Specific Aims

Cancer is the number two killer of Americans, exceeded only by heart disease[1]. Within cancer, breast/prostate and colorectal are number two and number three in incidence and mortality, respectively[2]. African Americans suffer a disproportionate burden of incidence and mortality for each of these three cancers[3]. Though the causes of these cancer disparities are likely multi-factorial in nature, there are no doubt disparities in early detection[4] that contribute to the mortality disparities. Community-based approaches have been increasing in the effort to raise awareness and early detection for these cancers[5] [6]. However, more often than not, such interventions are tested in randomized controlled trials, become evidence-based, and then fail to reach further implementation in the community. The intention of these evidence-based interventions thereby never comes fully to fruition, and their potential goes underutilized. Consistent with the Dissemination and Implementation Research in Health Program Announcement (PAR-10-038), the aim of the proposed project is to identify an optimal implementation strategy using a set of evidence-based interventions that aim to increase early detection of breast, prostate, and colorectal cancer among African Americans as a model. These interventions are culturally-appropriate, and delivered in church settings through trained Community Health Advisors (CHAs). These three interventions are spiritually-based in nature, meaning that spiritual/religious themes and scripture are integrated into the core cancer early detection content. The interventions are theory-based, incorporating the Health Belief Model[7] into intervention content and efficacy assessment. They were developed with extensive community input, pilot tested, and *tested for efficacy in randomized controlled trials*, thereby making them evidence-based. That they are designed to be implemented using the CHA approach makes them easy to disseminate and implement, with little or no translation, naturally building capacity in the community setting.

These three interventions will be packaged and interwoven into a single "Cancer Early Detection Ministry" (CEDM), which will be delivered through trained CHAs in church settings. The implementation and sustainability will be evaluated using the RE-AIM Framework[8].

Fourteen local African American churches will be randomized to a high or a low community autonomy implementation strategy, in which the level of technical assistance is varied (monitoring and evaluation only vs. monitoring/evaluation plus technical assistance and training, respectively). By varying the level of technical assistance, we will be able to determine what level of technical assistance leads to successful implementation and sustainability. We will also identify church organizational capacity characteristics that lead to successful implementation and sustainability.

The specific aims of this research are to:

1. **Package** the three interventions into a single Cancer Early Detection Ministry (CEDM), **develop** a local cancer screening *and treatment* resource guide, and **pilot test** the materials and training.
2. **Implement** the CEDM in 14 churches in Prince George's County, Maryland. We will evaluate the implementation outcomes involving treatment fidelity and identify church organizational capacity characteristics that led to successful implementation. We will compare the two implementation strategies (high vs. low community autonomy) to determine the optimal level of technical assistance necessary for successful implementation.
3. Evaluate the **sustainability** of the CEDM over a two-year period of time. We will identify church organizational capacity characteristics that lead to sustainability, and compare the two implementation strategies (high vs. low community autonomy) to determine the optimal level of technical assistance for successful sustainability.

   Hypothesis: Those churches with strong organizational factors (*based on the Greenhalgh, et al., 2004) model*)[9] are expected to do well under both implementation strategies. However those with less strong organizational characteristics will do well only under the low community autonomy condition, due to the critical role of technical assistance in such environments.

Research Strategy

A. Significance

A.1 Cancer disparities impacting African Americans

This application is submitted in response to PAR-10-038 Dissemination and Implementation Research in Health. Cancer is the number two killer of American adults[1] and this is true for African Americans as well[3]. Within cancer incidence, breast and prostate cancer are number one among women and men, respectively, lung is second, and colorectal cancer is third[2]. For cancer mortality, breast and prostate are second (lung is first) and colorectal is third. These patterns also hold true for African Americans[3]. African Americans suffer a disproportionate burden of breast, prostate, and colorectal cancer[3]. There are a variety of complex reasons for these disparities, however it is clear that disparities in early detection are a contributing factor[3].

A.2 Church-based interventions for cancer control

The church has emerged as an effective community venue to reach underserved populations with health information[5 6 10 11 12]. Previous interventions have reached African Americans through the church for health promotion in a number of areas including diabetes, physical activity, smoking cessation, substance abuse, and HIV/AIDS prevention[13 5 14]. Consistent with the movement toward culturally appropriate and community-based participatory interventions[15 16 17], when working in church settings more and more interventions appear to be using a spiritually-based approach rather than using the church solely as a venue for health promotion.[18] *Spiritually-based approaches integrate religious/spiritual content and scripture into the intervention itself*[19 20]. *This appears to be at least as effective, and in some cases more effective of an approach in church settings than secular messages*[18, 20, 21]. For example, an intervention combined Bible study with cardiovascular risk messages for African Americans[22]. In another intervention for African Americans, smoking cessation content was presented through sermons on smoking, testimony in church services, and a spiritual stop-smoking booklet with a day-by-day message[23].

In our own recent research, we have employed the spiritually-based approach in three *randomized controlled trials* that focus respectively on **breast, prostate, and colorectal** cancer early detection among African Americans. This resulted in three evidence-based cancer communication interventions with several strengths. The interventions: (1) are culturally appropriate and were designed with extensive community participation and pilot testing; (2) are theory-based, using the Health Belief Model[7] in both the intervention content and in the efficacy evaluation; (3) are evidence-based, each having been *tested in randomized controlled trials* for their impact on relevant cancer communication *and behavioral* outcomes; (4) were designed for dissemination and externally valid, meaning that they will take virtually no translation to put into "real world" practice; and (5) apply a Community Health Advisor approach, which naturally builds organizational capacity.

A.3 Role of dissemination and implementation in cancer disparities

It is well-documented in cancer control and other areas, that there is a significant gap between research and practice[24]. It is not sufficient to make available evidence-based interventions and think that they will simply disseminate themselves into practice[25]. Unfortunately, the field of translational research has been hindered by confusion over and inconsistent use of terminology[26 24 27 28 29]. Consistent with the current Program Announcement and with a glossary by Rabin, and colleagues[27], we will use these terms as follows: **Diffusion** is a passive process involving the unplanned and uncontrolled spread of new interventions, and is not relevant for the proposed project. **Dissemination** is the active process of spreading evidence-based interventions to a particular audience using planned approaches. **Implementation** is the process of integrating evidence-based interventions within a setting. It is implementation in which the proposed project will focus. The term **dissemination/implementation** will be used to refer to previous literature or to the broader translational field.

