SUPPORTING STATEMENT

Part B

Health Care Systems for Tracking Colorectal Cancer Screening Tests

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Agency of Healthcare Research and Quality (AHRQ)

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B. Collections of Information Employing Statistical Methods

1. Respondent universe and sampling methods

The primary goal of this project entitled "Health Care Systems for Tracking Colorectal Cancer Screening Tests" is 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 study's analysis will ascertain how effectively the intervention was transferred to the new setting (the LVPHO and its network of primary care practices) and how the intervention affected the various practices and their patients.

Data from some of the proposed data collections will be analyzed using appropriate statistical methods to ascertain how the intervention performed in this new setting and to identify factors that are associated with this performance in these practices and this health system. However, the study will be using a purposive sample, as opposed to a random sample, and study personnel are aware that results will not be scientifically generalizable, but rather will provide significant and important "lessons learned" from the experiences in these study practices.

Study Sample

The study will be implemented in 25 practices (20 intervention and 5 control) in the Lehigh Valley of Pennsylvania that are affiliated with the Lehigh Valley Physician Hospital Organization (LVPHO). 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. It differs significantly from the sites where components of the 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.

LVPHO will recruit the 20 intervention practices and 5 control practices based on the following attributes: (a) size (smaller practices with 1-3 clinicians and larger practices with more than 3 clinicians); (b) affiliation (MATLV practice, LVPG practice, LVH hospital-operated residency clinic, independent practices using PBS management services, and other independent practices); (c) specialty (family medicine and general internal medicine), and (d) location within the Lehigh Valley area (urban, rural, suburban). LVPHO will then randomly assign selected practices to the intervention and control groups. 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). Note that this is a recruitment process rather than a sampling process. Practices must consent to participate. The intent is to recruit practices in such a way as to achieve a mix of practices across each of the matrix's dimensions, rather than to achieve a stratified sample with sufficient statistical power to detect intervention effect differences.

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, to participate in the study. The intervention practices

will involve their patients in the study intervention as part of normal clinical care. Patients will also have the option to opt-out of the study through the Screening Eligibility Assessment (SEA) form (as described below).

Eligible patients in the intervention practices will be identified through a two step process: (1) an electronic records review of billing, claims, and electronic medical records data to identify patients who are potentially eligible; and (2) a mailed SEA form from LVPHO on behalf of their primary care practice to allow potentially eligible patients to verify their eligibility and provide selected additional demographic and perceived health status information. Eligible patients in the control practices will only be identified through the electronic records review (they 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 tool 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.

The electronic records review will establish initial eligibility for intervention patients and eligibility for control patients 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 information on file, (4) have no previously known family history of CRC diagnoses before age 60 in the medical record, and (5) have no electronic evidence of recent CRC screening tests. All patients in the intervention group 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. All potentially eligible patients who: (1) do not identify themselves as ineligible, (2) do not opt out on the SEA form, or (3) 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 hopefully encourage as many eligible patients to participate in the study as possible[1]. Above average-risk patients who have a family history or CRC diagnoses before age 60, have already previously been positively screened, who have a personal history of colorectal polyps, or who have been previously diagnosed with CRC will be excluded based on either the electronic records review or the SEA form because testing of such patients represents continuing care rather than screening.

The intervention is based on two prior studies conducted by project staff at Thomas Jefferson University (Myers 2007, Myers 2001, Myers 2004). Based on the findings reported in these publications, the project set goals and objectives for the intervention of at least a 40 percent screening rate for the intervention group compared with the prevailing baseline rate for the control group (the previously reported rates were 46 percent and 33 percent, respectively, or about a 40 percent increase in rate) and a 65 percent diagnostic follow up rate (the previously reported rates were 63 percent for the intervention group and 54 percent for the control group for about a 17 percent increase in rate). Note that the project's goal of a 40 percent screening rate is lower than the 46 percent achieved in the original study. The original study was conducted in a large, university-affiliated urban practice setting with a baseline screening rate of 33 percent. Information available to project staff strongly suggest that the baseline rate in the network of community-based practices from which study participants will be selected is below 30 percent. Since the baseline starting point will be lower, the goal for the intervention is set correspondingly lower. The original study achieved a 40 percent increase in screening rate from 33 percent to 46

