SUPPORTING STATEMENT

Part A

Health Care Systems for Tracking Colorectal Cancer Screening Tests

Version: *October 28, 2008*

Agency of Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see Attachment A), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. research that develops and presents scientific evidence regarding all aspects of health care; and

2. the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

3. initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

The proposed population-based study, Health Care Systems for Tracking Colorectal Cancer Screening Tests (contract number: HHSA290200600014, task order #1; task order number: 290-06-0014-1) is a population-based case study designed to assess whether, to what extent, and how easily a health system redesign intervention previously shown to improve screening rates and rates of diagnostic follow up for positive screens can be transferred to another clinical setting and achieve similar rate improvements. The intervention is based on two prior studies conducted by project staff at Thomas Jefferson University (Myers 2007, Myers 2001, Myers 2004). Components of these prior studies were previously shown to improve colorectal cancer (CRC) screening rates in a large urban academic practice, and to improve rates of diagnostic follow up for positive screens in practices affiliated with a large, for-profit managed care organization. This proposed study will examine if and how well the intervention can be transferred to a network of community-based practices and achieve similar rate improvements for both CRC screening and follow up in a setting distinct from the previous studies.

The study's intervention has the following features:

- It is a redesign of a health care system process intended to assist ambulatory primary care practices affiliated with the system to better provide population-based preventive health care. A health care system is any entity that owns, operates, and/or contracts with a network of providers of health care (e.g., hospitals or physicians) and provides one or more support services (e.g., management, business, or financial services) to that network. Health care systems can be integrated delivery networks of hospitals

and physicians, insurance companies or contracting mechanisms and the providers with which they contract, or loosely affiliated associations of providers with some joint processes and contracts. The health system for this study is the Lehigh Valley Physician Hospital Organization (LVPHO). LVPHO is an affiliation of Lehigh Valley Hospital and physician practices located in the Lehigh Valley of Pennsylvania. Through it, the hospital provides various business and management services for many of these practices and offers health insurance products to local employers for covering health care costs provided by PHO members and other providers.

- It will assist practices to provide population-based colorectal cancer preventive health services based on recently issued recommendations and guidelines of the American Cancer Society and the U.S. Preventive Services Task Force. It will seek to educate clinical providers and staff at intervention practices about the recommended CRC screening and follow up procedures, as well as to educate – on behalf of these practices – their patients regarding CRC screening.
- It will also provide a mechanism for facilitating CRC screening tests, monitoring test results, informing providers of the results, and facilitating appropriate follow up through feedback to providers.
- It will provide information and "lessons learned" that other health care systems interested in increasing CRC screening and follow up rates may find valuable.

Some other goals of the intervention include: (1) achieving a high level of satisfaction with the intervention among patients, clinicians, and practice staff, (2) promoting patient-centered care through the intervention, and (3) demonstrating economic and business benefits of implementing the intervention.

This research is sponsored by AHRQ. The Centers for Disease Control and Prevention (CDC) also has in interest in this study, as it is providing funding to AHRQ through an interagency agreement. As such, in addition to an AHRQ Task Order Officer, the project is being supervised by two technical advisors from CDC (Dr. Lisa Richardson and Dr. Brooke Steele). The technical advisors review all project material, approve all project status reports, and vet all data collection plans and instruments. This project is also designed to fit within the context of and complement other work being done within the Department of Health and Human Services (DHHS) including at the National Cancer Institute (NCI) (e.g. Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO), at CDC, and through the US Preventive Services Task Force, among others.

The study will be conducted for AHRQ by The CNA Corporation (CNA) and its partners Thomas Jefferson University (TJU) and Lehigh Valley Hospital (LVH) through the Lehigh Valley Physician Hospital Organization (LVPHO). The LVPHO is a joint venture between Lehigh Valley Hospital and the Greater Lehigh Valley Independent Physicians Association. Lehigh Valley Hospital is the region's largest hospital system, primarily serving the two Pennsylvania counties that surround the Lehigh River Valley (Lehigh and Northampton). The population served by LVH is comprised of 620,425 people, of whom approximately 177,078 (28.5 percent) are aged 50-79, the intended screening population for the CRC screening intervention. Data provided by the LVPHO, based on Medstat Demographics expert, indicate that 3.6 percent of the area's population was non-Hispanic Black or African American, 2.3 percent was Asian, and 11.0 percent was Hispanic or Latino. The fastest growing segments of the population are Hispanic and Asian according to figures cited by the Lehigh Valley Economic Development Corporation and supported the Medstat data.

The LVPHO network of primary care practices was selected based on a number of considerations. It is a network consisting of a good mix of types of primary care practices, and it is supportive of practice based research. The LVPHO network of primary care practices differs significantly from the sites where components of the CRC screening intervention were previously tested. The original site for the test of the screening intervention was a large, urban, university-based practice. The original site for the test of the follow up intervention was a geographically dispersed group of practices that each provided care for patients insured by a large for-profit Health Maintenance Organization. The LVPHO site is a network of smaller, less urban, more geographically compact community-based practices serving the Lehigh Valley and joining together with the Lehigh Valley Hospital to offer an insurance product to local employers. Many of the LVPHO practices are also part of three other large entities: (1) Medical Associates of The Lehigh Valley (MATLV, a large, private group association), (2) Lehigh Valley Physicians Group (LVPG, hospital-owned practices), and (3) Lehigh Valley Hospital (which operates residency-staffed primary care clinics that help meet the needs of the uninsured and underinsured in the region).

AHRQ seeks approval for the following information collections:

(1) Electronic patient records review (Attachment C7);
(2) A Screening Eligibility Assessment (SEA) form (Attachment C1);
(3) Focus groups of providers and staff at 20 intervention and five control primary care practices to be recruited for this study (Attachment C2);
(4) Brief informal interviews with selected providers and staff at each practice (Attachment C3);
(5) A survey of all clinicians and staff at each practice (Attachment C4);
(6) Patient chart audits at intervention and control practices (Attachment C5); and
(7) Patient focus groups (Attachment C6).

The data will be collected to obtain the following types of information needed for determining patient eligibility for the intervention and for conducting an assessment of the intervention: (a) patient's screening history and eligibility information; (b) patient demographics; (c) patient, provider, and practice staff satisfaction with the intervention; (d) provider and staff knowledge of attitudes regarding colorectal cancer screening; practice procedures and systems for colorectal cancer screening and tracking results; and (e) patient-perceived barriers and facilitators for following screening and follow-up recommendations.

The study's intervention will consist of identifying and then inviting and assisting eligible patients of intervention practices to be screened for CRC, providing academic detailing to intervention practice providers regarding CRC screening and appropriate follow-up for positive screens, and assisting providers to identify and follow up with their patients who have positive screens.

LVPHO will recruit 25 primary care practices (family medicine and general internal medicine) from among the 111 such practices in the PHO. Note that this is a purposive recruitment process rather than a sampling process, and practices must consent to participate. These practices will be recruited to assure adequate representation of the following attributes: (a) size (smaller practices with 1-3 clinicians and larger practices with more than 3 clinicians); (b) affiliation or ownership (MATLV practices, LVPG practices, LVH hospital-operated residency clinics, practices using PBS management services, and independent practices); (c) specialty (family medicine and general internal medicine), and (d) location within the Lehigh Valley area (urban, rural, suburban). The study will then randomly assign 20 of the recruited practices to the intervention group (which will

all receive the intervention) and 5 practices to the control group (which will not receive the intervention and will be used as a comparison to screening and follow up results in the intervention group).