Previous research has reported on what makes for effective dissemination/implementation[30]. It was found that passive techniques such as diffusional techniques were in general not effective. However active techniques that were more disseminational in nature such as train-the-trainer, media campaigns, and educating opinion leaders, were more likely to be effective, particularly when used in combination. *The current evidence base in dissemination/implementation research is scattered, and mainly focuses on provider-based interventions. More research is needed on community-based interventions.* **Peer educators** were viewed as a promising strategy that merited further study. There was a general disconnect between intervention research and approaches to disseminate the programs into the community, and an "**urgent need for more research into dissemination of effective cancer control interventions**." (p. 497). It was recommended that this research consider what would be the most appropriate study design as well as outcomes.

Glasgow and colleagues[24] concluded that efficacy trials are often so tightly controlled that the findings are not generalizable to real-world settings, and recommended that **interventions be tested on real-world participants with real-world community partners**. Interventions that involve **community stakeholders as true partners**[25], and that were **designed for implementation**[28], are more likely to be disseminated/implemented, and intervention research should be **guided by theory**.

The church-based dietary project PRAISE! was **designed with institutionalization and sustainability in mind**[31]. A comprehensive process evaluation was conducted based on **multiple data collection instruments from multiple perspectives** (e.g., Pastor, participant, health leader, county coordinator). Pastors also

completed a survey to determine **organizational capacity factors** specific to the church. **Pilot testing** of the process evaluation plan was recommended as one of the lessons learned. ***Each of these approaches, as well as the above research priorities, are incorporated into the proposed project.***

Dissemination/implementation research is called for that will determine the mechanisms underlying successful implementation of interventions, including those serving **culturally and ethnically diverse populations**[25]. Research is needed on the best ways to translate research evidence into practice, including interventions in **community settings** such as **faith-based settings** that use **community-based participatory methods**[29].

A.4 Implementation/dissemination models and the RE-AIM Framework

Dissemination/implementation research, like any other, needs to be theory-based. Typical program planning models do not address why some organizations are able to effectively implement programs and others are not. This is the role of implementation theory, which has not been articulated across content areas. [28, 32-34]. Implementation theory differs from adoption or diffusion theory because adoption involves a **decision**, often an organizational decision, while implementation involves the **actual behavior changes of implementing staff**. There can be a significant "adoption-implementation gap" ([28]p. 3). This is why the proposed study must use an implementation theory, because an adoption or diffusion theory, such as diffusion of innovations[35] does not fit. The optimal model will also have both **individual and organizational levels**, because both of these are important determinants of implementation success.

The model chosen for the proposed project is the RE-AIM Framework[8]. It was chosen because it provides a way to actually assess the dissemination/implementation strategy on multiple levels, and allows for the assessment of both individual and organizational level factors. The RE-AIM Framework provides five factors that can be used to assess the public health impact of an intervention (see Table 5 for more detail).

B. Innovation

The proposed study will begin to answer the calls for research on dissemination/implementation in several ways: (1) we will provide research on strategies on how to implement effective interventions into routine practice; (2) we will address the role of randomized controlled trials in implementation research through the ability to answer the research question of optimal level of technical assistance for successful implementation/sustainability; (3) through use of the RE-AIM Framework, we will determine what variables are important in implementation and sustainability; (4) we will begin to determine whether cancer communication interventions are as effective when they are implemented as in the original efficacy trials; and (5) we will explore the role of local (e.g., church level) barriers to effective implementation and sustainability.

Specifically, the proposed project will answer the following research questions:

1. Can a series of 3 evidence-based cancer communication interventions be successfully implemented and sustained in different African American church settings from where they were developed?
2. What is the optimal level of technical assistance needed for successful implementation and sustainability?
3. What church organizational capacity characteristics lead to successful implementation and sustainability?

In this time of uncertain resources, an effective implementation strategy will be a significant step toward the elimination of disparities in cancer early detection, which would have a significant impact on mortality in African American communities. *Such an outcome would have a significant public health impact. This is particularly the case for an approach that could have national applicability such as the proposed. As stated in the Program Announcement (PAR-10-038): "The National Institutes of Health have recognized that closing the gap between research discovery and program delivery is both a complex challenge and an absolute necessity if we are to ensure that all populations benefit from the Nation's investments in new scientific discoveries."*

C. Approach

Preliminary Studies

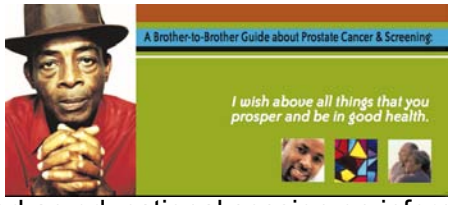
C.1 Investigative Team: We have assembled a multi-disciplinary team that is experienced in all the requisite areas to accomplish the specific aims set forth in this application: cancer communication (Holt), cancer and early detection among underserved populations (Holt; Bowie), ethnic and cultural issues associated with health promotion and disease prevention, particularly among African Americans (Holt; Bowie), intervention implementation (Holt; Atkinson; *Scheirer*), program evaluation (Atkinson; *Scheirer;* Desmond), randomized trials (Holt; Wang), and recruitment/retention of minorities and low-income populations in clinical trials (Holt; Bowie; Desmond). The studies described below illustrate our experience in these areas and show that the proposed study is a logical next step and extension of past cancer communication research.

Cheryl L. Holt, PhD (Principal Investigator) is an Associate Professor in the Department of Public and Community Health, in the School of Public Health, at the University of Maryland, College Park. She is a member of the Marlene and Stewart Greenebaum Cancer Center at the University of Maryland. Her research examines the efficacy of cancer communication interventions aimed at increasing knowledge and screening behaviors[36 21 19 37 38 18 39 40]; and the association between religiosity/spirituality and cancer-related behaviors among African Americans.[41 42 43] She has extensive experience in developing and evaluating community-based cancer communication interventions for African Americans aimed at increasing colorectal cancer screening[44 18], breast cancer awareness[21 36], and informed decision making for prostate cancer screening[37].