[1] Note: As this is a population-based study assessing an intervention's ability to achieve expected screening and follow up rates, the denominator for those rates will include those who *opt out*. Screening rates will be calculated as the number of eligible patients who get screened divided by the number of eligible patients regardless of whether or not they opt out.

percent. Applying that same 40 percent increase to a baseline of 28 percent -29 percent yields a target screening rate of 40 percent. As this study is a case study, rather than a scientifically rigorous randomized control study, it will not be addressing whether or not it has sufficient power to calculate the intended effect sizes. These figures presented above are our intended goals and objectives; not effect sizes.

Methods

Data from four of the data collections will be analyzed using quantitative statistical methods: the (1) electronic patient record review, (2) SEA form, (3) practice survey of clinicians and staff, and (4) chart audits. The remaining data collections in this study – the practice focus groups, informal interviews with selected providers and staff, and patient focus groups – will be analyzed using only qualitative, but not quantitative, methods for the study's evaluation of the dissemination process. Therefore, as these latter data collections do not involve quantitative statistical methods, they are not referenced hereafter.

Exhibit 1 shows the study's respondent universe and sample for each of the data collections employing statistical methods.

Exhibit 1. Study universe and sample

Data Collection Mode	Respondent Universe	Respondent Sample	Response Rate
Electronic patient record review	18, 750	9, 375 (7,500 intervention and 1,875 control)	50 percent[2]
Screening Eligibility Assessment (SEA) Form	7, 500 (intervention group determined to be potentially eligible based on initial electronic record review)	3,750 (of which 15% [562] will opt out or not be eligible, reducing the effective sample to 3,188)	50 percent
Pre-intervention survey of clinicians and staff	200 (20 practices x 10 individuals per practice)	160	80 percent
Post-intervention survey of clinicians and staff	200 (20 practices x 10 individuals per practice)	160	80 percent
Control survey of clinicians and staff	50 (5 practices x 10 individuals per practice)	40	80 percent
Chart audits	1, 250 (25 practices x 50 patients per practice)	1,125	90 percent

(1) *Electronic patient record review*. An electronic records review will be used to identify patients who are potentially eligible to participate in this study. The electronic records will be extracted from only four entities – Medical Associates of The Lehigh Valley (MATLV, a large, private group association), Lehigh Valley Physicians Group (LVPG, hospital-owned practices), Lehigh Valley Physician Hospital Organization (LVPHO, a physician hospital organization that

[2] Meet eligibility criteria and not response rate for the electronic patient record review.

provides physician practice services and health insurance products), and Lehigh Valley Hospital (which operates residency-staffed primary care clinics that help meet the needs of the uninsured and underinsured in the region). The study anticipates that there are 18,750 patients between the ages of 50 – 79 across the 25 practices. The study anticipates that 50 percent will then meet the remaining initial eligibility criteria (e.g. visited the practice within the past two years, have a complete mailing address on file, have no previously known family history of CRC diagnoses before the age of 60 in the medical record, and have no electronic evidence of recent CRC screening tests). Therefore, the final sample of patients initially eligible to participate in the study based on the electronic record review will be 9, 375 (7,500 in the intervention practices and 1,875 in the control practices). The electronic records review will also be used to determine which patients have completed a stool test kit or colonoscopy and to compare differences in screening and follow-up rates.

(2) *SEA form* (Attachment C1). The SEA form (a component of the intervention) will be 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. The study anticipates identifying 7,500 such patients across the 20 intervention practices and mailing an SEA form to each one. The SEA form serves the multiple purposes of verifying patient eligibility, allowing patients to opt-out of the intervention, and collecting additional socio-demographic and perceived health status data from intervention group individuals who participate in this study. The study expects to receive approximately 3,750 completed SEA forms back (50 percent response rate). Of the 3,750 returned SEA forms, it is expected that 7.5 percent of patients will request to opt-out of the study and an additional 7.5 percent of individuals will indicate they are not eligible to participate (based on the previously referenced eligibility criteria). Therefore, the final sample of patients providing demographic data through the SEA form will be approximately 3,188 patients.