The intent is to recruit practices in such a way as to achieve a mix of practices across each of the attributes rather than to achieve a stratified sample with sufficient statistical power to detect differences. The project's focus on gaining insights and lessons learned regarding the process of adopting and implementing the intervention guided the decision to have many more intervention practice sites (20) than control sites (5). Screening rates and rates of diagnostic follow up of positive screens will be compared between patients of intervention practices as a group vs patients of control practices as a group. Statistically rigorous comparisons will not be made to attribute differences in rates based on stratification variables. Qualitative analysis will be performed to gain insights into how, how well, and how easily different types of practices incorporated the system redesign intervention and improved their screening behavior.

For a practice to be eligible to participate, it must be: (1) located in Lehigh or Northampton county, (2) a family medicine or general internal medicine practice, and (3) a member of the LVPHO. Practices will be recruited by LVPHO system personnel, and all practices will voluntary consent to participate in the study. LVPHO will serve as the source for all participating practices, clinicians, and patients. When a practice agrees to participate in the study it is also giving general consent for the entire practice, including its clinicians and their patients. The intervention practices will involve their patients in the study intervention as part of normal clinical care based on recommended screening guidelines. Patients will also have the option to opt-out of the study through the SEA form.

Patients in the control practices will be identified by an electronic records review. Control practices or patients will not receive any components of the study's intervention, as this group will serve as the comparison group with which the intervention group's screening and follow up rates and screening behaviors will be compared. Eligible patients in the intervention practices will be identified through a two step process: (1) an electronic records review to identify potentially eligible patients; and (2) a Screening Eligibility Assessment (SEA) form (a component of the intervention) mailed by LVPHO on behalf of the participating intervention practices to allow potentially eligible patients to verify their eligibility. The SEA will also ask patients to provide selected additional demographic and perceived health status information. A screening eligibility letter will also be sent along with the SEA form (Attachment D1). Patients will also have the opportunity to opt out of the study on the SEA form. As this population-based study is a public health outreach intervention, it will proactively mail intervention materials to patients rather than distribute these materials to them only when they have an office visit with their health care providers. It is thus necessary to have the complete mailing addresses of patients. Thus, patients for whom this information is missing or incorrect in the available electronic records will not be eligible for the intervention. Study personnel estimate that less than 2 percent of patients will have missing mailing addresses. Patients with incorrect or out-of-date mailing information in the electronic records will not be excluded from the initial mail-out, but will be effectively excluded from the intervention by not receiving the mailed material (unless they have in-date forwarding information on file with the USPS).

The electronic records review will establish initial eligibility by identifying patients who: (1) are between the ages of 50-79, (2) visited the practice within the past two years, (3) have complete mailing address information on file, (4) have no electronic evidence of personal history of CRC or colorectal polyps or inflammatory bowel disease, (5) no electronic evidence of family history of CRC diagnoses before age 60, and (6) have no electronic evidence of recent CRC screening

tests. All patients in the intervention practices who are identified as being potentially eligible by the electronic records review will be sent an SEA form that asks them to verify their eligibility and provide additional demographic information about themselves not otherwise ascertainable through the available electronic records. Patients in the control practices will not be sent an SEA form, as the SEA form is a component of the intervention and the study does not want to introduce such a component to the control group, which may stimulate a portion of this population to be screened, a population that otherwise would not have sought screening due to normal activity of their practice. While the SEA form will collect valuable additional patient demographic information, the risk of having the control group exposed to a component of the intervention and perhaps influencing their normal activity outweighs the benefit of having this additional demographic information.

All potentially eligible intervention group patients who either (a) do not identify themselves as ineligible on the SEA form, (b) opt out on the SEA form, or (c) do not return an SEA form will be included in the intervention. Patients who do not return an SEA form will still be included in the intervention, as the SEA form is an opt-*out* form as opposed to an opt-in to allow the study to include as many eligible patients to participate as possible. As this is a population-based study, only patients known to be ineligible for CRC screening due to clinical or family history or having already had a recent screening will be excluded from the denominator of the screening and follow up rates. The denominator will include those who opt out because they will not be known to be ineligible. The intervention is based on current recommendations and guidelines for CRC screening for patients at average risk for colorectal cancer. Patients who are identified through either the electronic records review or the SEA form as being above average-risk because they have a family history of CRC diagnoses before age 60, have been previously positively screened, or have a personal history of colorectal polyps or inflammatory bowel disease will be excluded from the intervention because the guidelines do not pertain to them or because CRC testing for them represents continuing follow up care rather than screening. Patients who have been previously diagnosed with CRC also will be excluded because CRC testing for them is continuing follow up care.

As previously noted, many of the LVPHO practices are also part of three other large entities: (1) Medical Associates of The Lehigh Valley (MATLV, a large, private group association), (2) Lehigh Valley Physicians Group (LVPG, which staffs hospital-owned practices), and (3) Lehigh Valley Hospital (which operates residency-staffed primary care clinics that help meet the needs of the uninsured and underinsured in the region). Various sources of the electronic data required for this study reside within the PHO (for all participating practices) and within each of these three other entities (for those participating practices affiliated with these entities). The required electronic data will be collected centrally by staff within each of these four entities (LVPHO, MATLV, LVPG, and LVH) rather than by staffs at each of the practices affiliated with them. The electronic records review will include (a) claims submitted for payment by providers to LVPHO for health care provided to patients insured through an LVPHO insurance product regardless of whether the provider is a member of the PHO, (b) bills for health care provided by LVPHO providers for patients not covered by an LVPHO insurance product, and – where they are available – (c) patient electronic medical records. Acting in a HIPAA-compliant manner, LVPHO study personnel will then merge each entities' data to develop a central database for this study, which will contain information on all intervention practice patients identified as potentially eligible for the intervention. The database will also include information on all patients in the control practices who meet the same eligibility criteria.

Study personnel affiliated with LVPHO will then mail the CRC screening intervention material to all eligible intervention group patients who did not identify themselves as ineligible or opt out

through the SEA form. This material, mailed out by the PHO on behalf of the primary care providers in the participating practices, will include a letter signed by all of the providers at the practice attended by each intervention patient inviting/recommending the patient to be screened for colorectal cancer (Attachment D2). As such, the recommendation/invitation does not come directly from the provider and is not noted in the patient record by the provider. The intervention material also includes: (1) a brochure that describes the benefits of CRC screening and the alternative screening modalities that are consistent with 2008 American Cancer Society and U.S. Preventive Services Task Force guidelines, (2) a stool test kit with a return envelope for those patients who want to use that screening modality, and (3) a list of colonoscopists that the practice refers patients to for those patients who prefer colonoscopy to a stool test. In addition to the list of colonoscopists, the accompanying letter from the practice will also include wording to make sure patients are aware that they can select other colonoscopists who may not be on the list. These kits include use and return instructions in English and Spanish and a pre-addressed return envelop for sending the tests to the clinical lab used by the study for processing the tests. The laboratory will provide LVPHO system personnel information regarding who returned the kits and the test results. The study does not expect patients to use either stool test kits supplied to them from sources outside of the study or a different lab to process their stool tests. As this invitation mailing is part of normal recommended clinical practice and requires no response on the part of the patient other than participating in the clinically recommended screening, it is not considered to be a data collection.