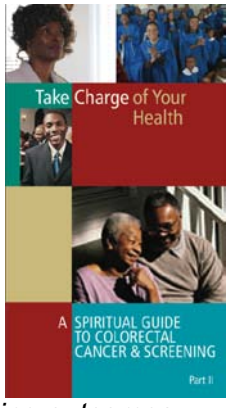
Preliminary data report: **Evidence-based interventions to be utilized in the proposed study**

Study 1. This is an NCI-funded project (CA-97741-01; Holt, Principal Investigator) in which a spiritually-based approach to breast cancer early detection education for African American women (see Appendix A) was developed and tested for communication efficacy compared to a demographically-targeted (non-spiritual) intervention[19]. Evaluation, ***through a randomized controlled trial***, was conducted through baseline, immediate, and one-month follow-up assessments. Recipients of the spiritually-based booklet perceived it as containing information that was more important to them personally (M=4.95, M=4.25, p<.05), as talking about issues more important to them (M=4.89, M=4.35, p<.05), as being more interesting (M=4.85, M=4.55, p<.05), and as more attention catching (M=4.80, M=4.50, p<.05) than the non-spiritual booklet of the same core content. Participants who received the spiritually-based booklet generated more positive (M=4.70, M=4.20, p<.05) and fewer negative (M=0.35, M=0.55, p<.05) cognitive responses than those who received the non-spiritual booklet. In addition, the spiritually-based booklet resulted in significantly more thoughts involving personal connection (p<.001), self-assessment (p<.001), and spiritually-based thoughts (p<.01), than did the secular booklet[21]. Knowledge about breast cancer and treatment from baseline to the 1-month follow up increased significantly in both groups (p<.001;p<.05), however mammography knowledge increased in the spiritually-based group only (p=.001). Both groups reported significantly fewer barriers to mammography at follow-up than at baseline (p=.001)[36].

Table 1. Pre-post outcomes both study groups combined		
Pre-post change scores	**M (SD)**	**N**
Knowledge 1 (9 items)	2.15* (1.75)	38
Knowledge 2 (4 items)	0.76* (1.05)	39
Attitude/beliefs	0.50$ (1.53)	40
Self-efficacy	1.29 (4.13)	41
Barriers	0.04 (0.61)	37
Self-efficacy IDM_PSA	0.55* (1.18)	35
Self-efficacy IDM_DRE	0.59* (1.12)	35
* = pre-post increase was significant at p < .05; $ = p < .10		



Study 2. This project was funded through the University of Alabama at Birmingham Comprehensive Cancer Center (Holt, Principal Investigator). Trained African American men served as Community Health Advisors and led an educational session on informed decision making for prostate cancer screening in church settings[38]. ***A randomized controlled trial was used to evaluate the intervention*** in a pilot sample. *A spiritually-based intervention was compared with a similar secular approach- both interventions used identical CHA-based delivery mechanisms – and both impacted recommended informed decision making outcomes (study group data are combined in Table 1).* The program was well-received by participants, and resulted in significant changes from baseline to immediate follow-up in measures of prostate cancer knowledge and self-efficacy for informed decision making about screening (see Table 1)[37].



Study 3. In this 4-year study funded by the Centers for Disease Control and Prevention (CDC), Dr. Holt (Principal Investigator) used formative research including an Advisory Panel, focus groups, and cognitive response interviewing, to develop a spiritually-based educational intervention to encourage colorectal cancer screening among urban African Americans[18]. The church-based intervention consisted of two educational sessions led by trained CHAs using targeted print materials (see Appendix A), followed by retention activities and a final 12-month follow-up survey. The spiritually-based intervention was evaluated ***using a randomized controlled trial*** (16 churches randomized to receive spiritually-based or non-spiritual intervention). ***90% of participants were retained at 12 months.*** *The spiritually-based intervention had a greater impact on increasing perceived benefits to colorectal cancer screening than the non-spiritual (p<.05). Follow-up data indicate that the spiritually-based intervention had a significant impact on a number of screening outcomes (p<.05; see Table 2).*

Table 2. Impact on screening related outcomes	***% reported yes Baseline***		***% reported yes at 1 month***		***% reported yes at 12 months***	
	Non-spiritual	***Spiritual***	***Non-spiritual***	***Spiritual***	***Non-spiritual***	***Spiritual***
Heard of fecal occult blood test	*61.7*	*58.5*	***53.7***	***70.5***	***74.9***	***80.9***
Ever had fecal occult blood test	*33.1*	*31.7*	***22.3***	***27.3***	*36.6*	*36.6*
Among only those who had ever had	*--*	*--*	***76.7***	***79.2***	***77.8***	***85.7***

FOBT at baseline						
Heard of flexible sigmoidoscopy	*40.6*	*37.2*	***42.3***	***63.4***	***64.6***	***68.9***
Ever had flexible sigmoidoscopy	*18.3*	*17.5*	***12.6***	***19.1***	*24.6*	*23.0*
Among only those who had ever had flexible sigmoidocsopy at baseline	*--*	*--*	***61.1***	***60.7***	***63.0***	***66.7***
Heard of colonoscopy	*76.6*	*69.9*	***46.3***	***67.8***	***76.0***	***81.4***
Ever had colonoscopy	*53.1*	*53.6*	***36.0***	***45.9***	*60.0*	*60.7*
Among only those who had ever had colonoscopy at baseline	*--*	*--*	***89.5***	***89.9***	***91.5***	***90.2***

RESEARCH DESIGN AND METHODS

Introduction to Methodology and Approach

Research in dissemination/implementation of health interventions has not accumulated into a clear set of recommendations for best practices. Therefore there are challenges and much is yet unknown about the optimal approach to dissemination/implementation research. The proposed methodology combines the strengths of efficacy research with the "real world" application necessary for a dissemination/implementation study. This involves a careful balance between issues of internal/external validity. *We have attempted to strike a balance, using an ecological approach of organizational and implementation variables connected to participant-level changes.*

C.2 Study setting

The proposed study will take place in Prince George's County, Maryland, the county with the highest percent racial/ethnic minorities in the State of Maryland[45] (*66.1% African American*). *Prince George's County, where 65% of residents are considered "middle class" and the median household income is $55,000[46], is actually very heterogeneous, with large sections of poverty, and a significant proportion of residents impacted by health disparities, particularly in areas of the County. The County is divided into seven public use microdata areas (PUMAs). In general, those living "inside the beltway" are African American residents of lower socioeconomic status (PUMAs 1, 3, 4 and 7) while those living "outside the beltway" tend to be primarily African American residents of higher socioeconomic status (PUMAs 2, 5 and 6)[47]. The proposed study will target the lower socioeconomic areas. For example, in PUMA 4, 27.2% of individuals live below 185% of the Federal Poverty Level[47].*

According to Maryland Cancer Registry data, Whites actually suffer a disproportionate burden of cancer incidence, however African Americans suffer a disproportionate burden of cancer mortality (see Table 3). Maryland BRFSS data indicate disparities in breast, prostate, and colorectal cancer screening data in Prince George's county, between African Americans and Whites[48]. Further, these data are self-report, which are likely to overestimate screening rates, particularly among minorities, and thus underestimate disparities[49].

