

IMPROVING COLORECTAL CANCER SCREENING RATES IN THE HISPANIC
POPULATION UTILIZING EDUCATION AND NAVIGATION

by

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As members of the DNP Project Committee, we certify that we have read the DNP project prepared by *Dia Cherie Madden*, titled *Improving Colorectal Cancer Screening Rates in the Hispanic Population Utilizing Education and Navigation* and recommend that it be accepted as fulfilling the DNP project requirement for the Degree of Doctor of Nursing Practice.



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Final approval and acceptance of this DNP project is contingent upon the candidate's submission of the final copies of the DNP project to the Graduate College. ®

I hereby certify that I have read this DNP project prepared under my direction and recommend that it be accepted as fulfilling the DNP project requirement.



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ABSTRACT

Colorectal cancer is the second leading cause of cancer related death, and the third most common cancer in the United States (Centers for Disease Control and Prevention [CDC], 2017). Despite the evidence that screening reduces morbidity, mortality, and cost of care; nearly one-third of eligible patients has never been screened for colorectal cancer (Syl D. de la Cruz & Sarfaty, 2014). Furthermore, national data shows that the number of unscreened patients nears 50% in the Hispanic population (National Colorectal Cancer Roundtable, 2016). This lack of screening leads to higher morbidity and mortality rates related to colorectal cancer.

The purpose of this quality improvement project was to apply evidence-based interventions to improve colorectal cancer screening rates in a rural federally qualified health center with a predominant Hispanic, Spanish speaking population. A review of the literature provided recommendations for multicomponent interventions, described as the implementation of two or more interventions to best improve screening rates (The Community Preventive Services Taskforce, 2017). The interventions in this quality improvement project included 1:1 education to promote patient engagement in combination with patient navigation to overcome barriers to completion of screening. Patient acceptance of screening increased from 38% to 82%, with an increase of nearly 30% in stool-based testing completed compared to the previous year. In combination with the use of pre-visit planning, standing orders for Fecal Immunochemical (FIT) testing; and transparency in sharing data this pilot project was able to show a significant increase in completion of screening rates with the interventions.

INTRODUCTION

Colorectal cancer is the second leading cause of cancer related death, and the third most common cancer in the United States (Centers for Disease Control and Prevention (CDC), 2017). Colorectal cancer starts as a slow growing polyp, making early identification and treatment crucial for improving outcomes. When identified as a localized cancer, survival rate markedly improves. Research shows between 40% and 60% reduction in colorectal cancer incidence with screening by colonoscopy (Brenner, Stock, & Hoffmeister, 2014; Nishihara et al., 2013; Pan, Xin, Ma, Hu, & Li, 2016) and 22% with screening by fecal immunochemical test (FIT) (Zorzi et al., 2015). The most recent estimates by the CDC of the burden of medical costs in the United States for the treatment of colon cancer was nearly \$14 billion dollars, increasing substantially as the age of the population increases (CDC, 2011).

Background Knowledge

Despite evidence that screening reduces morbidity, mortality, and cost of care, nearly one-third of eligible patients have never been screened (Syl D. de la Cruz & Sarfaty, 2014). In vulnerable populations, screening rates are even lower. Risks for not being screened are highest among the populations served by Federally Qualified Health Centers (FQHCs). The American Cancer Society additionally notes that there is an increased cost and mortality associated with uninsured, ethnic minority patients. Cancer in these patients are usually found at a later stage and therefore tend to have a higher cost to treat (American Cancer Society, 2017).

Studies show Hispanics are the lowest amongst screening rates by race which led the National Colorectal Cancer Roundtable (NCCRT) Taskforce to target this group along with other high-risk target groups (NCCRT, 2016). The NCCRT reports 1:2 Hispanic adults eligible for

colorectal cancer screening is not getting the recommended test. While screenings rates near 61.5% in non-Hispanic whites, only 47% of Hispanic/Latinos are screened (Domingo & Braun, 2017). In part, this low screening rate is due to Hispanics being the most uninsured population in the United States (NCCRT, 2016). Colorectal cancer is the second leading cause of death among Hispanics when men and women are combined.