The study intends to use data from the SEA form to determine if there are differences in screening and follow-up among patients with varying demographic attributes in the intervention group (e.g. do English speaking patients have a different CRC screening rate than non-English speaking patients) in these selected practice sites. The demographic attributes obtained from the SEA form will not be available for patients in the control practices (as control practices will not be receiving an SEA form), therefore this type of analysis and comparison will only be conducted with patients in the intervention practices.

(3) *Survey of all clinicians and staff at each practice* (Attachment C4): The intended population for the practice survey is all of the providers and clinical and non-clinical staff of each practice. There will be no selection process; all providers and staff will be asked to complete the survey (approximately 10 individuals per practice). This will be true for both pre and post intervention focus groups at intervention practices (20 intervention practices) and pre-intervention focus groups at control practices (5 control practices). The study anticipates an 80 percent overall response rate (160 individuals for the pre-intervention survey, 160 individuals for the post-intervention survey, and 40 individuals for the control group survey). Intervention practices will be surveyed both pre and post intervention whereas control practices will only be surveyed once. The survey administered in the pre-intervention period and in the control practices will ascertain prevailing knowledge and procedures regarding CRC screening and follow up at both intervention and control practices to understand the context and environment in which the intervention will be introduced and to establish the degree of comparability between intervention and control sites. The survey administered in the post-intervention period will ascertain whether the intervention changed prevailing knowledge and procedures in accordance with recommended guidelines and improved the quality of care. The surveys will gather both practice-level and

individual staff-level data, which will be used along with intervention outcome data (e.g. changes in screening and follow up rates) from other sources to estimate the association between practice-level and individual-level attributes and outcomes. Results of this analysis will be used to guide the development of "lessons learned" about this intervention.

(4) *Patient chart audits* (Attachment C5): Patient chart audits will be performed post-intervention at both intervention and control practices as a supplement to the information available through electronic records. The purpose of the audits is to look for evidence of 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. The study anticipates only a small proportion of patients will need to have their charts reviewed, as most will have this information available through the central electronic databases. Among the 25 practices, about 50 patients from each practice will have their charts audited. Data from the patient chart audits will be combined with the central electronic database to determine screening and follow up rates. Charts will only be audited when the electronic data is not available or conclusive. The study anticipates that 90 percent of the charts needing to be reviewed will be available for audit.

2. Information Collection Procedures

The study's data collections that employ statistical methods will seek to collect information from the entire population of persons eligible to provide it rather than draw a sample from the relevant populations. Thus (a) the electronic records review will be conducted to determine which patients are initially eligible for the study based on our eligibility criteria, (b) the SEA form will be mailed to all patients of intervention practices who are deemed potentially eligible for the intervention based on the electronic records review, (c) the practice surveys will be distributed to all clinical and non-clinical staff at each of the 20 intervention practices and each of the five control practices, and (d) the chart audit will be performed on the charts of all intervention and control patients with inconclusive electronic records. The study expects 50 percent of the records to meet the eligibility criteria from the electronic records review, a 50 percent response rate for the SEA form, an 80 percent response rate for the practice survey, and a 90 percent successful audit rate for the chart audit. The discussion below describes the study's data collection procedures and methods to maximize response rates.

Data Collection Procedures

Data collection procedures for each of the three collections employing statistical methods are described below.

(1) Electronic patient record review. Many of the study practices are part of four large entities – Medical Associates of The Lehigh Valley (MATLV, a large, private group association), Lehigh Valley Physicians Group (LVPG, hospital-owned practices), Lehigh Valley Physician Hospital Organization (LVPHO, a physician hospital organization that provides physician practice services and health insurance products), 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). The electronic data used during the records review (claims and billing records, and electronic medical records when available) will be centrally extracted by only four entities (LVPHO, MATLV, LVPG, and LVH). One data analyst and one administrative assistant from each of the four entities will conduct the electronic patient records review. Study personnel will then merge these data to develop the central patient database for this study. This central patient database will contain information on all intervention practice patients ages 50-79 identified as

being potentially eligible for the intervention. The database will also include all control practice patients who match the study's eligibility criteria.