Table 3. Racial/Ethnic differences in cancer data for Prince George's County

Cancer Site	Incidence White	Incidence African American	Mortality White	Mortality African American
Breast – invasive	141.5	118.4	26.9	30.7
Breast – in situ	28.6	25.5		
Prostate	170.8	256.0	*	49.5
Colorectal	57.9	56.7	23.2	32.0

Age-adjusted rates per 100,000 * = < 25 cases

	White	African American		White	African American
Ever had mammogram age 40+	90.8	88.1	**Ever had DRE**	86.7	77.7
Mammogram past 2 years age 50+	*71.0*	*0.0*	**Ever had PSA**	79.0	58.9
Last 2 years	*64.0*	*0.0*			
> 2 years ago	*27.4*	*16.1*			
Ever had FOBT	56.4	45.7	**PSA last 2 years**	69.8	46.6
Ever had endoscopy	69.8	60.8	**DRE last 2 years**	68.1	54.4

C.3 Community partners

Strong community partnerships are the foundation of the success of the proposed project (see Letters of Support). First is the Community Ministry of Prince George's County. Community Ministry is a community-based organization that has served the County for 35 years, on issues such as social justice and health.

Community Ministry is led by a volunteer Board of Directors, and works in partnership with over 400 local African American churches and community-based organizations. *Dr. Holt has worked with Community Ministry for 1.5 years, conducting church-based health promotion activities. Community Ministry serves as a significant community partner and subcontractor on Dr. Holt's current American Cancer Society project, another local church-based initiative.* The second is the Seat Pleasant/University of Maryland Health Partnership. For over 10 years the Partnership has conducted health initiatives in Prince George's County. *The Partnership has worked with many local churches and also will help facilitate the church recruitment for the project as well as help identify local resources (see Letter of Support)*. Through these two community partnerships, we expect be able to enroll 14 churches in the proposed time frame.

C.4 Intervention description

The CEDM will be based on a set of three evidence-based interventions (see Preliminary Studies) that aim to increase early detection of breast, prostate, and colorectal cancer among African Americans. These interventions are culturally-appropriate, and delivered in church settings through trained Community Health Advisors (CHAs). These three interventions are spiritually-based in nature, meaning that spiritual/religious themes and scripture are integrated into the core (cancer early detection) content. The interventions are theory-based, using the Health Belief Model[7] in the content and efficacy assessment. They were developed with extensive community input, pilot tested, and *tested for efficacy in randomized controlled trials*. That they are designed to be disseminated using the CHA approach makes them easy to disseminate and implement, naturally building capacity in the community setting.

Each intervention consists of print materials developed specifically for each project (see Appendix A), a CHA training manual (see Appendix C), CHA training materials, a powerpoint presentation for CHA delivery in the church setting, and protocols for program administration and evaluation. As such, the interventions are "manualized" and ready for dissemination. However, they need to be combined into one (e.g., one central training manual and protocol). The exception is that the breast cancer project was not delivered using CHAs, and thus the breast cancer module only will have to be developed based on our previous work. These activities will be done in Phase 1. The intervention structures were otherwise uniform across projects, and they will be synthesized into one coherent cancer early detection program (see Table 4). *As shown in Table 4, session 1 will be a split session where men and women attend prostate and breast (respectively), and sessions 2 and 3 are combined.*

Table 4. Structure of CEDM intervention*

CHA Training	**CHA Certification**	**↓ Church Members/Participants ↓**				
↑ CHAs ↑		Session 1: Men-Prostate; Women-Breast	Session 2: All-Colorectal	Session 3: All-Breast, Prostate, Colorectal	Individual-level maintenance	
Assessments ("0") ⇒		0			0	0
6 months		Month 1	Month 2	Month 3	Month 12	Month 24
⇐ Process Evaluation/Treatment Fidelity ⇒						

*Churches randomized to high and low community autonomy conditions prior to CHA training

C.5 Phase 1: Packaging/merging the three interventions into one

The project team will work with an Advisory Panel of 8 community stakeholders to merge the three interventions together. This will ensure that any decisions that need to be made will be relevant for the local population (e.g., graphics that may need to be replaced from original materials). The training manuals will be merged into one, and the breast cancer CHA training module will be developed based on procedures used to develop the prostate and colorectal modules in the other studies. Intervention protocols, such as those involving recruitment and data collection, will be merged into one, with a unified project name and logo. The Advisory Panel will meet monthly or as needed to provide advisement on the packaging/merging process, participate in project decision-making, and to discuss specific implementation strategies. For their involvement they will each receive a token of appreciation in the amount of $200.

It is not sufficient to provide education on the cancer screening guidelines without also providing intervention participants with local resources for obtaining recommended screening *and treatment*, including on a free or low cost (e.g., sliding fee scale) basis. We will develop a community cancer screening resource guide that lists the major providers in the study region, in accord with insurance coverage, or lack thereof (*see Appendix B as a previous example)*. *Information on treatment referral will also be identified*. We will compile this information for Prince George's County and provide it as part of the intervention package. *CHAs will receive this information in training so that they will be able to guide participants to appropriate local screening and*

treatment resources. CHAs will be trained to follow up with participants after screening appointments, for follow up of positive screenings.

Phase 1 will be utilized to refine our model of organizational factors related to successful implementation and sustainability [see C.13 for more detail]. We will also use this as a unique opportunity to synthesize the organizational literature on implementation and longer-term sustainability, a gap in the current literature.

