The US Preventive Services Task Force (USPSTF) recommends stool-based tests and direct visualization tests (colonoscopy, flexible sigmoidoscopy, or virtual colonoscopy) for CRC screening. In health care systems with limited capacity to provide direct-visualization screening tests, stool-based tests such as high-sensitivity, guaiac-based fecal occult blood tests (FOBT) and fecal immunochemical tests (FIT) are often the most accessible options for CRC screening. However, various patient and structural barriers exist to completing FOBT and FIT: geographic isolation, lack of a regular health care provider, failure of providers to recommend screening, lack of clinical tracking and reminder systems, lack of transportation, embarrassment, privacy concerns, distrust of the health care system, and insufficient knowledge about CRC, its risk factors, and screening recommendations. Many of these barriers can be mitigated. According to the Community Preventive Services Task Force, there is sufficient evidence that using patient reminders and small media (eg, letters, pamphlets, brochures, flyers) can increase CRC screening with stool tests. Reducing structural barriers (eg, eliminating or simplifying administrative procedures required for CRC screening, reducing time or distance for screening services) is also an effective way to increase the use of stool tests. Direct mailing of FOBT or FIT is an approach that can address both patient and structural barriers. Mailing FOBT or FIT kits to patients and providing outreach through telephone calls and home visits can reduce patient and structural barriers, and both have been shown to be effective strategies to improve participation in CRC screening in various underserved populations. The objective of our study was to determine if such evidence-based interventions could also lead to increased CRC screening among rural AI/AN populations.

Methods

Participant recruitment

We recruited 3 tribally operated health care facilities with which we had a previous working relationship to participate in our study. The selected facilities were in different tribal communities. At each facility, the clinic director used Resource and Patient Management System Query Manager to generate a list of active clinic users (people who had obtained services at least once in the past 3 years), were aged 50 to 75, were not up to date with CRC screening per USPSTF criteria at the time the study began (had not had an FOBT or FIT in the past year, flexible sigmoidoscopy in the past 5 years combined with FOBT or FIT in the past three years, or colonoscopy in the past 10 years), had no history of CRC or total colectomy. These criteria were met by 1,288 people. Our study was approved by institutional review boards of the Centers for Disease Control and Prevention (CDC) and the 3 participating tribal health care facilities.

Study design. At each facility, study participants were randomly assigned to 1 of 3 study groups: group 1 (the control or usual care group), in which participants visited the clinic with the same frequency as they would outside study conditions and received a FIT kit only if a provider recommended one; group 2 (mailing alone), in which participants were mailed FIT kits (Polymedco OC-Light), completion instructions (in English), a letter (in English) notifying them that they were due for CRC screening, and a prestamped, pre-addressed envelope for returning their completed FIT kit; and group 3 (mailing plus outreach), in which participants were mailed the same materials as group 2 and also received telephone and/or home visit follow-up from an American Indian Community Health Representative (CHR) if they did not return the completed test (Figure 1). At 2 study facilities, we randomized 133 CRC screening-eligible participants to each of the 3 groups, and included the remaining 205 screening-eligible patients at these 2 facilities in the usual-care group (124 people at one clinic and 81 people at the other clinic) (Table). Because 1 study clinic had a smaller patient population, we randomized all 285 CRC screening-eligible people at that facility equally among the 3 study groups (95 in each group). Providers were blinded to their patients’ involvement in the study or study group. We hypothesized that the percentage of eligible persons completing FIT in each of the 2 intervention groups would be significantly higher than the percentage completing FIT in the usual care group (group 1), and that the percentage completing FIT in the mail-out plus outreach group (group 3) would be significantly higher than the percentage completing FIT in the mail-out alone group (group 2).
outreach activity. As part of their outreach, CHRs were to confirm
incorrect, CHRs were to visit that participant’s home as the initial
a participant’s telephone number was found to be disconnected or
turned the kits by the end of week 12 (Figure 1). If at first attempt
attempts to contact nonrespondents by telephone who had not re-
those who had not returned their FIT within 8 weeks, and up to 5
make up to 3 attempts to conduct a home visit to
had not returned their FIT kits within 4 weeks of the mailing;
make up to 5 attempts to contact by telephone all participants who
The outreach intervention protocol (group 3) instructed CHRs to
through November 2014.
the intervention period for all study groups was April 2014
In August 2014, we mailed a follow-up letter to nonrespondents in
velopes to participants in the intervention groups (groups 2 and 3).
(figure 32 to 296x690)
about the study. In April 2014, we mailed FIT kits, instructions for
We also informed clinic administrators and staff at each facility
were de-identified after the study intervention period, and the data
files from all 3 facilities were merged. We used SPSS 22 (IBM
Corp) software to perform Pearson χ² testing to determine signifi-
cipsize decreases (3), clinic providers were instructed to refer any parti-
cip with a positive FIT result for colonoscopy.
Results
The mean age of the 1,288 study participants was 60, half were
aged 50 to 59, and 52% were women. (Table). Overall, 12.8%
(165/1,288) returned a completed FIT kit to their clinic, and FIT
completion did not differ by sex (P = .52). The proportion who re-
turned FIT kits increased with age: 10.8% (70/648) aged 50 to 59,
13.6% (66/484) aged 60 to 69, and 18.8% (29/154) aged 70 to 75
(P = .02). Most who completed FIT kits hand delivered them to
the clinic (83.0%), whereas 16.4% used the pre-stamped, pre-
addressed envelope to return the kit by mail. Only one completed
FIT kit (0.6%) was delivered to the clinic by a CHR.
The percentage of returned FIT kits varied by study group (Figure
2). Among the participants who received usual care (group 1),
6.4% (36/566) completed their FIT kits at home and returned them
to the clinic. In group 2 (mailing alone), 16.9% (61/361) returned
the FIT kits, a significant increase over group 1 (P < .01). In group
3 (mailing plus outreach), 18.8% (68/361) returned FIT kits to the
clinic, a significant increase over group 1 (P < .01), but not group
2 (P = .44) (Figure 2). Among those who returned a FIT kit, more
women than men returned them in group 3 (50.0% vs 31.6%) and
women than men returned in group 2 (43.0% vs 31.4%) (P = .06).