(2) SEA Form: After patients in the intervention practices are initially identified as being potentially eligible for the intervention based on the electronic records review, they will be mailed an SEA form by LVPHO on behalf of the participating intervention practices. This form will allow potentially eligible patients to verify their eligibility, and will also ask patients to provide selected additional demographic and perceived health status information. Through the SEA form, intervention group patients will also have the opportunity to opt out of the study or indicate they do not believe they are eligible to participate in this study (based on the study eligibility criteria). Data collected from the SEA form will be merged with existing central electronic records for analytical purposes.

(3) Survey of all clinicians and staff at each practice: To collect the pre-intervention information, prior to the academic detailing sessions and practice focus groups at the intervention practices a survey will be sent to practice administrators for distribution to all clinical and non-clinical staff in the practice. Distributing and collecting the survey prior to the academic detailing sessions and focus groups will minimize response bias (as this is a baseline assessment of current practices). To obtain the post-intervention and control group information, the practice survey will also be completed and collected prior to the start of the practice focus groups to minimize response bias. The post-intervention and control group practice surveys and focus groups will be conducted during each practice's debrief session at the end of the intervention period. Study personnel will then pick up completed surveys when they are on site for the focus groups. No further recruitment or follow up is anticipated.

(4) Patient chart audits. Study project personnel will conduct chart audits to look for evidence of 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 study personnel using a standardized data extraction form and protocol; however, practice staff will be required to identify, locate, and make charts available to study personnel. These audits will augment any missing data from the central electronic database.

Information collected through these methods will then be used for the study's assessment, as described in detail below.

Study Assessment: Outcome Evaluation

The assessment of intervention outcomes will follow a quasi-experimental research design similar to that of Campbell and Stanley, 1963. Study personnel will use 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 Physician Hospital Organization (LVPHO) that are geographically located within the Lehigh Valley. The study's analysis will ascertain how effectively the intervention was transferred to the new setting (the LVPHO and its network of primary care practices) and how the intervention affected the various practices and their patients. The study is a case study, and therefore it will not seek to generalize results to other settings (external validity). Practices will be recruited (purposively sampled) to participate in the study across a range of attributes (affiliation/ownership, size, specialty, and location) to assure that these attributes are well represented in the sample rather than randomly sampled to assure generalizeability. Although recruited practices will be randomly assigned to the intervention and control groups, the purpose of this randomization process is to assure a mix of

practice attributes in both groups rather than to assure internal validity. Since neither random sampling for external validity nor random assignment for internal validity apply in this study, and the intervention's effectiveness will be assessed by observing the measurable effect of the intervention on screening and follow up rates but not on the "statistical significance" of the effect, calculations of statistical power are not applicable. 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 changed their screening behavior.

This study will use a research design similar to Campbell and Stanley, as shown below. The data will be used to generate about what worked and didn't work to increase CRC screening and follow up rates in these selected practices.

	Pre Intervention	**Inter-vention**	**Post Intervention**		
Intervention Sites (N=20)	T_0	Yes	T_1	T_2	T_3
	O_1		O_{2-1}	O_{2-2}	O_{2-3}
Control Sites (N=5)	T_0	No	T_1	T_2	T_3
	O_3		O_{4-1}	O_{4-2}	O_{4-3}

Study personnel will collect baseline data (observations) prior to implementing the intervention (at $Time_0$) from both intervention and control practice sites. Data will be collected through seven modes: (1) Electronic patient record review; (2) a SEA form; (3) focus groups of clinicians and staff at each intervention and control practice; (4) brief informal interviews with selected clinicians and staff at each practice; (5) a survey of all clinicians and staff at each practice; (6) patient chart audits; and (7) patient focus groups.