A systematic review of facilitators for colorectal cancer screening (CRCS) included increasing awareness of screening options with risks and benefits, correcting public misconceptions, and increasing primary care provider recommendations (Honein-AbouHaidar et al., 2016). The same review indicated barriers to screening to include language, logistics to completing tests and cultural beliefs. Awareness of screening options in this review included understanding the disease etiology and progression, screening modalities with their associated risks and benefits, and the importance of screening in the asymptomatic state. Included studies showed that few patients who chose not to complete screening had enough knowledge to make an informed decision, showing that instructions for CRCS was insufficient during the primary care visit when testing was ordered.

Various methods are used in the community health center setting to improve CRCS rates. Common interventions with their correlating percent increase in screening rates can be found in Table 1.

TABLE 1. *Improvement rates with evidence-based interventions.*

Patient Based Interventions	% Improvement in Screening Rates
I on 1 education	15-42% (Holden et al., 2010)
Direct mailing of stool-based test	15-42% (Holden et al., 2010)
Client reminders	5-15% (Holden et al., 2010)
	11.5% (Baron et al., 2008)
Provider Level	% Improvement in Screening Rates
Chart Audits and Feedback	12-23% (Sabatino et al., 2012)
Electronic Provider Reminders	5% (Holden et al., 2010)
Training on communicating with patients	10-15% ((Naylor, K., Ward, J. & Polite, B., 2008)
Navigation	7-28% (Holden et al., 2010)
	10-15% (Naylor, K., Ward, J., & Polite, B., 2008)
Repeated and intense navigation	15% in addition to 1 on 1 education (Naylor, K., Ward, J., & Polite, B., 2008)

Interventions are frequently separated into either provider or patient-based interventions. The Community Preventive Services Task Force (CPSTF) recommends multicomponent interventions, combining two or more interventions to reduce barriers (CPSTF, 2017). These interventions include increasing community demand, increasing community access, and increasing provider delivery of screening services. The CPSTF reviewed evidence on interventions in these groups and made recommendations for interventions with strong evidence to improve cancer screening. Those recommended in the CPSTF's update include one-on-one education, client reminders, reducing structural barriers, and provider assessment and feedback (Sabatino et al., 2012).

A review of current evidence-based practices to improve colorectal cancer screening rates revealed consistent recommendations for two patient level interventions: increasing patient engagement through one-on-one education, and the identification of barriers with the use of patient navigation to overcome these barriers. One study showed a 15-42% increase in screening with one-on-one education, and an additional 15% with added navigation (Domingo & Braun,

2017). The Center for Disease Control and Prevention's Colorectal Cancer Control Program (CRCCP) reported an associated 17% screening rate with patient navigation (Escoffery et al, 2015). The CDC also noted that most federally qualified health centers utilized nursing for their patient navigation programs focused on CRCS due to the complexity of care associated. The CRCCP references the New Hampshire Colorectal Cancer Screening Program which reported that patients utilizing navigation were 11 times more likely to complete colonoscopy (CDC, 2016)..

Local Problem

Per the Uniform Data Systems (UDS) data from 2017, the site of the proposed project had a colorectal cancer screening rate of 19.42% (Health Resources and Services Administration, 2018). The completion rate of ordered FIT screening was 33.99% and was 11% for colonoscopy. Further review of the 2017 data showed that providers were ordering screening tests on 38% of eligible patients, while overall adherence to completion was only 25%. The Arizona Alliance of Community Health Centers average UDS screening rate was 39.2% in 2017. The national data for FQHCs in 2016 revealed a screening rate in community health centers of 39.9% (Health Resources and Services Administration, 2016).

Purpose

The purpose of this Doctor of Nursing Practice (DNP) project was to implement a quality improvement project to improve colorectal cancer screening rates in a FQHC on the Arizona-Mexico border. The project utilized evidence-based innovations established in the literature and apply them specifically to the Hispanic population. The impact of evidence-based innovations applied to special populations is important to assess, especially given the disparities which exist.