In addition to information supplied by the participating clinical lab, information provided by subsequent electronic records review will be tracked by LVPHO system personnel for evidence of screening. Patients with no evidence of screening within approximately six weeks after receipt of the invitation letter will be sent a reminder letter by study personnel on behalf of the patient's physician's practice (Attachment D3). As with the invitation mailing, this reminder mailing is part of normal recommended clinical practice and requires no response on the part of the patient other than participating in the clinically recommended screening, and is not considered to be a data collection. Colonoscopy screening claims for patients who are insured through an LVPHO insurance product (an expected majority of the patients who will be included in the study) will be available for electronic review by study personnel affiliated with the PHO regardless of which provider they use for the colonoscopy. LVPHO system personnel associated with this project will also monitor electronic records to track colonoscopy screenings and diagnostic follow up for patients not insured through the PHO.

Clinicians and staff of intervention practices will participate in a brief pre-intervention academic detailing session to review the current evidence-based guidelines for CRC screening from the 2008 American Cancer Society and U.S. Preventive Services Task Force CRC guidelines, to receive information regarding appropriate follow-up to positive screens, and to receive the operational details of the study intervention that will affect the practice (including being provided information about the intervention that may be necessary for answering questions from patients). Academic detailing will not be provided to control practices, as the detailing is a component of the intervention. The general structure of the academic detailing sessions will be as follows: (1) open with a brief introduction to the study, (2) collect the completed pre-intervention practice surveys from individual clinicians and other practice staff (note: these surveys will have been distributed and completed in advance of the session), (3) conduct the pre-intervention practice focus groups, and (4) conduct the actual detailing (dissemination of information about the intervention and study). As only educational information is being provided during parts (1) and (4) of these sessions, they are not considered data collections. The pre-intervention practice survey and practice focus groups are data collections covered by this ICR. Since practice personnel will be given ample lead time to complete the survey, and since the focus groups will

be conducted during the same session as the academic detailing that provides valuable information about CRC screening and the study's intervention, study personnel anticipate that nearly all clinicians and staff within each practice will participate in these data collections.

As part of normal clinical practice, study personnel will inform each practice of their patients' screening test results via a feedback form; and study personnel will especially flag positive (abnormal) results. Clinicians at each practice are expected to respond to a positive stool test result by discussing the need for a complete diagnostic evaluation (CDE) or other appropriate clinical response with the patient and for helping to arrange for such a CDE. Using electronic records and chart audits, study personnel will track the number and rate of positive stool test results for which the provider recommends a CDE and the number and rate of patients with positive results who actually complete the recommended CDE (along with the outcome of the CDE).

Below are descriptions of each of the seven types of proposed data collections for this study:

(1) Electronic Patient Records Review
An electronic records review will be used to identify patients who are potentially eligible to participate in this study based on the study's eligibility criteria. The electronic records will be extracted from only four entities – LVPHO, MATLV, LVPG, and Lehigh Valley Hospital. Electronic records review will also be used part way through the intervention period for patients of intervention clinics to determine who should receive a follow up reminder letter (attachment D), and then again at the conclusion of the intervention period for patients of both intervention and control practices to determine which patients have completed a stool test or colonoscopy and whether patients who screened positive received appropriate follow up diagnostic evaluation.

(2) SEA Form
Potentially eligible patients identified by electronic records review from the 20 intervention practices will receive a SEA form and accompanying letter. This form will ask patients to indicate if they are not eligible based on eligibility criteria. The form will also ask patients for additional socio-demographic and perceived health status data, and allow patients to opt out of participation in the intervention if they so choose. The SEA form will be sent to an estimated 7,500 patients in the intervention practices.

(3) Practice Focus Groups
The practice focus groups will be conducted both prior to the intervention and following the intervention at each of the 20 intervention practices, and at one time near the end of the intervention period at each of the 5 control practices. The intended population for the practice focus groups is all of the providers and clinical and non-clinical staff of each practice. There will be no sampling or selection process; all providers and staff will be invited (approximately 10 individuals per practice). This will be true for both pre and post intervention focus groups at intervention practices and pre-intervention focus groups at control practices. The pre-intervention focus groups are designed to collect information to establish a baseline. The pre-intervention focus groups will be conducted during the academic detailing sessions, but prior to when the detailing actually begins to ensure accurate baseline information (that is unaffected by the information disseminated during the detailing). The post-intervention focus groups will be conducted during debrief sessions that will occur at each intervention practice at the conclusion of the intervention period. The post-intervention focus groups will assess satisfaction with the intervention and identify changes in attitudes and behaviors regarding screening and follow-up and changes in management of normal and abnormal screening tests resulting from the intervention. In addition, focus groups at control practices will be conducted late in the

intervention period using the pre-intervention focus group guide/protocol to gather control information similar to the baseline information gathered from intervention practices. They will be conducted late in the intervention period to avoid introducing any new information that could influence their usual colorectal cancer screening or follow up practices. Informed consent will be obtained from all focus group participants (Attachment D4).

Collecting these data through qualitative focus groups will allow multiple individuals from a practice to participate in a group discussion where they respond and interact with one another to generate and comment on more ideas than possible through other data collection methods alone. Focus groups also allow new explanations, ideas, and information to emerge through the group discussions. This information may not be realized prior to the start of the study, thus could not be included in a quantitative instrument such as the practice survey (but can be gathered effectively through focus groups).

(4) Brief Informal Interviews with Selected Providers and Staff

Brief informal interviews with selected providers and staff will be conducted as a follow-up to the focus groups at intervention practices to ascertain additional baseline information about procedures and systems for screening results (pre-intervention), and additional information about each practice's experience with the intervention and facilitators and barriers to the intervention's implementation (post-intervention). In addition, similar baseline (pre-intervention) information will be collected from control practices late in the intervention period. These interviews will collect information obtainable from selected knowledgeable practice personnel who can provide information related to the practice as a whole, as well as allow the study to obtain answers to questions that remain unanswered or unclear based on the data received from the practice focus groups and survey. Informal interviews will be conducted with approximately three individuals per practice. Individuals will be selected for interviews based on their area of expertise and the types of additional information that is needed as a follow-up to the practice focus group discussions.

(5) Practice Survey of Clinicians and Staff

A pre-intervention practice survey of providers and staff will be administered in the intervention practices to provide further data regarding the current CRC screening environment at each practice. The survey will be administered again post-intervention to ascertain changes in behavior or attitudes resulting from the intervention. In addition, the survey will also be administered in the control practices late in the intervention period to gather comparison information similar to the baseline information gathered from intervention practices. The practice survey will also collect individual-level information that may impact attitudes and practices towards CRC screening. Collecting data through the practice survey will use a standardized set of questions, thus allowing the results to be analyzed with quantitative statistical methods not appropriate to the more qualitative data to be collected through the practice focus groups and informal interviews. The individual level data from and about each clinician and staff member of the practice can only efficiently be collected through a method such as a survey (e.g. it could not be efficiently collected through focus groups). The intended population for the practice survey is the same as for the practice focus groups, which are all of the providers and clinical and non-clinical staff of each practice. There will be no sampling or selection process; all providers and staff will be asked to complete the survey (approximately 10 individuals per practice).