C.6 Phase 1: Pilot test of the implementation strategy

During the final part of Phase 1, we will pilot test the implementation protocols and all CHA training and intervention materials for the implementation process in Phase 2. This brief period of piloting will provide an opportunity for fine-tuning the protocols/procedures and CHA training procedures, to ensure that the logistics of the three interventions have been combined and synthesized effectively. We will conduct the piloting of each study condition (high vs. low community autonomy) in one church each, that will not be included in the Phase 2 implementation work. CHAs will be recruited and trained, and will begin the intervention protocol and conduct the first educational session. Pilot churches will be able to conduct the full program on their own, having been through the full CHA training program, but will not be required to do so as part of the pilot test. They will be provided with technical assistance should they wish to complete the full CEDM. Thirty participants from each church will be recruited (enrolled and written informed consent obtained from trained study staff) to attend the pilot test first educational session. These participants will be asked to complete a one-time follow-up on-site assessment, and will be provided with a $25.00 store gift card for doing so. The pilot test assessment will be used to refine and finalize logistics in preparation for Phase 2.

C.7 Phase 2: Study design

Consistent with previous writing on implementation research[24], we maintain that a randomized controlled trial (RCT) design is not necessary for implementation research because the RCT had preceded the implementation phase and was conducted in the efficacy phase (see Preliminary Studies). However, a randomized design will allow us to answer an important implementation research question: what level of technical assistance will lead to successful implementation and sustainability? Thus, we have designed the proposed project with two conditions to which churches will be randomized. The two conditions differ on the level of technical assistance provided by the university. In the first condition (high community autonomy), the university role will involve monitoring and evaluation only. The CHAs will be trained using a train-the-trainer model where the university provides training for the CHA trainers from the community. In the second condition (low community autonomy), the university role will involve monitoring and evaluation, plus ongoing technical assistance, and feedback. CHAs will be trained by the investigative team and study staff.

C.8 Phase 2: Implementation procedure

Church Recruitment. Fourteen African American churches in Prince George's county, Maryland will be recruited through our partnerships with the University of Maryland-City of Seat Pleasant Partnership and the Community Ministry of Prince George's County (see Letters of Support). The project will be of minimal burden to churches because it will only involve 3 educational sessions and CHA involvement. We have found that projects such as this either integrate nicely with churches existing health ministry activities, or serve as a way for churches to start or to expand a modest health ministry. Churches will be selected that are relatively homogeneous in terms of denomination, such that the spiritually-based intervention would be applicable to them. This unfortunately excludes faith-based groups such as Muslims and Jewish groups, which illustrates both the strength and the limitation of any targeted intervention approach. Churches will also be somewhat homogeneous in terms of size. We have learned that working with "megachurches" (e.g., thousands of members) is often difficult due to extensive organizational layers, and a project such as this may not be able to adequately serve such a large group. Similarly, a church has to have enough "critical mass" to be able to reach enrollment targets. Each participating church will receive a token of appreciation in the amount of $500.00, to defray intervention-related costs such as space and utilities. Upon enrollment, the Principal Investigator and each church will sign a Memorandum of Understanding, which outlines roles the specific roles and responsibilities of both the university and the church. We used these recruitment procedures successfully in Preliminary Study 3, enrolling 16 churches in roughly two months.

CHA Recruitment. CHAs will be recruited as was done in the Preliminary Studies. We learned in Preliminary Study 3 that it was best to recruit two CHAs per church. In each church, the study staff will work through the Pastor or a key church volunteer or staff member, to identify potential CHAs. If possible, individuals who have health or educational experience will be approached. The potential CHAs will attend an informational session, where they will view a presentation on the role of the CHA. The CHAs will receive a $50 store gift card for completion of training, and another $50 store gift card mid-way as a retention incentive.

Suggested CHA inclusion criteria include: (a) be a member of a participating church; (b) at least 19 years of age; (c) have a working home telephone; and (d) have own transportation. We have found that the CHAs are typically the individuals who are over the church's health ministry, if the church has a health ministry. Integration with the churches' health ministries is part of what has made these interventions so successful, and why we have chosen to call the program "CEDM" (Cancer Early Detection Ministry) in this application.

CHA training. In the low community autonomy condition, the investigative team and study staff will be responsible for the CHA training. We will provide CHAs with detailed intervention manuals and didactically cover all the topics in the manual (*e.g., project overview, overview of cancer; breast, prostate, colorectal cancer; prevention/early detection; treatment; leadership/communication; ethics/confidentiality; spirituality & health; conducting the educational sessions; documentation; local screening/treatment resources; see Appendix C for example training manual*). Based on the Preliminary Studies, we expect these trainings to take place over 3 Saturdays or 6 evening sessions. Then, the CHAs will complete a written examination on the content of learned material. If they score less than 85%, individual sessions with the CHA will be conducted to address the areas of weaknesses. The CHAs will also receive training on confidentiality, HIPAA, and protection of human subjects. Following the training phase, CHAs will meet monthly with project staff to report on their activities, discuss difficulties, receive additional training, and plan future activities. We have used these procedures successfully in Preliminary Studies 2 and 3.

In the high community autonomy condition, the CHA training will be conducted using a train-the-trainer model. In this model, the investigative team and study staff will train a team of community members from Community Ministry staff (see Section C.3) to serve as the CHA trainers. This training process involves the same elements that our CHA training process involves, such as a competitive selection process, structured curriculum delivered over multiple days, and knowledge and skill testing prior to certification[50]. The trainers will undergo a selection process based on the criteria above, and will interview with the investigative team and study staff. Top candidates will be trained and certified as trainers. A team approach will be used so that if one or several of the individuals drops out for any reason, a core of trainers will remain.

C.9 Phase 2: Participant eligibility, recruitment, and baseline data collection

Three hundred and thirty eight African Americans will be recruited from 14 Prince George's County churches. Through Community Ministries and the Seat Pleasant/University of Maryland Health Partnership we have an existing relationship with a network of local churches in a health educational context, and considerable support for this project has been expressed. Following services and ministry meetings, the Pastor and CHAs from each church will give a brief introduction and express their support of the project. The CHAs will give potential participants more information about the project and answer any questions. If interested, participants will attend the initial session. In our previous experience, men and women are willing to attend such sessions particularly if there is support from church leaders such as ministers and the Deacon board. In the interest of trust and inclusiveness, all church attendees will be invited to attend all sessions. However, only men and women who meet the study eligibility criteria (African American, age 40+ for women; 45-75 for men, no history of breast, prostate, or colorectal cancer, and able to complete a self-administered questionnaire written at 5th grade reading level) will be asked to complete study questionnaires and incentivized. The age eligibility was determined by breast and prostate screening guidelines[51] (those under age 50 can skip colorectal cancer screening questions), which recommend screening beginning at age 40 for women and 45 for men (at normal risk). The upper age bound was determined by the 2008 revisions to screening guidelines for prostate and colorectal cancer[52] by the *US Preventive Services Task Force*. *While we recognize that the US Preventive Services Task Force recently recommended that only women age 50 and older receive mammography[53], these guidelines were not based on African American women, who may be susceptible to breast cancer at an earlier age than White women[54].*

