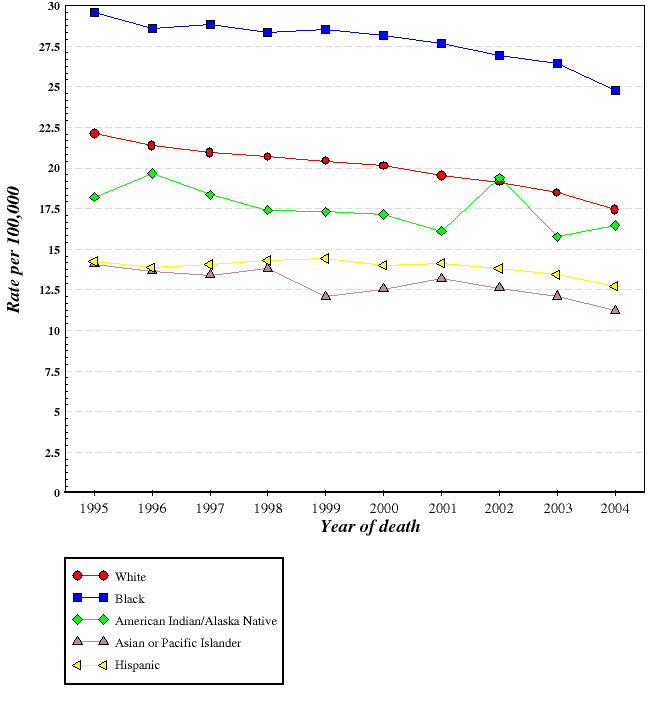
**RESEARCH PLAN:**

**Overview and background:** Approximately 2,437,163 deaths occurred in the United States in 2009 with 245,921 attributable to an underlying GI cause (10%).1 Outpatient endoscopy is an integral part of the care plan to diagnose and treat these disorders. In the last decade, endoscopic screening for detection of premalignant lesions such as colon polyps and Barrett’s esophagus has been increasing.2,3  Underserved populations have a disproportionally higher burden from gastrointestinal diseases that are commonly prevented, diagnosed or treated with endoscopy such as peptic ulcer disease due to higher prevalence of Helicobacter Pylori infection4-6  and colorectal cancer (CRC) **(Figure 1)**.7-10 Unfortunately, a high rate of non-compliance to outpatient endoscopy, particularly colonoscopy, has been reported among underserved populations especially in safety net hospitals.11-14  **Figure1: CRC death rates by race (SEER)**

Studies have suggested lower healthcare accessand utilization among blacks as compared to whites.15,16 CRC screening has been demonstrated in randomized trials to reduce mortality, 17-19 but screening rates are lower among minority populations in general even when CRC screening is a covered benefit.20-22 A high rate of non-adherence to scheduled CRC screening have been reported among blacks.12-14, 23-25 Different interventions have been attempted to improve adherence to CRC screening with varying levels of efficacy. Notification of patients by telephone reminders 26 or text message reminders,27 customized mailed brochures,25,28 and use of a study employee acting as a peer coach 24 have been shown to improve adherence by 9.7% to 17.6%. Recent studies have shown that the use of patient navigators has demonstrated some efficacies in increasing participation in cancer screening and adherence to diagnostic follow-up care after the detection of an abnormality.13, 29-33 Patient navigators are paid personnel who assist patients in overcoming logistic challenges in order to facilitate receipt of medical care. Many patient navigation programs are externally funded demonstration projects, and as such, **adoption of this strategy is not routine in most minority serving institutions due to the additional manpower cost**. Rather, patient navigators concentrate their efforts on patients with actual cancer diagnosis.