Figure 1. Participant selection, randomization, and outcomes in 3 study
groups, intervention to increase colorectal cancer screening among American
Indian and Alaska Native people (N = 1,288) served by 3 tribally operated
health care clinics, April to November, 2014. Group 1, usual care, consisted of
people who either did not visit the clinic, visited the clinic and did not receive
a fecal immunochemical test (FIT) kit, or visited and received a FIT kit and
instructions to complete at home. Group 2 participants received a FIT kit and
completion instructions by mail. Group 3 participants received a mailed FIT kit
and instructions, and nonrespondents received follow-up from a tribal
community health representative after 4 weeks (by telephone), after 8 weeks
(by home visit), and after 12 weeks by telephone. Abbreviations: CHR, community
health representative; FIT, fecal immunochemical test.

Intervention design. We educated CHRs from each facility about
CRC screening recommendations and our intervention protocol.
We also informed clinic administrators and staff at each facility
about the study. In April 2014, we mailed FIT kits, instructions for
completion, an official letter from the clinic, and prestamped en-
velopes to participants in the intervention groups (groups 2 and 3).
In August 2014, we mailed a follow-up letter to nonrespondents in
groups 2 and 3 who had not yet returned kits, encouraging them to
do so. The intervention period for all study groups was April 2014
through November 2014.
The outreach intervention protocol (group 3) instructed CHRs to
make up to 5 attempts to contact by telephone all participants who
had not returned their FIT kits within 4 weeks of the mailing;
CHRs were to make up to 3 attempts to conduct a home visit to
those who had not returned their FIT within 8 weeks, and up to 5
attempts to contact nonrespondents by telephone who had not re-
turned the kits by the end of week 12 (Figure 1). If at first attempt
a participant’s telephone number was found to be disconnected or
incorrect, CHRs were to visit that participant’s home as the initial
outreach activity. As part of their outreach, CHRs were to confirm
that the participant received the mailed FIT kit (and provide an-
other FIT kit if the participant did not receive the first), discuss
the importance of CRC screening, review procedures for completing
the FIT kit, encourage the participant to complete the FIT kit, an-
swer questions, and offer to transport the completed FIT kit to the
clinic laboratory.

Data tracking procedures. We created 2 databases to track results:
1 for laboratory staff to collect patient contact information and
demographics, how and when FIT kits were disseminated and re-
turned, and test results and another for CHRs to gather patient
contact information and demographics, outreach type (telephone
call or home visit), and other outreach details. Only clinic direc-
tors (or their designees), laboratory directors, and CHRs had ac-
access to the databases.
On-site clinic laboratories processed all completed FIT kits. Labora-
tory staff recorded FIT results in the participant tracking
database and patient medical charts. Per standard operating pro-
cedures (3), clinic providers were instructed to refer any parti-
cipant with a positive FIT result for colonoscopy.