(6) Patient Chart Audits

Study project personnel will conduct chart audits to determine whether a complete diagnostic evaluation was performed as follow up to a positive stool test screen for CRC for those cases of positive screens for which the electronic record is incomplete or inconclusive. Chart audits will

be performed by LVPHO system personnel; however, practice staff will be required to identify, locate, and make charts available to study personnel. It is estimated, that among the 25 practices approximately 50 patients from each practice will have their chart audited. The project conservatively estimated an average of as many as 50 chart audits per practice. This average results from a mix of EMR-present and EMR-absent practices. The presence of an EMR is expected to greatly reduce the number of incomplete or inconclusive records, whereas such records are expected to be greater in number for practices without an EMR.

(7) Patient Focus Groups

Focus groups of patients will be conducted to better understand the intervention from the patient's perspective. Focus groups with patients of intervention practices will be held at two sites geographically separated across the region. At each site, three focus groups will be conducted for each of the following types of intervention patients: (1) those who did not get the recommended screening after receiving the invitation packet, (2) those who did get the recommended screening and whose test was negative, and (3) those who did get screened and whose screening test was positive (but whose follow-up complete diagnostic exam (CDE) was negative). Participants for the patient focus groups will be selected at random from those meeting the selection criteria for each focus group. Patient focus groups will likely include six groups of 10 patients from the intervention group practice sites, and two groups of 10 patients from the control group sites (80 patients total). LVPHO system will recruit the patients to participate in these focus groups based on the eligibility criteria of each specific focus group (e.g. no screen, positive screen (but negative follow-up diagnostic exam, and negative screen) on a voluntary basis. Patient focus groups will only be conducted once – in the post-intervention time period.

Individuals who screened positive will be included so the study can learn about their satisfaction with the follow-up CDE processes; however, the study will only include individuals who had then since received a CDE that was negative (e.g. they do not have a cancer diagnosis). The study does not want to include individuals who have a confirmed cancer diagnosis, as these patients may be going through treatment and other health-related issues, and could be expecting the focus group to be more of a self-help session rather than a group discussion about the study. In addition, the IRB reviewing the project's research protocol advised against including patients diagnosed with cancer from participation in the focus groups.

For purposes of comparison, two focus groups of patients (one at each site) from control group practices will also be conducted. One of the control focus groups will include patients who were screened for colorectal cancer during the time period of the study, and the other will include patients who were not screened.

Focus groups will not be practice-specific; that is, patients from across the practices will be recruited for each of the groups rather than restricting a group to a single practice's patients or conducting separate groups for each practice. The intervention is being implemented centrally by the LVPHO health system rather than practice-by-practice. Thus patients of the various intervention practices are expected to experience the same intervention. Further, the study is not attributing screening and follow up results on a practice-by-practice basis. Screening rates and rates of follow up to positive screens will be compared between intervention practices as a group and control practices as a group. The patient focus groups are only intended to illuminate how patients feel about CRC screening and (for intervention practice patients) how they feel about the intervention – regardless of the type of practice at which it was implemented – and how the intervention may have affected their experience in getting screened and followed up compared with how control patients feel. Thus, it would not greatly add to the study to conduct patient focus groups by practice. Participants will be asked about their attitudes and beliefs regarding

colorectal cancer screening and what they believe would help them get the screening they need. Informed consent will be obtained from all focus group participants (Attachment D5).

2. Purpose and Use of Information

The purpose of this project is to assess whether, to what extent, and how easily a health system redesign intervention previously shown to improve CRC screening rates and rates of diagnostic follow up for positive screens can be transferred to another clinical setting and achieve similar rate improvements. The data collected from providers, practice staff, and patients will provide information about how effectively the intervention was transferred and about how the intervention process affected the various practices and their patients.

Specifically:

- Data collected from *patients* (obtained through the electronic patient records review, SEA form, patient focus groups, and chart audits) will be used to (a) identify patients eligible for the intervention, (b) ascertain who was and was not screened and, where necessary because of a positive screen, properly followed up, (c) understand patient facilitators and barriers to screening and follow up, and (d) ascertain patient experiences with the intervention. In addition, these data collections will provide information on factors believed to impact patient decisions regarding screening and follow up.
- Data collected from *clinical providers* (obtained through focus groups, informal interviews, and a survey) will be used to (a) ascertain pre- and post-intervention knowledge, attitudes, and behaviors related to CRC screening and follow up, (b) identify provider and practice attributes associated with intervention experiences and outcomes, as well as (c) gain insight into how these attributes affect the process, acceptance, and outcomes of the intervention. It will also be used to understand provider satisfaction or dissatisfaction with the intervention as well as other issues that impact a provider's decision to recommend CRC screening and follow up.
- Data collected from *practice staff* (obtained through practice focus groups, informal interviews, and a survey) will be used to identify current systems and procedures related to screening and follow up as well as facilitators and barriers for screening and follow up in the practice.

The data will be analyzed using qualitative and quantitative methods. The study will compare screening and follow up rates before and after the intervention (pre and post) and how the intervention group differs from the comparison group. The data will generate lessons learned for this case study analysis. Study results will be compiled into a toolkit to explain what was done, what worked in the practices, and what didn't work in the practices. Findings particular to the study will likely be shared at meetings and online with AHRQ and CDC. They will also likely be submitted to appropriate journals. Publication of study results are intended to inform other health care systems and interested parties about the study's experiences with the intervention. The dissemination of results is described in greater detail in section 16.

3. Use of Improved Information Technology

The study will use electronic records to initially identify potentially eligible patients for the study, and to track screening and follow up, which will minimize the amount of data collected through the SEA form and the patient chart audits, thus relieving the burden on the patient, practice and providers. This electronic data will be collected centrally from only four entities (LVPHO, MATLV, LVPG, and LVH) as described below.

Four centralized entities house and maintain the electronic data required by this study and will centrally provide these data to the study so that individual practices will not be required to do so. These four entities are the LVPHO itself (a physician-hospital organization that provides physician practice services and health insurance products), Medical Associates of the Lehigh Valley (MATLV, a large, private group association), Lehigh Valley Physicians Group (LVPG, which staffs hospital-owned practices), and Lehigh Valley Hospital (LVH, which staffs and operates residency-based primary care clinics that help meet the needs of the uninsured and underinsured in the region). Study personnel will merge the following types of data from these four entities to develop the central patient database for this study: (1) claims data from the LVPHO; (2) billing and EMR data from MATLV; (3) billing and EMR data from LVPG; and (4) billing and EMR data from the hospital clinics. Data for independent practices that are members of the PHO but not affiliated with MATLV or LVPG will come only from the LVPHO claims. Study personnel will identify all intervention practice patients ages 50-79 (as of the date of the data run) within each database used, and initially qualify or disqualify them for inclusion in the intervention based on the eligibility criteria. The initial patient database for each practice will be made available to study personnel. Study personnel will also identify control practice patients that meet the same eligibility criteria.

