Patient Recruitment for the Comparative Effectiveness of Fecal Immunochemical Tests vs. Colonoscopy Study

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Funded NIH: R01 CA215034

Introduction

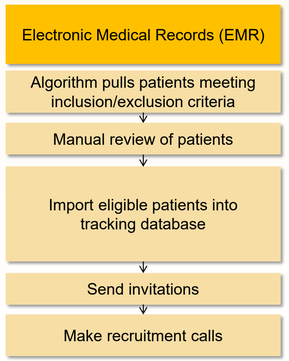
- Participant recruitment is essential for the Comparative Effectiveness of Fecal Immunochemical Tests vs. Colonoscopy study.
- Recruitment can be difficult and sometimes is the most arduous part of the research process.[1]
- Insufficient recruitment has serious consequences, such as an extended recruitment phase leading to extra cost and resources or compromise of adequate sample size.[2]
- In the parent study, patients scheduled for a colonoscopy at three sites (1,200 subjects per site) are invited to collect samples for four different fecal immunochemical tests (FIT) from one bowel movement to compare the FIT test characteristics using colonoscopy as the gold standard.

Purpose

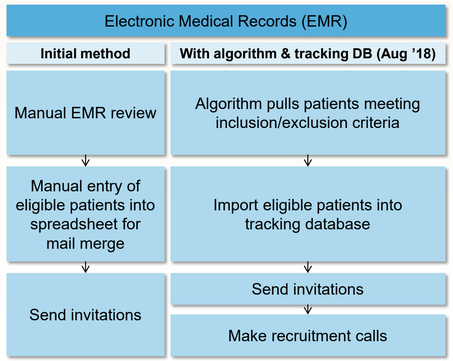
- This report describes and compares the recruitment strategies and barriers at the three sites of the Comparative Effectiveness of FITs vs. Colonoscopy study.

Methods

- Patients scheduled for a screening or surveillance colonoscopy are invited to participate at the University of Iowa (UI), University of North Carolina (UNC), and Texas Tech University Health Sciences Center (TTUHSC).
- IRB approval received at three sites.
- Inclusion criteria: age 50 to 85 years and can read and write English or Spanish.
- Exclusion criteria: iron deficiency anemia, a personal hx. of colorectal cancer, ulcerative colitis, Crohn's disease, rectal bleeding in the previous two months, familial adenomatous polyposis, hereditary non-polyposis colon cancer, or the colonoscopy being recommended for diagnostic purposes.
- **Recruitment at UI**



Recruitment at UNC



- **Recruitment at TTUHSC**: Patients presenting for the colonoscopy pre-visit at the hospital endoscopy center are approached by a research assistant. If interested, they are taken to a private room and consented.

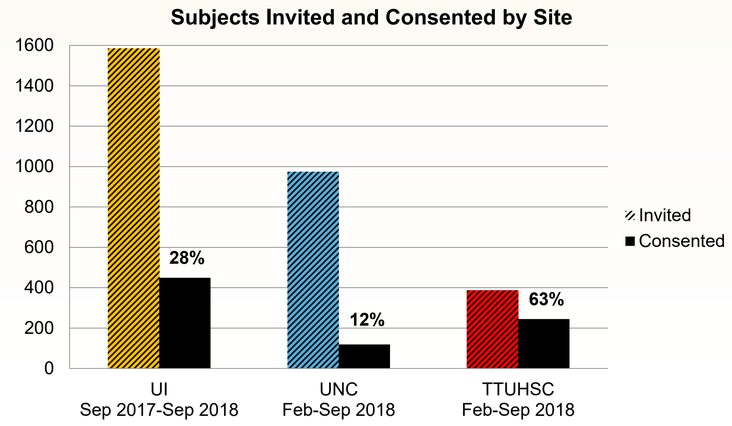
Statistical Analysis

- Descriptive statistics were calculated.
- Chi-square test of significance difference was conducted for consent by site.
- It may be premature to statistically compare sites as various extraneous factors influenced delays in recruitment such as: IRB approval, staff hiring, recruitment site approval, and negotiations for a fifth FIT.

Results

- Total of 2,944 patients invited with 813 (28%) enrolled.
- There was a significant difference in consent rate by site ($p < 0.001$).
- Mean age 62 years (age range 50 to 85 years).

Demographics of Consented Subjects	UI n (%) n=449 (55)	UNC n (%) n=119 (15)	TTUHSC n (%) n=245 (30)	Total n (%) n = 813
Gender				
Female	249 (56)	78 (66)	177 (73)	504 (62)
Race				
White	410 (91)	104 (87)	221 (90)	735 (90)
Black	14 (3)	11 (9)	10 (4)	35 (4)
Other	25 (6)	4 (3)	14 (6)	43 (5)
Ethnicity				
Hispanic	12 (3)	5 (4)	169 (69)	186 (23)
Education				
College or higher	342 (77)	90 (76)	110 (45)	542 (67)
Income				
< $40,000	113 (26)	34 (30)	167 (71)	314 (40)
≥ $40,000	319 (74)	79 (70)	69 (29)	467 (60)



Barriers

At UI
- Algorithm development in EMR took 12 months to refine and validate in the pre-award phase.
- Recruitment was limited for three months negotiating for a fifth FIT.

At UNC
- Started with manual EMR review of each subject's eligibility, then adapted Iowa's algorithm to identify potential patients.
- Difficulty hiring and retaining a research assistant resulting in follow-up recruitment telephone calls not being conducted.

At TTUHSC
- Permission for face-to-face recruitment in the endoscopy center took a few months' time.

Discussion

- At UI and UNC, patients review material and consent in their homes.
- At TTUHSC, patients scheduled for colonoscopy present at their endoscopy center for a pre-assessment visit and are recruited and consented in a private room.
- Face-to-face recruitment had the highest success rate for recruitment.
- RA time was 40 hours/week for face-to-face recruitment compared to mailed invitations and follow-up telephone calls at about 25 hours/week.
- UNC initially was doing manual review of records and mailings resulting in low percent recruitment; they have now transitioned to an electronic medical record pull which is expected to increase recruitment rate.
- Using an algorithm with inclusion/exclusion criteria enhanced speed of recruitment and may be more cost-efficient than face-to-face recruitment.
- Inclusion of multiple geographically dispersed sites has resulted in a diverse sample.

Limitations

- Delays in IRB approval hindered sites starting recruitment at the same time.
- Clinic and facility recruitment approval also hindered recruitment start time.
- Language barriers limit recruitment of Spanish speaking subjects at Iowa.

Conclusion

- For this study, both mailings and face-to-face recruitment methods worked.
- Recruitment methods for this study were adapted to each sites' settings.
- Comparison of recruitment methods by site will be possible towards the end of the study when all mechanisms are in place.
- Enrollment rates appear to be increased substantially by adding recruitment calls to the mailings.
- Face-to-face recruitment has an even higher enrollment success rate than mailed outreach, but is labor intensive.
- Recruitment is a critical component for study success.

References

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2. Thoma A, Farrokhyar F, McKnight L, Bhandari M. How to optimize patient recruitment. Can J Surg. 2010:53(3);206-210.