Howard University Hospital, a minority serving tertiary institution in the District of Columbia, is an example of such an institution. We have reported that the non-adherence rate for esophagogastroduodenoscopy (EGD) and colonoscopy are 18% and 22%, respectively among the predominantly black population that we serve.34-36 We noted, however, that married patients were 36% more likely to be adherent. We surmised that this may be because of the logistic challenges associated with endoscopy such as bowel preparation and the need for an escort due to the administration of conscious sedation. We examined compliance to mammography which does not require any pre-procedural preparation or conscious sedation, and found that 25% of scheduled patients were non-adherent, but that married patients were 42% more likely to be adherent when compared to non-married patients. 37 This suggests that the patient’s social support may play a role in their utilization of healthcare resources. **Therefore, we propose that active involvement of the patient’s social contact person may increase adherence and improve colonoscopy delivery to the underserved.**

**Social support and health:** Social support is defined as a network of social contacts such as family, friends, and neighbors etc who provide practical and emotional help. Social support and social networks have played, and continue to **play a substantial role in health as** **natural helpers**.38,39 Studies have suggested that social support from family members was associated with reduced smoking among youth 40 and improved quality of life among those with depression.41Although survival may not be impacted for patients with advanced cancers, 42,43 robust social support has been associated with improved quality of life (QOL) among patients with cancer. 44-50 For preventive services utilization, it has been suggested that discussions between adolescent daughters and their mothers may increase cervical cancer screening and represents a viable health promotion initiative.51 It is noteworthy that social support is mainly derived from family members,52 however, important health promotion occurred among African Americans through non-family social contacts such as cosmetologists,53 andbarbers.54,55 Social networking and personalized contact methods (including word of mouth) improved participation in fitness promotion research.56 Furthermore, favorable opinions about CRC screening occurs among African Americans with high traditional cultural orientation, less mistrust of the medical system, and who report that their primary healthcare provider is an African American physician.57 This underscores the importance of the social environment, including interactions with family, friends, and the community and the role that they may play in eliminating health disparities.58

**SIGNIFICANCE OF THE PROPOSED RESEARCH**

Eliminating health disparities is a top public health priority. While some patients do not make their appointments to schedule CRC screening test after such has been recommended by their primary care provider, others do not show up for the procedures after scheduling them. **Non-adherence after scheduling endoscopy imposes enormous burden on our limited healthcare resources with substantial negative impact on other patients who could have secured an earlier appointment, on healthcare staff with dampened morale, on care providers with reduced productivity (lower Relative Value Units (RVU) in academic institutions) and constitute loss of revenue for institutions serving the underserved population.** The proposed project seeks to determine whether involving patients’ social contact (family, friends or emergency contact person) as facilitators is acceptable to the patients and whether this intervention will improve compliance to out-patient endoscopy. If effective, **the use of a patient’s social contact person as a healthcare facilitator (similar to a patient navigator) would be a readily available and relatively inexpensive resource for all institutions since this information is typically obtained from all patients.**

**INNOVATION**

**We are not aware of any prospective study that has evaluated the use of a patient’s social contact as a facilitator to improve endoscopy delivery.** We envisage that **this approach has a potential to positively impact many dimensions of healthcare services delivery to minority populations.**

**1) Increased patient and social contact education:** Social contacts will be educated about colon cancer prevention through interaction with them as facilitators of healthcare utilization. This may even encourage the social contact to be up to date with cancer screening too.

**2) Improved patient-family communication:** Interaction with patient’s social contact who may be a family member is envisaged to improve the communication of family members on health matters. Among the minority populations, people tend not to know their family medical history. Patients also do not readily share information about their chronic diseases.59,60 Although persons with a first degree relative with CRC are at a higher risk for the disease, low rates of CRC screening has been reported among these subjects.61

**3) Readily available and relatively inexpensive intervention:** Making telephone calls to the patient’s social contact and mailing them information about CRC screening process is a relatively inexpensive intervention to provide a social support and facilitation of quality healthcare delivery to minority populations. If this intervention is found to be effective, it would not require additional manpower or additional infrastructure on the part of minority serving healthcare institutions for adoption in routine clinical use.