Study personnel are currently pursuing having the SEA form be available electronically as well, but if that is not possible, then study personnel plan to use just the hard copy form. Study personnel will next distribute the SEA form to intervention group patients in this master database of potentially eligible patients. The SEA form only asks a minimal amount of information. Study personnel will use information from the SEA forms to update and expand the central patient database and to determine the final set of patients in the intervention practices eligible for the intervention. Since much of the initial identification of potentially eligible patients will be done centrally and electronically, the burden on the patient is greatly minimized. The electronic database will also be used to identify eligible patients in the control practices, but patients from the control practices will not receive the SEA form, as the SEA form is a component of the intervention. Introduction of the SEA form to the control practices could influence and alter the patient's normal behavior, thus contaminating the control group.

This electronic project database will then also be used to track CRC screening and follow-up rates. Only in instances where patients' electronic data are inconclusive will study personnel track patient screening rates and outcomes as well as follow-up rates at intervention and control practices by conducting patient chart audits. Again, much of the burden on the practice caused by such chart audits will be minimized by collecting the majority of the required data centrally and electronically.

The study's other data collections that do not use electronic systems will only ask the minimal amount of information necessary to answer the research questions in order to minimize the burden on respondents. The pre-intervention practice focus groups and practice surveys will be conducted during the academic detailing sessions (a key component of the intervention) to make sure these data collections occur at a convenient time and location for the clinicians and practice staff. Study personnel will disseminate the pre-intervention practice survey prior to the academic detailing and focus groups to minimize a response bias and to permit respondents to complete the surveys at their convenience. Study personnel will collect these surveys at the beginning of the academic detailing session. Then study personnel will conduct the pre-intervention practice focus groups (prior to the actual detailing, again to minimize a response bias). After which, study personnel will provide the detailing (information about the study and its intervention). The post-intervention practice survey and focus group sessions will be conducted during debrief sessions at each practice. Brief informal interviews will be conducted as needed following the practice focus

groups to ascertain additional baseline information about procedures and systems for screening results, and additional information about each practice's experience with the intervention and facilitators and barriers to the intervention's implementation. Only the minimal amount of information needed to augment the practice focus groups will be asked. The patient focus groups with the intervention and control practices will be held at two sites geographically separated across the region to make it easier for patients to participate. Again, only the minimal amount of information necessary to answer the research question will be asked.

4. Efforts to Identify Duplication

The primary purpose of this study is to assess to what extent, and how easily elements of an integrated health system redesign intervention – components of which were previously shown to improve screening and diagnostic follow up rates for positive screens – can be transferred to a different setting and achieve similar rate improvements. The intervention is based on two prior studies conducted by project staff at Thomas Jefferson University (Myers 2007, Myers 2001, Myers 2004). The first prior intervention focused on increasing CRC screening and was implemented within a large practice associated with Thomas Jefferson University, within the University Health System. The second prior intervention addressed the problem of ensuring complete follow up for patients who had an abnormal CRC screening result, and was implemented in 120 primary care practices affiliated with a national health maintenance organization. These two successful interventions are being extended through this study to a new health care system setting (LVPHO) and its network of community-based primary care practices in the Lehigh Valley of Pennsylvania. The study will assess how well the intervention functioned in this different setting and will generate lessons learned about what worked and what didn't work.

This project is also designed to fit within the context of and complement other work being done within DHHS including at the NCI, at CDC, and through the US Preventive Services Task Force, among others, as colorectal cancer is a national priority for the several federal agencies. The CDC and NCI have several funded projects dealing with this topic and work collaboratively on the Colorectal Cancer Roundtable which is a private-public partnership to advance colorectal cancer screening. Currently, the two agencies are working on data analyses of the National Survey of Primary Care Providers' Recommendations and Practice for Breast, Cervical, Colorectal, and Lung Cancer Screening and the NHIS population-based survey Cancer Control Supplement that deals with cancer screening and follow-up. In addition, CDC is working with NCI on an upcoming Consensus Conference to be held to update the colorectal cancer screening recommendations. The work in the current task order *builds on the past work* of both agencies to implement evidence-based work in the community.

NCI funded a randomized controlled trial in an HMO to increase primary care providers' recommendations of complete diagnostic colon evaluation after an abnormal FOBT.[1] In addition, there are three other NCI grants in progress that have a component to examine follow up after a positive FOBT; however, these studies are in HMO settings and in an exclusively underserved population (a different setting and population than the current study).[2] This current project will examine moving this intervention with providers into a non-HMO setting in Lehigh Valley using proven interventions. In addition, this project will examine health system redesign as a means to

[1] Randall W. Burt, 1 R21 CA107216-01A1,Increasing colorectal cancer screening (completed)

[2] Beverly Green, 1 R01 CA121125-01A1, Systems of support to increase colorectal cancer screening and follow-up (in progress); David A. Lieberman, 1 R21 CA120974-01A2, Screening for colorectal cancer in an Asian community center (in progress); Steven Ornstein, 1 R01 CA112389-01A1, Colorectal cancer screening in primary care practice (in progress)

make changes at the health system level which is complementary to the work done with providers.

This study is also aware of another existing trial, the PLCO Cancer Screening Trial, which is a large-scale randomized clinical trial sponsored by NCI to determine whether certain cancer screening tests reduce the number of deaths from prostate, lung, colorectal, and ovarian cancer. For colorectal cancer, the trial is testing the effectiveness of flexible sigmoidoscopy for early detection of disease (not stool test and colonoscopy, as this study examines). Data collection instruments are also distinct from this study's instruments, as the PLCO instruments included (1) a baseline questionnaire completed at the time of enrollment on demographics, personal and family history, lifestyle habits, and history of screening, (2) annual study update questionnaires to identify occurrence of and mortality from the cancers screened for, (3) dietary questionnaires to look at relationships between diet and cancer, and (4) a risk factor questionnaire mailed in 2006. Results of this trial to date have primarily identified number and rate of detected polyps. Results regarding the ability of screening to reduce morbidity and mortality will not be available for several more years.

Some of NCI's other data collection efforts (e.g., a cancer screening module for the HIS) seek to ascertain prevailing screening and diagnostic follow up rates through national surveys. This study is different, as it seeks to use such rates as a background or baseline to which to compare the rates achieved through this system redesign intervention. Further, this project was conceived as a next step to results of such data collection by NCI which found that positive CRC screenings are not being appropriately followed up in many cases. Although shown in clinical trials to be effective in detecting early disease, such screening is not effective in community based clinical practice outside of such trials if positive screens are not followed up. This study seeks to assess whether a system redesign intervention intended to address tracking and follow up of CRC screening can be applied in a community setting.

In addition, to ensure that efforts would not be duplicated, extensive literature reviews were conducted through an environmental scan. The reviews focused on:

(1) recently available information on CRC screening that further informs the proposed intervention;
(2) recent information related to the implementation and dissemination of interventions;
(3) recent assessments of similar types of interventions to identify evaluation methods and techniques;
(4) other ongoing CRC screening demonstration programs and related efforts that are part of the environmental context of this intervention; and
(5) the local (Lehigh Valley) environment into which study personnel will introduce its intervention.

5. Involvement of Small Entities

This study has been developed to minimize the burden on small entities. As previously noted, the study is only collecting the minimal amount of information needed to answer the research question. A significant portion of the data collection effort will be done through central electronic methods, thus greatly reducing the burden on the practices. In instances where electronic information is not complete, study personnel will analyze patient's charts to determine CRC screening and follow-up rates. Practice staff will only be asked to manually pull patient charts from the files when the electronic data is not available or inconclusive. The practice focus

groups, informal interviews, and survey will be brief and conducted at times convenient for the respective respondents.

