Promoting Veteran-Centered Colorectal Cancer Screening (PROM-IS)

NCT02027545

Most recent IRB continuation approval: 10/30/2018

PROTOCOL AND STATISTICAL ANALYSIS PLAN

Specific Aim and Hypotheses

To evaluate the impact of a 3-part decision aid (DA) intervention of an individualized decision-aid (1), provider education (2), and modified performance measure/reminder (3) versus a pragmatic control (PC) that includes provider education and modified performance measure/reminder, but no decision aid, on the frequency of CRC screening orders in a cluster-randomized controlled trial.

H1a: Individuals in the DA group will receive screening orders less often than those in the PC group.

H1b: Individuals in the DA group will receive screening orders that are more concordant with screening benefit than those in the PC group.

Research Design and Methods

The 30-month, 3-part intervention is directed at patient-, provider-, and system-level factors. First, we provided patients with a personalized decision aid (intervention component 1 of 3) that worked to educate Veterans about the underlying reasons for screening and informed them about the risks and benefits (tailored to demographic characteristics and comorbidity burden), thereby enhancing their conceptual understanding and increasing the accuracy of their perceptions about CRC and screening. The decision aid also included a values-clarification exercise to help them clarify their personal values and preferences regarding screening. Second, we educated providers (intervention component 2 of 3) to increase their general knowledge of the underlying data on screening in elderly individuals. Individualized risk information from the decision aid was also available to providers, enhancing their knowledge of the risks and benefits of screening specific to their patients. Finally, we addressed system-level factors by modifying performance measurement and clinical reminder (performance management) systems to ease institutional pressures on providers to order screening without discussing risks and benefits (intervention component 3 of 3).

Patient Recruitment

We identified Veterans who were scheduled for a primary care visit 4 weeks from the recruitment date and met the following inclusion criteria: age 70-75 and due for CRC screening according to the 2008 USPSTF guideline (using Logical Observation Identifiers Names and Codes (LOINC) to identify FOBT in the last 12 months and Current Procedural Terminology (CPT) codes to identify colonoscopy in the last 10 years, as well as data from the clinical reminder system). The medical records of these potential participants were then manually reviewed by the research assistant to confirm eligibility. Individuals with limited life expectancy (documented electronically under “Health Factors”), or for whom the medical record indicates provider intention to not screen due to health problems, will be excluded. Veterans whose eligibility was confirmed were mailed an invitation along with a return postcard. This invitation will briefly outline the purpose and nature of the study and ask the participant to call a toll-free number and leave a message if they are not interested in participating. If no “opt out” response is received after 1 week, the Veteran was contacted via telephone by the research assistant to confirm eligibility and a desire to participate. Interested Veterans were asked to arrive at the clinic 1 hour prior to their scheduled appointment to provide informed consent, complete survey instruments, and review the decision aid materials, if primary care provider was randomized to the decision aid, or review a brief CRC screening control booklet.

Study Visit Procedure

Providers who consented to participation in the study were randomized to the intervention or control arm of the study (1:1 FTE randomization). Veterans who consented to participate were asked to complete a survey (“pre-visit survey”) on the day of the clinic visit to collect relevant baseline data. Participants then received the decision aid or control booklet (based on the randomization of their provider). Those who received the decision

aid were asked to review the materials just prior to the clinic visit, with the help of the research assistant. The participant then proceeded with the scheduled clinic visit. A second survey ("post-visit survey") was administered immediately after the clinic visit, to collect data on informed decision making and conceptual understanding of screening. Participants received a $40 gift card for participating in the study. We used manual record review of EHRs to determine whether screening was ordered at the visit (gave 2 weeks for the order to appear in patients' medical records) and whether screening was utilized at 6 months.

Research Specifications

Table 1: Design of Pragmatic Cluster-Randomized Trial

Design	Cluster-randomized controlled trial (RCT) 1:1 provider (Full Time Equivalent or FTE) randomization
Setting	VA Ann Arbor Medical Center and its largest CBOC (Toledo), both of which are under the jurisdiction of VAAAHS leadership and a single IRB.
Study Population	*Veterans aged 70-75 who meet the following criteria:* *1) Average risk for CRC* *2) Due for screening according to the 2008 USPSTF CRC screening guideline* *3) No documentation of limited life expectancy*
Veteran-Centered Intervention (VC) (3 components)	1) CRC screening decision aid 2) Provider training and education 3) Modified CRC screening performance management system a. Modified clinical reminder b. Modified performance measure c. Modified provider feedback and performance pay
Pragmatic Control (PC) (3 components)	*1) No CRC screening decision aid* *2) Provider training and education* *3) Modified CRC screening performance management system* *a. Modified clinical reminder* *b. Modified performance measure* *c. Modified provider feedback and performance pay*
Outcomes	1) Proportion of primary care clinic visits where CRC screening is ordered (H1a) 2) Benefit-concordance of screening orders (H1b) 3) Screening tests completed (utilization) (H1c)