With respect to literacy, estimates from the Census show that 95% of African Americans age 25 and older have attained a 5th-8th grade education or higher[55], so we do not expect literacy to significantly reduce the pool of eligible participants. If interested and eligible, participants will then read and sign the informed consent form. Recruitment of 338 participants from the 14 churches will be a challenge but one that is achievable because of the experience of the project team and the characteristics of the project. We will take the approach used in Preliminary Study 3, and only enroll churches with a pool of at least 60 or more eligible participants, so that a pool of 30-40 would likely enroll. Trained (and IRB/HIPAA certified) study staff will obtain written informed consent and enroll eligible participants, and administer the baseline surveys.

Maximizing compliance and retention rates. Participants will be told about the intervention ("A health/wellness and fellowship program") by the minister and CHAs in their church, and invited to attend a series of three sessions held at convenient times (e.g., when church members are already meeting at the church). Refreshments will be offered in each session. We have had successful participation rates in previous cancer educational sessions (See Preliminary Studies).

We gave careful consideration as to whether to offer participant incentives for participation. Incentives are common practice and were offered in the initial efficacy studies. However, in the "real world" (e.g., as in implementation) individuals are not incentivized for attending health education sessions. Though we wanted to maximize participation, we felt that a reasonable compromise would be to offer participants incentives for completion of the research assessments (being that the proposed is implementation "research"). Therefore, participants will be offered a $25 store gift card for each assessment, for an opportunity of $75.00 for completing the three assessments (baseline, 12-month, 24-month). We had the same debates regarding

incentives across the board (e.g., churches and CHAs), however we decided that in the interest of community-based research principles, it would be best to distribute incentives to all community partners.

C.10 Phase 2: Follow-up data collection

To assess the intervention efficacy and maintenance/sustainability outcomes, participants will complete a follow-up survey at the 12-month and 24-month intervals. Participants will complete the follow-up assessments, administered by trained study staff, using paper-and-pencil methods as was done at baseline. The follow-up surveys will contain efficacy assessments (see C.14) as well as implementation and sustainability assessments. Twelve months was chosen as an intermediate follow-up period consistent with screening guidelines and from our experience in Preliminary Study 3, in which we maintained a 90% retention rate. Twenty-four months was chosen as a final follow-up interval based on the sustainability interval from the RE-AIM Framework[8].

C.11 Phase 2: Implementation monitoring and evaluation

The RE-AIM Framework[8] will be used to guide the implementation evaluation. This framework provides the ability to evaluate from efficacy, through implementation, and to sustainability, using both the individual and organizational level. Outcomes will be mapped onto the RE-AIM Framework dimensions. Table 5 indicates the RE-AIM dimension, how operationalized, and the source of data.

Table 5. Application of the RE-AIM Framework to the proposed study

Dimension	How Operationalized in Proposed Study	Source of Data	Level
Reach – extent to which participants are representative of priority population; and extent to which they participated in intervention	-% of eligible congregation that enrolled in the project -Number of participants that attended educational sessions	-church enrollment logs -church attendance logs	Individual
Efficacy – success rate; positive minus negative outcomes	-Knowledge -Perceived benefits -Perceived barriers -Self-efficacy for screening -Self-report screening -Ratings of program	-participant surveys	Individual
Adoption – proportion of settings that will adopt the intervention	-Cooperation rate of churches (# agreed / total approached)	-program logs and records	Organizational
Implementation – extent to which intervention is implemented as intended in real world	-Number of training events -Number of CHA trainees -Completion of training -Adherence to program delivery protocol -Self-report of modifications or problems with program delivery -Number of booster sessions -Number and percent of survey completion -Number of educational sessions participants attended	-staff & church logs -staff & church logs -staff & church records/CHA certification -random staff observations; participant surveys -CHA quarterly interviews/surveys -staff & church records -survey completion rates -church attendance logs	Organizational
Maintenance – extent to which intervention is sustained over time	-Number of additional training cycles completed by location and year -Amount of supplemental funding for health education -Amount of marketing done for the program (flyers, announcements) -Number of collaborative meetings among CHAs (not initiated by researchers) -Number of health-related collaborative activities/events with network/partners -% of participants registering for the education	-staff & church records -CHA interviews; key informant interviews -staff observations; CHA and key informant interviews - CHA quarterly interviews/surveys -CHA interviews; key informant interviews -participant surveys	Organizational Individual

	sessions recruited by other participants -Number and % of new participants recruited from nonparticipating churches -Number and % of participants becoming certified CHAs -% of participants maintaining lifestyle practices based on educational sessions information -% of participants completing project surveys at any point in time	-participant surveys -CHA quarterly interviews/surveys -participant surveys -survey completion rates	

Source: Glasgow, Vogt, & Boles, 1999

C.12 Phase 2: Community autonomy and university involvement

Participating churches will be randomized to a high or a low community autonomy implementation strategy, in which the role of the university is varied (monitoring and evaluation only vs. monitoring/evaluation plus technical assistance and training, respectively). In the high community autonomy condition, the community will be responsible for training the CHAs (using the aforementioned train-the-trainer process), and for leading the implementation and sustainability activities. The university's role will be to conduct the evaluation activities and data collection (this is the case in both conditions). In the low community autonomy condition, the university will be responsible for training the CHAs, and the community will lead the implementation and sustainability activities, with technical assistance and support from the university. Technical assistance will take the form of activities such as meeting with the CHAs regularly to provide encouragement, feedback and troubleshooting; providing additional training in the form of "booster" sessions; and providing additional informational resources as needed. By varying the level of university involvement, we will be able to determine what level of technical assistance leads to successful implementation and sustainability. Those churches with strong organizational capacity factors (e.g., as evidenced by factors such as active health ministries, leadership endorsement, and volunteer bases) are expected to do well under both study conditions however those with less strong organizational characteristics may do well only under the low community autonomy condition, due to the role of technical assistance.