Data analysis. Both the laboratory and CHR tracking databases
were de-identified after the study intervention period, and the data
files from all 3 facilities were merged. We used SPSS 22 (IBM
Corp) software to perform Pearson χ² testing to determine signifi-
cant differences (P < .05) in FIT completion between study groups.
Among all group 3 participants, 11.4% (41/361) returned their FIT kit during the 4-week period before any CHR outreach began. After receiving a single round of CHR outreach, an additional 3.3% (12/361) returned their FIT kit. Following a second round of CHR outreach, another 4.2% (15/361) returned their FIT kit. No additional FIT kits were returned to the clinics among participants who received a third round of outreach (Figure 1). Because of delays in the implementation of the CHR intervention, varying rounds of outreach were still being conducted with participants in the months following the mailing of a reminder letter at the end of the intervention timeframe. Following the reminder letter mailing, 17 people in group 3 and 13 in group 2 returned their FIT kits. Of these 17 from group 3, 10 also received CHR outreach during that time. Overall, 51.5% (35/68) of group 3 participants who returned their FIT kits received outreach of some kind (telephone call and/or home visit) during the intervention period, including a few who received telephone call or home visit outreach even though they had already returned their FIT kit. Of the 293 participants in group 3 who did not return FIT kits, 76.8% (225/293) received outreach of some kind (telephone call and/or home visit) during the intervention period.

Of the 165 FIT kits returned, 39 had a positive result; all 39 were referred for colonoscopy, and 23 of the 39 completed the colonoscopy. Results of those colonoscopies showed that 12 participants had polyps, and 1 participant was diagnosed with CRC.

**Discussion**

Our study showed that a significant increase in CRC screening participation is possible in AI/AN communities by mailing FIT kits and instructions to eligible community members and providing easy options for returning the kits to the clinic. The addition of telephone and home visit outreach following the FIT mailing also increased screening compared with the usual care group in our study, but not significantly beyond the level attained by only mailing FIT kits. Results similar to ours were reported by Coronado et al (8), with post-intervention CRC screening rates of 26% among Hispanic patients who received mailed FOBT only and 31% in the group that received mailed FOBT plus telephone call and home visit outreach; both results were significantly higher than the 2% screened in the usual care group, but not significantly different from one another. Another study demonstrated that the addition of telephone calls to encourage screening and to address barriers did not result in increased FIT completion compared with just mailing a FIT kit with printed educational materials (13). In contrast, Walsh et al (7) reported that self-reported FOBT screening rates among Latinos and Vietnamese patients at 1-year follow up increased by 7.8% in the usual care group, 15.1% in an FOBT mailing and brochure group, and 25.1% in a mailing, brochure, and telephone counseling group. The differences were significant between usual care and each intervention and between the 2 intervention groups.

One possible reason that our study’s CHR outreach failed to significantly boost the FIT return percentage compared with mailing alone was the lack of the CHR intervention among many group 3 participants. Of those in group 3 who did not return their FIT, nearly 1 in 4 did not receive any outreach. This most likely occurred because of staff turnover during the study period and competing CHR job duties that limited the time available to implement the outreach as specified in the study protocol. In some instances, CHRs could not reach participants because of incorrect phone numbers or addresses — a common barrier to conducting community outreach. In a similar study by Jean-Jacques et al (14), 23% of participants had incorrect or nonfunctional telephone numbers. Lasser et al (15) reported that of those eligible for patient navigation, 25% could not be contacted after 8 to 11 telephone call attempts. When a tribal facility or health system chooses to use CHRs to assist with cancer screening, CHRs need to have designated time to focus on this task. Patient navigators hired in 1 facility in Alaska specifically to assist with CRC screening efforts dramatically increased the number of CRC patients’ first-degree relatives who completed screening (16). Future studies could seek to determine how much outreach is appropriate before reaching saturation. In our study, no additional FIT kits were returned after the second round of outreach.

Even though our study showed a significant increase in return of FIT kits from participants who received mailed kits compared with usual care, the percentage of mailed kits that were returned in both intervention groups combined (17.9%) was still low. Many reasons have been identified for nonresponse to a direct mailing of stool test kits, including fear of results, cost of follow-up colonoscopy.
scopy, not having received the mailed test, concerns about mailing fecal matter, and forgetfulness (17). Cultural barriers in AI/AN communities, such as medical mistrust, may also be a factor (4). Most participants in our study hand-delivered their completed FIT to the clinic instead of using the mailing envelope. Concern over mailing fecal material could be investigated further in this population. Additionally, some study participants may have had a language barrier. In our study, all written information with the FIT kit was in English. One alternative is to send out wordless instructions (eg, images/photographs) for completing the mailed FIT kit (18).