Primary Outcome Measure

CRC screening orders (H1a): We hypothesized that Veterans randomized to the DA intervention would receive fewer screening orders than those randomized to the pragmatic control (H1a). Thus, the primary dependent variable in our analysis was whether screening was ordered at the clinic visit (dichotomous; gave 2 weeks for the order to appear in patients' medical records)). We then determined whether screening was ordered through manual record review.

Secondary Outcome Measures

Expected benefit of screening (H1b): We hypothesized that Veterans randomized to the DA intervention (who will have received individualized benefit and risk information in the decision aid) will receive screening orders that are more concordant with screening benefit than those randomized to the pragmatic control (H1b). The expected benefit of screening (reduction in CRC mortality) will be calculated using the MISCAN-Colon model. For a given patient, this value will be a function of age, gender, ethnicity, health status, and prior screening history, all of which were obtained from CDW and the pre-visit survey.

Screening utilization: We determined whether screening was utilized within 6 months of the clinic visit from CDW data using an electronic algorithm that we previously developed for a study of CRC screening overuse; utilization was confirmed through manual record review.

Data Analysis

CRC screening orders (H1a): To assess the primary outcome (CRC screening orders), we used a generalized linear mixed-effects model with logit link, using screening orders as the dependent variable. The primary independent variable was study arm. Because randomization was done at the provider level, we anticipated that patients with the same provider would show a positive intraclass correlation (ICC). The mixed-effects model will account for such clustering by including providers as random intercepts. We did not account for patient dropout since all data collection was done at the clinic visit, with the exception of ordering and completion of screening, which is collected electronically via EHR data and does not require further patient participation.

Benefit-concordance of screening orders (H1b): We examined whether the expected benefit of screening was an important factor in determining ordering of screening (H1b). This analysis followed the approach outlined above for screening orders, but we added as covariates the expected benefit of screening and an interaction term between study arm and expected benefit of screening.

Sample Size Calculation

Table 2: Sample Size Calculations
(40 providers/clusters, ICC = 0.02, power = 0.8)

Screening Orders (Control Group)	Screening Orders (Experimental/Intervention Group)	Sample Size (Total)
50%	30%	240
	35%	440
	38%	760
40%	20%	200
	25%	400
	28%	680

Preliminary data demonstrate that approximately 1,200 screen-due Veterans between 70-75 years of age with comorbid illness will present to the VA Ann Arbor Medical Center and the Toledo CBOC over a 24-month period. Assuming a 50% participation rate (based on the participation rate observed in co-investigator Sarah Hawley's ongoing VA-funded CRC screening decision aid trial, which uses a similar recruitment method), we will have the capability of enrolling 600 patients over this time period. Preliminary data show that 35% of these individuals will complete a screening test within 6 months of the clinic visit. Based on this value and prior data on screening completion rates,[101] we estimate that a screening test is ordered at approximately 50% of visits among patients who receive usual care (control event rate (CER) = 50%). Our survey data (see Preliminary Data, B.5.c) suggest that the VC intervention will reduce the CER by at least 30%, yielding an estimated experimental event rate (EER) of 35%. Study sites employ over 50 primary care providers (clusters), and we

expect that approximately 75% of these providers will choose to participate (based on an ongoing CRC screening study involving primary care providers at VAAAHS). Finally, based on preliminary data, we assumed an ICC of screening orders within provider of 0.02. Under these assumptions, a sample size of 440 patients would provide 80% power to detect a meaningful reduction in screening orders (H1a) (Table 4). Thus, with the proposed sample size of 600 patients, we will have more than 80% power to detect a meaningful difference in screening orders (H1a) between control and experimental groups (using two-tailed tests at an alpha of 0.05). We anticipate that this sample size will also be adequate to detect a difference in benefit-concordance of screening orders between study arms (H1b), since this analysis will simply require the addition of two additional terms in our regression equation.