6. Consequences if Information Collected Less Frequently

The data will be collected the minimum number of times necessary in order to assess to what extent, and how easily elements of an integrated health system redesign intervention – components of which were previously shown to improve screening and diagnostic follow up rates for positive screens – can be transferred to a different setting and achieve similar rate improvements. In fact, several of the data collections will only be collected one time. The SEA form will be mailed to individuals in the intervention practices potentially eligible to participate in the study only once, and the patient focus groups will only occur once as well.

For intervention practices, the *practice* survey, informal interviews, and focus groups will be conducted twice – once before and once after the intervention in order to assess the impact of the intervention (i.e. to obtain baseline and post-intervention measurements). These data collections will only occur once in the control practices using the pre-intervention data collection instruments only.

The patient chart audits will only occur when the electronic information is not available. If the study were not to collect this information it would not be able to track screening and follow up rates in patients from these selected study practices.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on March 27, 2008, page 16308 - 16311 for 60 days (see Attachment B). No comments were received.

8.b. Outside Consultations

At the onset of this project, a Steering Group comprised of experts in health services research, primary care, medical oncology, and health policy was formed to discuss issues pertaining to the design, implementation, and assessment of this study. Every week since, the Steering Group has met to discuss project-relevant issues, such as the availability of the data, types of data collection, the frequency of the collections, and the clarity of the instructions and recordkeeping, disclosure, reporting formats, data elements, and the overall process of data collection. Some of the Steering Group members are also part of the LVPHO system (where the intervention will be implemented), therefore their input has been very valuable in ensuring that the data collections will not place any undue burden on the practices or patients. Individuals from TJU have prior experience with the previously referenced CRC screening and follow up studies, including studies that used similar data collection instruments; therefore they have provided valuable input on ways to further minimize respondent burden.

The Steering Group members are:

- Mona Sarfaty, MD, Research Assistant Professor Department of Health Policy; Co-Principal Investigator; TJU
- Ron Myers, MD, Professor Department of Medical Oncology; Co-Principal Investigator, TJU

- Martha Kasper-Keintz, Research Associate Department of Medical Oncology, TJU
- Richard Wender, MD, Professor and Chair Department of Family and Community Medicine, TJU
- Randa Sifri, MD, Associate Professor Department of Family and Community Medicine, TJU
- Brian Leas, Project Manager, TJU
- Brian Stello, MD Director, Eastern Pennsylvania Inquiry Collaborative/Network, LVH
- Melanie Johnson, Coordinator, Eastern Pennsylvania Inquiry Collaborative/Network, LVH
- Dan Harris, PhD, Project Director, CNA
- Betty Tao, PhD, Research Analyst, CNA
- Amanda Borsky, MPP, Associate Research Analyst, CNA

In addition, this study and its data collection instruments are being reviewed by the IRBs at both LVH and TJU to ensure that the data collection procedures, clarity of instruction, and recordkeeping and disclosure procedures are compliant with the requirements of human subjects' protection as outlined in federal statute, regulations, and guidelines. (These approvals will be obtained before the study begins.)

Study personnel also have two technical advisors for this study from the Centers for Disease Control and Prevention (CDC) who have provided valuable ongoing input. The CDC advisors are:

- Lisa C. Richardson, MD, MPH, Medical Officer, Division of Cancer Prevention and Control
- Brooke Steele, D.O., Comprehensive Cancer Control Branch

In addition, CDC, AHRQ, and CNA have been in close communication with representatives at NCI to ensure that this study is complimentary and not duplicative of any existing studies as previously noted in question #4).

Outside consultation is also conducted with the public through the 60- and 30-day Federal Register notices. The 60-day Federal Register notice was posted on March 27, 2008. The 30-day Federal Register notice was posted on July 17, 2008.

9. Payments/Gifts to Respondents

There are two types of payments being made to participating physician practices in conjunction with this study. The study itself will reimburse practices to offset expenses incurred in participating in the study's activities. These activities include serving as the drop-off point for stool specimens, administrative time devoted to arranging for the academic detailing/focus group sessions, and time spent by clinic staff when study personnel are on site and when answering questions about screening procedures. This payment is not a payment for providing data, but rather is a payment to partially cover business expenses and possible loss of patient revenue associated with participation. The payment will also be nominal, approximately $100 per practice. This is a usual procedure for studies conducted with participating practices.

The second type of payment will be made by the LVPHO directly to its physician members who participate in the study. Again, this is not a payment for providing data, rather it is a payment for improving quality of care. The PHO routinely pays member physicians for engaging in activities that can improve quality of care (and subsequently reduce health care costs), including attending

CME meetings/conferences, improving clinical practices, monitoring patients with chronic conditions, and participating in studies such as this one that promise to improve clinical care and outcomes and/or to reduce costs. This is a usual business practice of the PHO, which is a private business entity. The amount of the payment is determined by the PHO, not the study, and the payment will come from PHO funds rather than study (government) funds. The payment amount is tied to the amount of time the physician expends on the study by engaging in such activities as talking with patients about the intervention and about CRC screening in general, attending the academic detailing/focus group sessions, and completing the written survey. The PHO translates the estimated time spent into value units (RVUs) and pays physician members the going RVU rate for their time.

Patients who participate in post-intervention focus groups will receive an honorarium. The amount of this honorarium has not yet been determined but it is anticipated to be approximately $10 per participant. Patients will receive no compensation for participating in screening or completing the SEA form; however, patient public and private insurance coverage will pay for screening and follow up related care, as per their normal policies.

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose.

Individuals and organizations contacted will be further assured of the confidentiality of their replies under 42 U.S.C. 1306, and 20 CFR 401 and 4225 U.S.C.552a (Privacy Act of 1974). In instances where respondent identity is needed, the information collection will fully comply with all respects of the Privacy Act.

Information that can directly identify the respondent will not be collected from patients during this intervention. The study will have patients sign an informed consent statement in order to participate in the patient focus group, but will keep this identifying information separate from all notes, recordings, and electronic data bases containing information from the focus groups. Providers and practice staff will also sign an informed consent statement in order to participate in the practice focus group and the same precautions will be taken to protect their confidentiality. Only LVPHO system personnel will have access to identifiable data, which they will de-identify before sending to CNA and TJU for analysis. Consistent with this protocol, only LVPHO system staff will have access to patient names and addresses and will conduct all mailings of letters and related material to patients. Independent of this study, the LVPHO system already has access to identifiable data of their patients. LVPHO system will identify patients by a unique identification number on the SEA forms.

In addition to the protection provided by IRB review (which will be obtained from LVH and TJU before the study begins), CNA and LVH have a business associate agreement, and all parties involved with the study (CNA, LVH, and TJU) will comply with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 CFR Parts 160 and 164.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature, such as sexual behaviors and attitudes, or religious beliefs, on any of the surveys. However, patients will be asked to provide responses to questions about their medical conditions and health, which may be perceived as sensitive in nature by some respondents. Patients will be asked whether they have received a diagnosis of CRC or polyps or

inflammatory bowel disease, if they have a family history of CRC diagnoses before age 60, and whether they have had a recent CRC screening.