4) **Physician, patient and patient’s family interaction:** In the current clinical practice paradigm, the patient’s family is not involved in the care of a patient except when consent is needed to care for an incapacitated patient or when there is a poor outcome. In recent times, there have been increased efforts to get the physician to engage patient’s family at an earlier stage so as to assist and guide them in making important decisions.62 The intervention proposed in this project is a step in this direction.

**PRELIMINARY STUDIES:** We previously evaluated CRC disparity by race by examining the rate of diagnostic colonoscopy following an abnormal screening flexible sigmoidoscopy among 57,561 white and 3,011 black participants in the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO).15 We observed similar prevalence of polyps or masses during sigmoidoscopy among whites and blacks (23.9% vs 25.5%, P=0.26) at screening, but **blacks were less likely to undergo colonoscopy within one year of the abnormal screening** even after adjusting for lifestyle factors and socioeconomic status (RR=0.88; 95%CI: 0.83-0.93). Among subjects with diagnostic colonoscopies (n=10,424), blacks had comparable yield of adenoma (RR=1.01; 95%CI: 0.92-1.11), advanced adenoma (RR=1.11; 95% CI: 0.94-1.30) and CRC (RR=1.58, 95%CI=0.80-3.12) when compared with whites. **Our study was published with an editorial in the April 2010 issue of the *Journal of National Cancer Institute* and it suggests that healthcare utilization factors may be playing more of a role in CRC disparity.15** This study underscores the need to encourage healthcare utilization **63** among the underserved. These subjects fare poorly after cancer diagnosis **64** and this situation can worsen with scarcity of resources. **65**

We evaluated the factors associated with non-adherence to out-patient endoscopy in Howard University Hospital from January to August 2010. 34-36 Among 2,183 scheduled for endoscopy (18.3% EGD only), 18% were non-adherent with EGD and 22% for colonoscopy procedures. However, married patients were less likely to be non-adherent (16% vs 24.3%; RR=0.64; 95%CI: 0.48-0.87).35 Our finding mirrored the report that married couples were more likely to accept screening in the UK flexible sigmoidoscopy trial.66,67 We surmised that this may be due to the fact that endoscopy requires extensive pre-procedural logistic challenges including need for an escort, clear liquids diet the day before the procedure and extensive bowel preparation for colonoscopy. Nonetheless, we evaluated adherence to the free monthly mammography screening which takes place on Saturday mornings at Howard University Cancer Center which would not present the same logistic challenges of endoscopy. We reviewed attendance from July 2009 to June 2010. Of 460 patients scheduled, 115 (25%) were non-adherent. However, married patients were also less likely to be non-adherent (16.7% versus 29.2%; (RR=0.58; 95% CI: 0.40 – 0.84).33 These studies, taken together, suggest that marital status (as a surrogate for availability of social support) affect healthcare utilization among underserved populations.

Furthermore, we conducted a survey among 250 patients and their escorts at Howard University Hospital Ambulatory Care Center between July and August 2011. Colonoscopy and the process involved were explained to the respondents. The mean age of respondents was 53.4 years and 63% were females, 36% were married, 83% of respondents would like to be reminded about scheduled colonoscopy, 82% would agree for the care provider to contact their social contact or next of kin as a facilitator, but only 55% indicated that they would be willing to participate in such a study. When asked who will accompany them for colonoscopy if the procedure was scheduled for them, among married respondents, 64% will be accompanied by their spouse, 21% by other family members and only 15% will be accompanied by friends. For unmarried respondents, 39% will be accompanied by a friend and 58% by a family member. This suggests that most people can find a social contact to assist them in completing their colonoscopy if they are willing to get it done.