At the time of the implementation of the intervention (T_0), study personnel will initially compare O_1 with O_3 to determine the degree of equivalence/non-equivalence between intervention and control sites. Study personnel will attempt to take into account any pre-intervention non-equivalence study personnel uncover in interpreting results of post-intervention outcome comparisons. For each post-intervention time period T_1, T_2, T_3, study personnel will compare (1) O_2 with O_4, and (2) ΔO_2-O_1 with ΔO_4-O_3 to assess the effect of the intervention. Comparing O_{2-1}, O_{2-2}, and O_{2-3} will allow study personnel to assess when various outcomes are achieved, whether outcomes improve over time (comparing outcomes early, mid, and late in the intervention), and whether early successes are sustained over time. Any comparisons made will be sure to take into account any differences in the population.

Post-intervention observations will begin with the identification of early screening responders and non-responders (T_1), continue with identifying later screeners (T_2), and conclude (T_3) with final electronic records reviews, chart audits, and focus groups.

In addition to applying the preceding four-cell quasi-experimental design with intervention and control practice groups, study personnel will also apply a pre-post two-cell design. In this design, study personnel will only collect observations from intervention practices (omitting the pre-post control group observations of a complete four-cell design). This design will be necessary for comparing pre-post screening and follow up processes, attitudes, and knowledge at intervention practices based on pre-post focus groups and informal interviews. Note that the process evaluation portion of the intervention assessment will also largely follow a two-cell design since the intervention process will only occur at intervention sites.

Process (Implementation) Evaluation Design

In addition to the strictly outcomes-focused portion of the assessment, study personnel also will conduct a process evaluation of the intervention implementation. This portion of the assessment will focus exclusively on the intervention sites as well as the LVPHO system. It will identify commonly experienced facilitators and barriers, common or particularly successful ways of overcoming barriers, how various kinds of facilitators and barriers affected implementation, and what appear to be the requirements for successful implementation in these selected practices. The process evaluation will also address how the implementation process rolled out in practices with differing attributes. Finally, study personnel will use the process evaluation to help identify critical redesign elements by assessing how well each element of the intervention package was implemented.

Economic and Business Effects

A final component of the assessment will be to assess the economic and business effects of the redesign intervention in these selected settings. A business case analysis will be conducted to see if the intervention can be justified on business and financial grounds for the LVPHO system and its network of primary care practices. In order to make this case, it is necessary to identify and evaluate associated costs and benefits, including both monetary and non-monetary benefits and benefits that are expected to occur in the future. Study personnel will use process flow charts of the intervention, along with time and materials cost estimates from the practice sites, to assist us in making such determinations.

Study personnel will also need to include "important but hard-to-measure benefits" but study personnel will not necessarily moneterize them. Study personnel can calculate the dollar value of the cost of the intervention, the dollar value of direct business benefits, and then compare the two. Some benefits can not or should not be monetarized, or can only be monetarized through much estimation. These benefits include increased employee satisfaction and lower turnover, and enhanced reputation and ability to attract and maintain enrollees and patients. The analysis will include these non-monetarized benefits to offset costs.

Study personnel will also look at the benefits of the intervention from a societal perspective. From a societal perspective, a program that sufficiently increases health outcomes may be worth its cost. A cost-effectiveness analysis (CEA) provides guidance for evaluating programs which improve quality, but also increase costs, and is a supplement to the business case. Colorectal cancer screening has been shown to be cost-effective; thus, this assessment will not focus on further demonstrating this to be true. What study personnel want to know is if *this particular intervention* is cost-effective in these select practices. Study personnel will assess this by looking at the incremental cost effectiveness ratio (ICER) of the intervention in these select practices.

Dissemination Plan

Study personnel will draw on the experience and expertise of project staff who have developed toolkits sponsored by the American Cancer Society (How to Increase Screening For Colorectal Cancer in Practice: A Primary Care Clinician's Evidence-Based Toolbox and Guide) to lead the effort to develop a coordinated set of products and tools for the intervention. For example, study personnel will develop a comprehensive intervention program manual that explains the study's experiences, successes, and difficulties of implementing this redesign intervention in the selected practices. The toolkits and manuals about the experiences of this intervention will be presented to the LVPHO's and LVH's organizational leadership, AHRQ, CDC, and the broader practitioner community through a combination of AHRQ knowledge transfer activities and mobilizing partnership dissemination capabilities. Any findings that are presented will be based on the "lessons learned" from the experiences in these selected practices.