C.13 Phase 2: Church factors associated with implementation and sustainability

Consistent with the program announcement reflecting the literature in dissemination/implementation research, it will be tremendously important to identify church organizational capacity characteristics that are associated with successful intervention implementation and sustainability. *The organizational theory and literature in dissemination/implementation research focuses mainly on health care organizations. Therefore, we have a unique opportunity to adapt/develop an organizational model for the proposed community-based (e.g., church) settings. We have not been able to identify an organizational factors model specific to such community settings. We recognize that this will present an outstanding opportunity to contribute to the implementation literature and may also require reasonable flexibility and prudent adaptation of the proposed model.* Using the *Greenhalgh, et al.[9] model as a guide, as well as other models of implementation factors,[32, 34, 56, 57] we will, in the Phase 1 work [C.5], map on relevant church factors to examine their relationship, if any, to successful implementation (e.g., treatment fidelity) and sustainability. Because a review of the literature in church-based interventions revealed no suitable instrument to assess these factors, an instrument will be compiled based on those previously used to assess church and congregational characteristics that may be associated with successful implementation and sustainability.[58 59 60 61], and using the Greenhalgh, et al.[9] model as a guide.* A draft tool is shown in Appendix D. The tool will be administered at church enrollment by the study staff as an interview, to be conducted with the Pastor or a Pastor's delegate.

C.14 Study assessments

A strength of the assessment approach is that data will be collected at multiple timepoints from multiple perspectives[31]. Additional information on study assessments is discussed in Table 5 (*Appendix E for draft)*.

Individual Level – Participant Measures *(examples below reflect one cancer site each construct)*

Knowledge (colorectal cancer) will be assessed using an established and validated instrument previously used with African Americans[62]. The knowledge survey consists of 16 true/false items and internal reliability was acceptable in the previous sample (HR-20 = .81). Example items include "Colorectal cancer screening is not necessary if there are no symptoms" and "Risk of colorectal cancer is greater as a person gets older."

Perceived benefits of screening (breast cancer) will be assessed using 5 items based on previous research[63 64 65 66]. They will be measured in yes/no/not sure response format to assess participants' perception of whether: mammograms find all breast cancers; and a mammogram could find a breast lump before it is big enough to feel. Test-retest reliability for these items was acceptable, $r = .62$, $p < .001$ in previous work[39].

Perceived barriers to screening (breast cancer) will be assessed with 8 items from Preliminary Study 1 and based on previous research[63 64 65 66], for example being too busy to get a mammogram, lacking transportation,

or associating mammography with pain. These items will use a yes/no/not sure response format, and test-retest reliability for these items was acceptable, r = .70, p < .01 in previous work[39].

Self-efficacy for screening will be assessed using a 4-item (colorectal cancer) scale pretested and used in previous research with this priority population, used in Preliminary Study 3. The items are measured in 5-point Likert-type format, and the scale has sufficient internal reliability (α = .74 - .86) in previous work.

Self-report screening will be assessed as was done in Preliminary Study 3. In separate items, the screening tests will be defined, and the participant will be asked if they have ever had the test (yes/no/not sure). If the participant had had the test, they will be asked to indicate when they had it (month, year). They will also be asked how many times they have had each test and when.

CHA – Level Measures

Key characteristics of CHA's, including but not limited to prior experience with health promotion, teaching experience, and leadership experience, will be assessed, as well as their fidelity of implementation. CHAs will complete interviews, quarterly surveys, and will be observed periodically by study staff (Table 5; Appendix F).

Organizational Level Measures

Church organizational capacity characteristics associated with successful implementation/sustainability are discussed in Section C.13. No validated instrument assessing congregational factors, or those associated with successful implementation/sustainability in this setting could be found in the literature. However, we compiled an array of promising factors *using the Greenhalgh, et al.[9] model* as a guide. *Areas of the model will be assessed using the church survey (see draft, Appendix D,* subject to amendment from Advisory Panel*).* Factors including but not limited to *Pastor endorsement, size and resources of the church, and prior history of health-related work* will be assessed.

C.15 Phase 3: Sustainability monitoring and evaluation

The RE-AIM Framework[8] will be used to guide the sustainability evaluation. Outcomes will be mapped onto the RE-AIM Framework dimensions (see Table 5). The sustainability phase of the project will be monitored by project staff to determine if activities are being executed according to the plan that involves CHAs, participants, churches and the university. The assessment of sustainability will take an approach customized to each church. This is because each church will likely not take the same approach to sustaining the program, based on their different strengths and capacities. For example, Congregation A may choose to hold an annual series of three cancer early detection educational sessions just like the original three sessions on breast, prostate, and colorectal cancer. Congregation B may choose to hold an annual health fair.

Finally, we will have an opportunity to disseminate the current interventions and protocols to the wider faith-based community. Community Ministry offers its relationship with a wide network of churches across the region using an internet-based system to disseminate the CEDM to other African American churches and other interested parties. Community Ministry's website was renovated and launched in September 2009 as www.cmpgc.com. In October 2009, the first month after launch, the website had 7,291 hits, 668 visits, and 2,580 page views. By April 2010, the site had 14,314 hits, 3,563 visits and 6,387 page views. All project materials, manuals, and protocols will be available and downloadable, and program contacts provided.

Strategies used to establish feasibility

Feasibility is anticipated due primarily to the team's previous significant success in recruitment and retention of African American churches, CHAs, and participants into randomized controlled intervention trials. For example, in Preliminary Study 3, we recruited 16 churches in two months, and retained 90% of participants over a 12 month period. In addition, the commitment of our local community partners will help ensure success of the proposed project. Importantly, we have been working closely with our local partners (e.g., Community Ministry, local churches) in the development of the proposed project.

C.16 Statistical analyses

A three-level hierarchical linear model will assess the effects of the community autonomy condition on the outcomes of cancer knowledge and perceived barriers to screening (efficacy outcomes used in Preliminary Studies). The condition of community autonomy will be randomly assigned to churches into high and low community autonomy groups. Age, education and income will be used as covariates in the model to control the demographic effects on the outcomes.

The first-level units in the model are longitudinal measures of participants' cancer knowledge and perceived barriers to screening, assessed at baseline, 12 months, and 24 months. The second-level units are participants residing in the 14 churches that comprise the third-level units in the model. Age, education, and income measured at baseline will be used as time-invariant covariates modeled as the second-level units, together with the intervention effect that will be a dichotomous variable indicating the treatment condition.