**APPROACH**

The goal of this 2-year project is to use patients’ social contacts to improve screening colonoscopy uptake among blacks. The flow through the project is depicted in **Figure 2.**

**Overview:** This project examines social contacts’ direct involvement as facilitators on health care delivery to improve outpatient endoscopy attendance and increase CRC screening with colonoscopy among blacks. The patients will provide information on their demographic characteristics and lifestyle choices by providing age, marital status (married, single, widowed, separated and divorced) personal medical history, family medical history, medication use, highest education attained, annual income, height, weight, smoking status, alcohol use, recreational drug use and previous endoscopy and CRC screening experience. They will also be asked to complete the Lubben Social Network Scale 68 This is a validated scale and it is used to assess the level of social support available to a patient. Participants will also identify two social contacts (spouse, family member, friends, neighbor etc) that they would be willing for our research team to engage to be their facilitator for the scheduled endoscopy. We will obtain consent to review their colonoscopy reports.

**Colonoscopy:** Colonoscopy involves the use of a flexible video endoscope to examine the colorectum. It is recommended that patients undergoing colonoscopy should only ingest clear liquid diet (such as apple juice, jello, broth and water) the day before their procedure to minimize further stool formation. They are required to ingest bowel laxative (such as polyethylene glycol) in 2 split doses with the first dose ingested the day before the procedure and the second dose ingested in the morning of the procedure no later than 2 hours before the start of the scheduled procedure. The procedure is typically performed under conscious sedation with intravenous administration of a narcotic and a fast acting sedative. The use of sedation mandates the need for an adult escort and patients are asked not to operate automobiles, heavy machinery or make important far-reaching decisions after the procedure because of the potential side effect of sedation which includes forgetfulness. Thus, patients take the day of procedure off from work and this can have financial implications for them. Colonoscopy is fast becoming the dominant primary CRC screening modality in the United States.2,3 It is the recommended modality for postpolypectomy surveillance 69 and it is the diagnostic procedure following an abnormal result from other screening tests.70 Furthermore, being the most invasive screening test, requiring an escort, full bowel preparation, and the need for at least one day off work to complete the screening process makes colonoscopy the modality with the most challenging logistic barrier and therefore, the ideal procedure for testing our hypothesis. However, colonoscopy has the distinct advantages that precancerous lesions seen during the procedure can be removed during the procedure and it is the endoscopic procedure that can examine the proximal part of the colon. Studies have suggested that African Americans are more prone to developing proximal CRC beyond the reach of a sigmoidoscope.71 This made the American College of Gastroenterology (ACG) to recommend colonoscopy as the preferred screening modality, particularly for African Americans.72

**Study population:** We plan to recruit competent, non-institutionalized black men and women (n=400) who are 45 years of age or older and have been scheduled screening colonoscopy from gastroenterology clinics of Howard University Hospital. Our referral base includes Howard University primary care clinics and many non-affiliated primary care clinics which serve low income populations in the District of Columbia. Most of these outside clinics are run by DC government and charity organizations and the patients are referred to us for screening colonoscopies. We perform over 3,500 out-patient colonoscopies per year. We do not have open access endoscopy in our institution in part because of our vast outside network referral. Therefore, every patient undergoes face to face consultation with a gastrointestinal endoscopist prior to scheduling. This will actually make patient recruitment for the study easier. The interval between consultation and procedure date is generally between 2 – 4 weeks. An information booklet to educate patients about their procedures with detailed information about the required preparation as well as information about their endoscopists is given to patients during consultations. It also provides instructions for patients to call the facility if they were unable to keep their appointments. All participants in this study must have access to a telephone (cell phone or land phone) and be willing to give information on two social contacts who could serve as facilitators for them. The patient will designate one of the contacts as the primary contact and the other as the alternate. We will exclude patients who were referred for colonoscopy as in-patients because their risk profile may be substantially higher. We will also exclude patients with high risk for CRC such as those with personal history of familial adenomatous polyposis syndrome (FAP), those with family history of Hereditary non-polyposis colorectal cancer syndrome (HNPCC), those with inflammatory bowel disease (Crohn’s disease or ulcerative colitis) or those with personal history of CRC. We will also exclude patients who have had bowel resection. Participation will be voluntary, and refusal to participate will not affect the clinical care of the patient.