When stratified by age, our results showed that the percentage of returned FIT kits was highest at older ages. In the overall US population, CRC screening has been shown to be about 18% at age 50, increasing to 28% by age 51 (19). AI/AN people are less likely than other racial/ethnic groups to initiate screening at the recommended aged of 50 (20) and are more likely to be diagnosed with CRC at ages younger than 50, compared with non-Hispanic white people (21). Providers serving AI/AN populations need to ensure that their patients begin screening at the appropriate age and continue screening at the correct intervals, depending on their chosen method of screening and CRC risk level.

A large percentage of participants who returned FIT kits in our study (24%) had a positive FIT result. In a study by Hubbard et al (22), the risk of having a false-positive result from an FOBT was significantly greater among AI/AN than white patients. The greater risk of false-positive results among AI/AN populations could be a result of using FOBT for both symptomatic and asymptomatic patients. Any facility considering implementing population-based screening with FOBT or FIT in a population that has not been screened previously may need to prepare for a higher-than-expected proportion of positive test results and secure a facility that can perform the necessary follow-up colonoscopies.

Screening with FOBT or FIT reduces mortality from CRC only if patients with positive results undergo a follow-up colonoscopy. In our study, 41% of those with positive FIT results did not receive a follow-up colonoscopy. Several documented reasons for not completing colonoscopy are competing health concerns, failure to respond to follow-up outreach telephone calls and mailings, refusal, moving, and comorbidities that preclude safe colonoscopy (23). Others have suggested that noncompliance may be due to a combination of factors at the patient, provider, and health systems levels (24). Stock et al (25) showed that a notification sent directly to FOBT-positive screening patients increased colonoscopy uptake. A telephone call reminder, in addition to a mailed notification, may also improve the acceptance rate of colonoscopy in patients with a positive FIT (26).

Our study had several limitations. We conducted the study in 3 Southwest tribal communities, so results are not generalizable to all AI/AN populations. CHRs were unable to carry out all outreach as directed by the study protocol, compromising the comparison in FIT return between groups 2 and 3. Finally, we cannot conclude that group 3 participants who returned FIT kits after the outreach did so as a proximal result of outreach instead of the mailing itself.

The elimination of structural barriers through direct mailing of FIT kits to eligible community members is a useful, population-based approach to increase CRC screening among AI/AN people. The role of CHRs in improving CRC screening efforts could be studied further. Identifying interventions that increase the use of FOBT or FIT among AI/AN populations could have important implications for the uptake of CRC screening services and for decreased CRC mortality.

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Table

Table. Colorectal Cancer Screening Interventions in 3 Tribally Operated Health Care Centers Using the Fecal Immunochemical Test (FIT), 3 Intervention Groups, April–November 2014

| Variable | Group 1, Usual Care \(^b\)  (n = 566) | Group 2, Mailing Alone \(^c\)  (n = 361) | Group 3, Mailing + Outreach \(^d\)  (n = 361) | Total (N = 1,288) |
|----------|---------------------------------|---------------------------------|---------------------------------|-----------------|
| Center   |                                 |                                 |                                 |                 |
| 1        | 257 (45.4)                      | 133 (36.8)                      | 133 (36.8)                      | 523 (40.6)      |
| 2        | 95 (16.8)                       | 95 (26.3)                       | 95 (26.3)                       | 285 (22.1)      |
| 3        | 214 (37.8)                      | 133 (36.8)                      | 133 (36.8)                      | 480 (37.3)      |
| Age, y\(^e\) |                                 |                                 |                                 |                 |
| Mean, (standard deviation) | 60.6 (7.0)                      | 60.8 (6.8)                      | 59.8 (6.7)                      | 60.4 (6.9)      |
| 50–59    | 284 (50.3)                      | 170 (47.2)                      | 194 (53.7)                      | 648 (50.4)      |
| 60–69    | 204 (36.1)                      | 149 (41.4)                      | 131 (36.3)                      | 484 (37.6)      |
| 70–75    | 77 (13.6)                       | 41 (11.4)                       | 36 (10.0)                       | 154 (12.0)      |
| Women    | 291 (51.4)                      | 179 (49.6)                      | 200 (55.4)                      | 670 (52.0)      |

\(^a\) Values are number (percentage) unless otherwise indicated.

\(^b\) No outreach apart from provider screening advice given during clinic visits.

\(^c\) Mailing FIT kit with instructions for use.

\(^d\) Mailing FIT kit with instructions for use. If no response, follow-up telephone call after 4 weeks, follow-up home visit after 8 weeks, and telephone call after 12 weeks.

\(^e\) Values for 3 groups may not equal totals because some participants did not provide age.