To examine the hypothesis that those churches with strong organizational factors (e.g., as evidenced by factors such as active health ministries, leadership endorsement, and volunteer bases) are expected to do well under both implementation strategies, in contrast to those with less strong organizational characteristics that are expected to do well only under the low community autonomy condition, due to the critical role of technical

assistance in such environments, we will test the coefficients. Significant coefficients for church programs and leadership will show that these variables are related to the changes in the outcomes over time, regardless of intervention condition.

A similar three-level hierarchical linear model will evaluate whether churches with weaker organizational factors will do well only under technical assistance. Both church characteristics and technical assistance will be third-level variables, and interaction terms of church characteristics and technical assistance will be evaluated as interaction effects. A significant product term will show whether churches with vs. those without technical assistance show different results for the effects of church characteristics on longitudinal outcomes.

C.17 Statistical power of the sample size

Implementation of a statistical model requires determination of appropriate sample size so that sufficient statistical power can be obtained. There are four factors that determine statistical power: statistical test, alpha level, sample size, and effect size[67]. The effect size is the most complicated factor among these four factors. While the effect size is a population parameter, in practice, it may be estimated from sample data.

The formula for the effect size (ES) for two independent samples is: $(\mu_1 - \mu_2) / \sigma$

where μ is mean of measurement. The subscripts 1 and 2 represent the group 1 and group 2, respectively. σ is the common standard deviation.

We selected one representative variable from the primary outcomes and the secondary outcomes. The ES of each dependent variable is estimated from Preliminary Study 3.

The ES of the primary outcome (colorectal cancer knowledge scale) = [(7.51-9.18)–(9.54-8.90)] / [(6.62+6.14)/2] = 0.36

The ES of the secondary outcome (perceived benefits of screening scale) = [(3.52-5.33)–(4.90-5.30)] / [(3.93+3.80)/2] = 0.37

Based on the computed effect size, the sample size of 130 per group (a total sample of 260) will be needed to achieve a minimum of 80% statistical power based on the alpha level of .05 and one-tailed[67], (power chart, page 91). Building in for attrition (see below, section C.19) we anticipate the need to recruit a total of 338 participants at baseline. These calculations are derived from our preliminary data, and are consistent with or exceeded those from previous research in church-based health interventions ([5, 18, 22, 23]).

C.18 Attrition

Based on our previous work, we conservatively expect a 30% attrition rate over a 24-month period. This is based on roughly 15% for each of two years.

C.19 Qualitative data analysis

To examine the data from the key informant and CHA interviews, an inductive process will be used, employing an open coding method. Drs. Holt and Atkinson are experienced in qualitative data analysis, and will independently review all field notes for themes and patterns. A discussion will then take place, and a preliminary list of themes (codes) will be developed, defining each theme, criteria for inclusion and exclusion, and sample representative passages. Two coders (Drs. Holt & Atkinson) will be trained in the codebook using 1 or 2 interviews, and then codes will be applied independently. Discrepancies will be resolved through discussion in a process of constant comparison[68]. Inter-rater reliability will be calculated for each code through use of an intra-class correlation coefficient, and will be deemed acceptable if the coefficient is in the .80 range[69]. Patterns of code usage will be examined for each code, to draw conclusions about factors that contributed to successful and less successful implementation. Member checking will be done to increase the validity of the conclusions drawn from the data. After the initial coding process, participants will be provided with the codings and alongside the field notes to make sure the codes correspond to the participants' meanings[70]. *When the qualitative codings yield clearly defined variables describing differences among the 14 churches, these variables may be included as categorical variables in the statistical modeling described above.*

C.20 Data management

The hard copy data (excluding identifiers) will be entered into a database by one staff member and then entered again by another staff member for 100% quality check, where the entries are compared against each other and discrepancies resolved through comparison with the original hard copy form. The data will then be examined using a cleaning protocol that uses a system of checks and balances for each variable, conducting range checks, edit checks, and skip pattern checks. Each participant will be assigned a four-digit identification number at baseline, and this number will be used to track their data. Participants will put their name only on a cover page, that will be separated from the remainder of their questionnaire upon data entry, to enable their data to be tracked across follow-up assessments.

C.21 Potential problems alternative strategies

Our previous interventions have been tremendously well-received in the communities in which they were previously implemented, so well such that we receive continued requests for subsequent projects and requests

from non-participating churches to house the interventions in their church. However, because the original interventions were developed in a Southeastern context, it is possible that they may not transport seamlessly to the Mid Atlantic region. The interventions were developed for a general African American church-attending population, which may reduce this risk, and may require some minor modifications in the packaging (Phase 1) and pilot testing phase. The Advisory Panel will also be able to advise us if there is anything particularly unsuitable in the content or approach. *Second, although the researchers' random observations of the CHAs might introduce some reactivity, any such effect would be equal across study groups. In our previous research, study staff were very welcome attending CHA sessions and viewed as partners. The potential problem that might arise is that unobserved sessions may not be fully implemented, however we will have an opportunity to detect this through triangulation of data (e.g., participant surveys, key informant interviews).*

C.22 Project management and timeline and benchmarks in achieving study aims

In her role as Principal Investigator, Dr. Holt will provide oversight and scientific leadership to the team, working closely with Dr. Bowie. The Project Manager (Dr. Brathwaite) will be responsible for working with the Project Coordinator to manage the day-to-day activities of the project. Dr. Desmond will serve as a liaison to the community, which will be critical in Phase 1 activities, through her 10-year history with the Seat Pleasant Health Partnership. Drs. Atkinson and Brathwaite will play leadership roles in the implementation and sustainability evaluations, respectively. Housed in Community Ministry of Prince George's County, the Project Coordinators will play a lead role in the CHA training activities. Our Doctoral Fellow, Ms. Debnam, will assist with and receive meaningful training experiences throughout all phases of the project. Study major activities and timeline are shown in Table 6. Benchmarks include successful piloting of the merged intervention (Aim 1), successful implementation of the interventions (Aim 2), and evidence of sustainability (Aim 3).

Table 6. Study major activities and timeline

Activity	Year 1		Year 2		Year 3		Year 4		Year 5	
Phase 1: Packaging										
Merge three interventions into one										
Develop screening resource guide										
Pilot test implementation strategy										
Phase 2: Implementation										
Church relationship building/maintenance & recruitment										
CHA training										
Implementation										
Evaluate implementation										
Phase 3: Sustainability										
Evaluate sustainability										
Further dissemination activities										

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