**Intervention arm:** The participants will be randomly assigned into usual care and the intervention arms stratified on marital status, using a computer based random number generator to produce customized sets of random numbers. A research staff will use a standardized transcript to call the designated primary contact. **An excerpt is reproduced below:**

1. INTRODUCTION:

Hello, I am (NAME). I am calling from Howard University.

2. REASON WHY YOU ARE CALLING:

Mr/Ms (PATIENT’S NAME) is participating in a study which is geared towards preventing and reducing colon diseases including colon cancer among African Americans. He/She gave us your contact information that you could serve as his/her facilitator by (STATE FUNCTION OF THE SOCIAL CONTACT). I want to confirm that you will be willing to assist him/her in this regard (Wait for response).

**Social contact:** In summary, we will obtain a verbal consent to participate from the social contact. In the event that we could not reach the primary social contact after 3 attempts within 1 week of participant’s recruitment or he/she refused to participate, we will notify the participant and contact the alternate social contact instead. We will also make 3 attempts to reach that individual and secure his/her willingness to participate. If this was also unsuccessful, we will notify the participant and designate this as “no social contact”. If the social contact agrees to participate, we will inform him/her about the study using the transcript described above, explain the process involved in undergoing colonoscopy including bowel preparation, conscious sedation, need for an escort, and the potential benefits and risks. **We will not discuss the patient’s medical condition with the social contact under any circumstance.** We will inquire about the relationship between the patient and the social contact, the age of the social contact (only adults can be escorts for endoscopy), highest education attained (to determine degree of literacy since facilitators may need to assist with completing paperwork if the patient has limited reading proficiency) and whether he/she has ever had colonoscopy previously (personal experience). We will request the social contact to perform the typical tasks of a patient navigator (encourage the patient to comply with instructions for the bowel preparation, assist with paperwork, serve as an escort and arrange transportation as needed). **We will also mail information about CRC screening, and the process involved in colonoscopy to the social contact.** Both patient and social contact will also be reminded of the colonoscopy appointment 3 days before the scheduled procedure via a telephone call. Any issues, questions or concerns regarding the colonoscopy will also be addressed during this reminder call.

**Usual care arm:** Participants in the usual care arm would also receive detailed information about colonoscopy, complete the intake form and provide information about 2 social contacts, but their social contacts will not be contacted. Only the patient will be reminded of the colonoscopy appointment and any issues, questions or concerns regarding the colonoscopy will also be addressed during this reminder call as in the intervention arm.

**Research Design and Methods:** The flow of participants through the study is depicted in **Figure 2**.

**Figure 2: Schematic diagram of the proposed project**

All patients scheduled for colonoscopy

Declined participation

Patient or social contact

**AIM 1**

Social contact group

Showed up for colonoscopy **(AIM 2)**

Quality of bowel preparation **(AIM 3)**

Usual care

Included in the study

Showed up for colonoscopy **(AIM 2)**

Quality of bowel preparation **(AIM 3)**

**Aim 1:** To determine the percentage of patients willing to involve their social contacts and percentage of social contacts reached and willing to serve as facilitators.

**Aim 2:** To test the hypothesis that directly involving the patient’s social contact will be associated with a 15% increase in African American men and women showing up for their scheduled colonoscopy.