Following completion of the data analysis, study personnel will draft and submit at least one manuscript for publication in a peer-reviewed journal and one in a trade journal (required deliverables of the study's contract). Potential peer-reviewed journals include *Annals of Family Medicine, Annals of Internal Medicine, The New England Journal of Medicine, American Journal of Preventive Medicine, BMJ,* and *JAMA, CA: A Cancer Journal for Clinicians, Journal of the National Cancer Institute, Cancer, Journal of General Internal Medicine, Archives of Family Medicine, Preventive Medicine, American Journal of Gastroenterology,* and *Cancer Epidemiology Biomarkers & Prevention*. Potential trade journals include those published by primary care professional societies, such as *Family Practice Management*. Publication in journals is intended to inform potential adopters of the intervention of the results of this attempt to implement it as a guide to their decision about adopting 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.

3. Methods to Maximize Response Rates

The expected response rates for this study are largely based on the experiences of the researchers at TJU who have conducted similar studies in the past. The study will seek to maximize response rates as described below.

(1) Electronic patient record review. This data collection is an electronic patient record review used to determine who is initially eligible to participate in this intervention. The data analysts and administrative assistants will work to ensure accurate and reliable data is collected to determine the eligible population.

(2) SEA Form: These forms will be mailed to potentially eligible patients in the intervention practices by LVPHO on behalf of their provider's practice. A brief letter signed by all clinical providers at a given practice will accompany the SEA form sent to patients who attend that practice inviting them to be screened for colorectal cancer. This letter (see Attachment D1) will explain the purpose and importance of the form and encourage patients to respond to it. Having the form be sent behalf of their doctor's office, along with an encouraging letter signed by their primary care provider, is expected to increase the legitimacy of the form to patients and maximize the response rate to it.

(3) Survey of all clinicians and staff at each practice: In order to be enrolled as a participating practice in this study, all clinical staff at a given practice will need to agree to participate. Their agreement is expected to indicate a willingness to respond to the survey. The LVPHO has chosen to reimburse its physicians who participate in this intervention and its assessment (including their participation in the survey) to compensate them for their time and effort in this quality improvement initiative. Non-clinical staff are expected to respond to the survey if the clinical providers at their practice do. Survey forms will be distributed at a given practice sufficiently in advance of the focus group session planned for so that practice respondents can complete them at their convenience.

(4) Chart Audits: Practice staff will be given sufficient time to locate and make charts available to study staff for data extraction. The study will also provide sufficient identifying information to practice staff to uniquely identify the patient whose chart is needed. Ninety percent of the charts that need to be retrieved will be available for audit, and data extraction will occur for 100 percent of these charts located and available to study staff.

4. Tests of Procedures

To help ensure the effectiveness of the intervention and data collection materials, the study will pretest the intervention in one practice following receipt of Lehigh Valley Hospital and TJU Institutional Review Board approvals. Results from this pre-test will only be used for internal learning purposes about the process of the intervention and data collection procedures, and the results will not be combined with any data from the main intervention. Results from the pilot will not be publicly reported, as they are only for internal learning purposes.

5. Statistical Consultants

While the study will not be using generalizable quantitative statistical methods, the following individuals have been consulted on quantitative statistical aspects of the study design, and/or will be collecting and/or analyzing the information:

- Dan Harris, PhD, Research Analyst, CNA, 703-824-2283
- Betty Tao, PhD, Research Analyst, CNA, 703-824-2202
- Amanda Borsky, MPP, Associate Research Analyst, CNA, 703-824-2209

- Mona Sarfaty, MD, Research Assistant Professor Department of Health Policy; Co-Principal Investigator, TJU, 215-955-2797
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