HIPAA compliance was carefully considered in the design of this project and was carefully and fully reviewed by the IRBs at both LVH and Thomas Jefferson University. Both IRBs concluded that there were no compliance violations.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for the respondents to participate in this project. The electronic patient records review will be performed by only four entities (LVPHO, MATLV, LVPG, and LVH) which will each extract an average of 1,875 records, requiring about 68 hours total. The SEA form will be sent to a maximum of 7,500 patients across the 20 intervention practices and will require an average of 10 minutes to complete each. Practice focus groups will be conducted with 10 individuals per practice, and will last approximately 30 minutes each. The pre-intervention and post-intervention practice focus groups will be held with each of the 20 intervention practices. One focus group will also be held at each of the 5 control practices to gather comparative pre-intervention information. Informal interviews will be conducted with three individuals per practice, and will last about 10 minutes each. The pre and post-intervention informal interviews will be conducted among the 20 intervention practices. Informal interviews will also be conducted in the 5 control practices for comparison purposes. A survey of providers and staff will be conducted with 10 individuals at each practice, and the survey will take approximately 15 minutes to complete. The survey will be administered to the intervention practices during the pre and post-intervention practice focus group (20 practices). The survey will also be administered one time to the 5 control practices for comparison purposes. Patient chart audits will be performed post-intervention at both intervention and control practices as a supplement to the information available through electronic records. Among the 25 practices, about 50 patients from each practice will have their charts audited, which should take about 10 minutes per chart. Patient focus groups will be held post-intervention and will include six groups of 10 patients from the intervention group practice sites, and two groups of 10 patients from the control group practice sites (80 patients total). These focus groups are expected to last about 2 hours. The total burden for all phases of the project is estimated to be 2,046.33 hours.

Exhibit 1. Estimated annualized burden hours

Data Collection Mode	Number of Respondents	Number of Responses Per Respondent	Est. Time per Respondent in Hours	Total Burden hours
Electronic patient record review*	4	3	5.66	68
Screening Eligibility Assessment (SEA) Form	7,500	1	10/60	1250
Pre-intervention practice focus groups	20	10	30/60	100
Post-intervention practice focus groups	20	10	30/60	100
Control practice focus groups	5	10	30/60	25
Pre-intervention informal interviews with selected providers and staff	20	3	10/60	10
Post-intervention informal interviews with selected providers and staff	20	3	10/60	10
Control informal interviews with selected providers and staff	5	3	10/60	2.5

Pre-intervention survey of clinicians and staff	20	10	15/60	50
Post-intervention survey of clinicians and staff	20	10	15/60	50
Control survey of clinicians and staff	5	10	15/60	12.5
Chart audits	25	50	10/60	208.33
Patient Focus Groups (post-intervention)	80	1	2	160
Total	**7,744**	**---**	**---**	**2,046.33**

* In the intervention practices, electronic records review will be conducted pre-intervention, mid-intervention, and post-intervention. Mid-intervention electronic records review will be conducted in order to determine which patients should be sent the Reminder Letter if they have not yet completed a stool test kit or colonoscopy. In the control practices, electronic records review will be conducted pre-intervention and post-intervention. The electronic records review will be performed by administrative assistants (16 of 68 burden hours) and data analysts (52 of 68 burden hours).

Exhibit 2 shows the estimated annualized cost burden for the respondents' time to participate in the project. The total cost is estimated to be $31,446.73.

Exhibit 2. Estimated annualized cost burden

Data Collection Mode	Number of Respondents	Total Burden hours	Average Hourly Wage Rate*	Total Cost Burden
Electronic patient record review	4	68	$23.56	$1,602
Screening Eligibility Assessment (SEA) Form	7,500	1,250	$12.54	$15,675
Pre-intervention practice focus groups	20	100	$28.00	$2,800
Post-intervention practice focus groups	20	100	$28.00	$2,800
Control practice focus groups	5	25	$28.00	$700
Pre-intervention informal interviews with selected providers and staff	20	10	$28.00	$280
Post-intervention informal interviews with selected providers and staff	20	10	$28.00	$280
Control informal interviews with selected providers and staff	5	2.5	$28.00	$70
Pre-intervention survey of clinicians and staff	20	50	$28.00	$1,400
Post-intervention survey of clinicians and staff	20	50	$28.00	$1,400
Control survey of clinicians and staff	5	12.5	$28.00	$350
Chart audits	25	208.33	$10.00	$2,083.33
Patient Focus Groups (post-intervention)	80	160	$12.54	$2,006.40
Total	**7,744**	**2,046.33**	**---**	**$31,446.73**

*Wage rates were calculated using the following data: (1) for the electronic patient record review the hourly rate is a weighted average for administrative assistants ($14.00 per hour) and data analysts ($26.50 per hour); (2) for the SEA form and patient focus groups the patient average hourly wage was based on the average per capita income of $26,088 (computed into an hourly wage rate of $12.54) in Lehigh Valley, Pennsylvania: "Demographic Information for the Lehigh Valley" from the Lehigh Valley Economic Development Corporation 2006; (3) for the practice focus groups, informal interviews, and survey the provider and practice hourly wage was based on an average of the following estimates from LVH - physician = $70/hour; manager = $19/hour; clinical staff = $13/hour; and clerical staff = $10/hour; (4) for the chart audits the practice clerical staff hourly wage was estimated by LVH to be $10/hour (note: practice clerical staff will retrieve the charts to be audited by study personnel; therefore only the time of the practice clerical staff is included in Exhibit 1 and in the Exhibit 2 cost estimate).

13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no direct costs to respondents other than their time to participate in the study. As colon cancer screening is recommended as routine care for all subjects in the study frame, those who choose to be screened will have no additional cost beyond that which occurs in the usual delivery of health care. Patients insured through a LVPHO insurance product will be covered for diagnosis and treatment. Study personnel expect that most patients covered through non-LVPHO plans (public as well as private) will also be covered, but study personnel will document coverage to determine its impact on the effectiveness of the intervention in these selected practices. Patients who are underinsured or uninsured are eligible to use systems for charity and discounted care available in the Lehigh Valley Hospital and Healthcare Network, including access to hospital clinics and access to financial advisors. Upon sharing relevant financial information, patients will be eligible for a reduced cost-of-care that is matched to the level of the patient's financial need. Lehigh Valley Hospital by volume is the largest provider of charity and reduced cost-of-care in the region.

14. Estimates of Annualized Cost to the Government

The estimated total cost to the Federal government is $271,764.68. The average annualized cost over the two years of the project is $135,882.34 per year. Exhibit 3 shows a breakdown of the costs. The costs have been divided into three components: the cost of developing the data collection instruments; the cost of implementing the data collections; and the cost of analyzing the data and publishing the results. As the study is a redesign intervention, the data collection instruments have previously been developed; however, they have been revised and tailored for the purposes of this study. Therefore the necessary labor and overhead to make these revisions, and indirect costs for printing the forms and surveys, postage, and mailing preparation materials are included in the cost of developing the instruments listed below. The cost of implementing the data collections primarily consists of the labor, travel, and overhead costs of study personnel to carry out the data collections during the implementation of the intervention as well as costs related to conducting post-intervention data collections at the practices and those associated with the patient focus groups. The cost of analyzing the data and publishing results includes labor, overhead, and costs for computer storage fees and printing.