**Aim 3:** To test the hypothesis that bowel preparation ratings of good to excellent will be 15% higher among patients whose social contacts were facilitators for colonoscopy using the validated Aronchick scale.73

**Outcome assessment:** We will use the final endoscopy schedule which is typically published in the afternoon preceding the day of the procedures, and on Friday afternoons for Monday procedures. We will exclude procedures that were cancelled by the endoscopists. Therefore, our study will only focus on patients who are expected for their scheduled procedures the following endoscopy day. We will identify no shows for their scheduled procedures. These are patients who did not cancel or reschedule or notify the facility of their inability to adhere to the care plan up to 24 hours before their procedures. We will also determine the quality of bowel preparation using the validated Aronchick scale which is selected in a drop down menu format in our Endoworks ® software. This is rated as excellent, good, fair, inadequate and poor based on how clearly the colonic mucosa is seen and the percentage examined. The endoscopists will not be informed of patients’ group assignments. **Secondary outcomes will be to ascertain the prevalence of adenoma at colonoscopy and evaluate the reasons for non-compliance among participants who missed their procedures.**

**Sample size and power calculations:** AIM 1 assesses the willingness to participate in this study by the patient and social contact. Aims 2 and 3 seek to determine whether involving the social contact will increase compliance to out-patient colonoscopy and performance of high quality examinations. We defined an increased compliance of 15% and improved bowel preparation of 15% as clinically meaningful. In our facility, approximately 75% of patients have optimal bowel preparations and our preliminary data showed 78-82% compliance for scheduled endoscopy.34,35 Therefore, with compliance rate of 70%-80% and adequate bowel preparation rate of 70%-80% among usual care patients, our study has 85%-99% power to detect an absolute 15% increase in the social contact group using a two sided test and alpha error=0.05 **(Table 1)**.

**Table 1: Power calculations for AIMS 2 and 3**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| N, Usual care | n, Intervention | % compliant usual care | % compliant intervention | RR | α error | power | AIM |
| 200 | 200 | 70 | 85 | 1.21 | 5 | 93.8% | 2 & 3 |
| 200 | 200 | 75 | 90 | 1.20 | 5 | 97.1% | 2 & 3 |
| 200 | 200 | 80 | 95 | 1.19 | 5 | 99.4% | 2 & 3 |
| 150\* | 150\* | 70 | 85 | 1.21 | 5 | 84.8% | 3\* |

\*For AIM 3, we also considered if 25% of patients scheduled for colonoscopy did not show up

**Statistical analysis:** We will calculate the percentage of patients who agreed to participate in the study among those who are eligible. We will also determine the percentage, characteristics and the relationship of social contacts who agreed to participate in the study. We will compare the demographic and lifestyle characteristics of patients who showed up for their procedures to those who did not. We will use logistic regression models to evaluate demographic factors that predict the willingness to participate as a participant and as a social contact. We will compare the percentage of patients who showed up for their procedures by group assignment (intervention versus usual care). We will compare the percentage of those with optimal bowel preparation (good/excellent) at colonoscopy by group assignment and also determine and compare the interval (in days) between study enrolment/gastroenterology clinic consultation and adherence to the scheduled colonoscopy. We will use chi square test to compare categorical variables and t-test to compare continuous variables (or ranksum test if the data is not normally distributed). We will use logistic regression models to evaluate factors that are associated with compliance with colonoscopy appointments and optimal bowel preparation. **However, the main analysis will be by the group assignment (intention to treat approach) whether there was involvement of social contact in the intervention group or not.** We will also perform a per-protocol analysis and include only the participants whose social contacts were reached and agreed to participate as facilitators. Using the Lubben Social Network Scale 68 (LSNS-6 version; social support score range = 0 - 30), we will evaluate the association of the social support score (<12 vs ≥12) and as continuous data with our outcomes of interest. We will conduct exploratory analysis to evaluate the association of different demographic and lifestyle factors on our outcomes of interest and also compare the prevalence of adenoma in a secondary analysis.

**Challenges:** We anticipate some concerns on the part of patients with respect to protecting their health information. However, only the social contact person that the patient designates will be contacted and the information to be provided to this person will be restricted to the process involved in completing colonoscopy. **Medical information about the patient will not be discussed.**

**Future directions:** We will plan a multicenter community based comparative effectiveness study to compare patient navigation versus patients’ social contact versus usual care in screening colonoscopy uptake.