Exhibit 3. Estimated Annual Costs to the Federal Government

Estimated Annual Costs to the Federal Government			
Component	**Year 1**	**Year 2**	**Total**
The cost of developing the data collection instruments:	$24,765.38	$0.00	$24,765.38
The cost of implementing the data collections:	$99,061.52	$24,601.75	$123,663.27
The cost of analyzing the data and publishing the results:	$49,530.76	$73,805.26	$123,336.02
Total:	**$173,357.66**	**$98,407.02**	**$271,764.68**

15. Changes in Hour Burden

This is a new collection of information.

16. Time Schedule, Publication and Analysis Plans

Below is the implementation, analysis, and publication time line (Exhibit 4). As many of these dates are contingent on receipt of OMB approval, they are noted in months post-OMB approval.

Exhibit 4. Time Line

Time Frame	Activity
Completed prior to time of Task Order award	Obtain LVH agreement to participate in intervention and its assessment
2/2008 – 5/2008	Submit research protocol to IRB
6/2008 – 9/2008	Receive IRB approval
5/2008 - 10/2008	Recruit practices
3/2008 – 7/2008	Submit OMB Clearance package
09/2008 – 11/2008	Conduct Pilot
TBD	Receive OMB Clearance
Months 1-2 after OMB approval	Pre-intervention practice surveys, pre-intervention focus groups and academic detailing, and informal interviews with intervention practices
Month 1 after OMB approval	Initial collection of electronic claims, billing, & EMR data to identify potentially eligible patients at intervention and control practices
Month 3 after OMB approval	Screening Eligibility Assessment form mailed to intervention practice patients identified as being potentially eligible for the intervention based on electronic records review
Month 4 after OMB approval	Inspect Screening Eligibility Assessment forms returned by patients
Month 4 after OMB approval	Mail screening invitation to eligible patients included in the intervention
Months 5-6 after OMB approval	Identify screening responders and non-responders (electronic records review)
Month 6 after OMB approval	Mail reminders to non-responders
Month 7 after OMB approval	Identify additional screening responders and remaining non-responders
Months 5-7 after OMB approval	Identify responders with abnormal screening results
Months 6-7 after OMB approval	Mail performance feedback for patients with abnormal screening results to their providers
Months 8-10 after OMB approval	Perform final electronic records review for intervention and control practices to ascertain screening and follow up rates
Months 8-9 after OMB approval	Practice chart audit at intervention and control practices
Months 8-9 after OMB approval	Post-intervention focus groups and key informant interviews with intervention practices
Months 8-9 after OMB approval	Practice focus groups, practice surveys, and informal interviews at control practices
Months 8-10 after OMB approval	Focus groups of patients included in the intervention (separate groups for non-responders, responders with negative screening, and responders with positive screening but whose follow-up complete diagnostic exam (CDE) was negative)
Month 9 after OMB approval	Focus groups of patients drawn from control practices (separate

Time Frame	Activity
	groups for patients who have and have not been screened for CRC)
Months 8-10 after OMB approval	Conduct data analysis
Month 12 after OMB approval	Final assessment report
Month 12-16 after OMB approval	Develop dissemination plan and disseminate findings and implementation tools
Month 18 after OMB approval	Write and submit peer-reviewed manuscript and trade journal article

The assessment will be based on the CIPP (Context, Input, Process, and Product) evaluation model (Stufflebeam, 2002), and PRISM (Practical Robust Implementation and Sustainability Model) intervention evaluation approach (Feldstein and Glasgow, 2007). PRISM also contains the five elements of RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) that can also be used to evaluate programs (Glasgow, et al, 1999). These two approaches (CIPP and PRISM) are not antithetical but rather are complementary and provide a more comprehensive model than either alone. Study personnel will use a mixed-methods approach by using both quantitative and qualitative data in the assessment. The primary goal of the analysis will be to uncover "lessons learned" about what worked well and what didn't work well to increase CRC screening and follow up rates in these selected practices.

The assessment of the intervention outcomes will take an approach similar to Campbell and Stanley (1963) for the research design, using a four-cell non-equivalent control group design with 20 intervention practice sites and 5 control practice sites selected from among primary care practices affiliated with the Lehigh Valley Hospital (LVH). In addition to the outcomes-focused portion of the assessment, study personnel will also conduct a process evaluation of the intervention implementation, which will identify commonly experienced facilitators and barriers to the intervention and other lessons learned. The study will also look at the economic and business benefits of the intervention.

The study's findings will be presented to LVH's organizational leadership, AHRQ, CDC, and the broader practitioner community through a combination of AHRQ knowledge transfer activities and mobilizing partnership dissemination capabilities. Per the contract with CNA for this study, study personnel will also draft and submit at least one manuscript for publication in a peer-reviewed journal and one in a trade journal. Publication in journals is intended to inform other researchers and potential adopters of the intervention of the results of this attempt to implement it. Publication of study results in a peer-reviewed journal is not an indication that AHRQ or CDC intends to use the results of this project as empirical support for policy decisions or recommendations.

Please see Supporting Statement B, question # 2, for a detailed description of the entire Assessment Plan.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

Attachments:

Attachment A: AHRQ's Authorizing Legislation

Attachment B: 60 Day Federal Register Notice

Attachment C: Questionnaires/Data Collection Instruments

- C1: A Screening Eligibility Assessment (SEA) form;
- C2: Focus groups of providers and staff at each intervention and control practice;
- C3: Brief informal interviews with selected providers and staff at each practice;
- C4 A survey of all clinicians and staff at each practice;
- C5: Patient chart audits; and
- C6: Patient focus groups.
- C7: Electronic records review programming guide

Attachment D: Recruiting/Participation Materials

- D1: Screening Eligibility Letter
- D2: Patient Invitation Letter
- D3: Patient Reminder Letter
- D4: Practice Consent
- D5: Patient consent

References

Campbell D, Stanley J, Experimental and Quasi-Experimental Designs for Research. Boston: Houghton Mifflin (1963).

Feldstein A, Glasgow R, A Practical Robust Implementation and Sustainability Model (PRISM) for Integrating Research Findings into Practice. Kaiser Permanente Center for Health Research (2007).

Glasgow R, Vogt, T, Boles S, Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *American Journal Public Health*. 89(9): 1322–1327 (1999).

Myers RE, Sifri R, Hyslop T, et al, A Randomized Controlled Trial of the Impact of Targeted and Tailored Interventions on Colorectal Cancer Screening. Cancer, Vol 110 (9):2083-2091 (Nov 2007).

Myers RE, Turner B, Weinberg D, et al, Complete Diagnostic Evaluation in Colorectal Cancer Screening: Research Design and Baseline Findings. Preventive Medicine, 33:249-260 (2001).

Myers RE, Turner B, Weinberg D, et al, Impact of a Physician-Oriented Intervention on Follow-Up in Colorectal Cancer Screening. Preventive Medicine, 38:375-381 (2004).

Stufflebeam, D, CIPP Evaluation Model Checklist: A Tool for Applying the Fifth Installment of the CIPP Model to Assess Long-Term Enterprises. Available at: http://www.wmich.edu/evalctr/checklists/cippchecklist.pdf. Accessed January 30, 2008 (2002).