The intended outcome of the project was to decrease mortality and morbidity associated with colorectal cancer while reducing cost and improving patient satisfaction.

Study Question

Does the implementation of a bilingual patient education and navigation program improve colorectal cancer screening rates in the Hispanic population?

THEORETICAL FRAMEWORK AND SYNTHESIS OF EVIDENCE

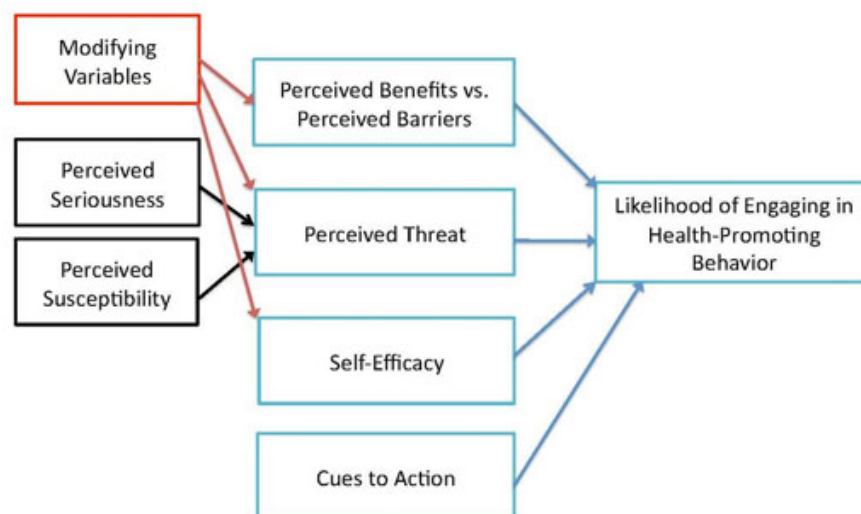
Theoretical Framework

Understanding why some individuals comply with preventive screenings and others do not has been the basis for the development of many theories and frameworks over the years. One such framework is the Health Belief Model, which arose from the work of social psychologists in the 1950's (Rosenstock, 1970). The framework predicts whether a person will act on the recommended health behavior, and guides the development of interventions to affect behavior.

The developers of the Health Belief Model identified increased intention to act with patterns in patient perception. These four constructs were defined as:

- Perceived susceptibility: one's opinion of their chances of getting the condition
- Perceived severity of illness: one's opinion of how severe the illness would be
- Perceived benefit: one's opinion on what benefit the test will have in reducing the severity of the illness (i.e., their susceptibility of the illness)
- Perceived barriers: one's opinion on what would prevent them from having the testing done

The Health Belief Model



(Han, 2013)

FIGURE 1. The health belief model.

Further research identified two additional constructs: cues to action and self-efficacy. A patient's belief that they can and will follow through with screenings has been shown to be one of the strongest individual factors associated with screening (Sohler, Jerant, & Franks, 2015).

Application of Constructs

The Health Belief Model provided a framework for better understanding as to why patients frequently choose not to comply with colorectal cancer screening despite the reduction in barriers such as lack of insurance, and to utilize this understanding to develop interventions in promotion of screening health behaviors. In prior studies, even brief education regarding CRCS positively affected health beliefs (Christy et al., 2017). Despite the strong effect education has on the intention to screen, less than a quarter of patients who had orders for CRCS reported having been provided any education regarding CRCS (Davis et al., 2015). General education on

colorectal cancer screening increases belief that testing will reduce the risk for colorectal cancer, increases perception of risk, and perception of self-efficacy while significantly increasing reported intention to complete testing (McGregor et al., 2015). Colorectal cancer screening has been shown to require more confidence than other screenings do, often identified as coordinating preparation, obtaining stool specimens, and arranging for transportation after colonoscopy (Davis, Morris, Rademaker, Ferguson, & Arnold, 2017)

The aim of this project was to not only provide patients with education on colorectal cancer and screenings, but to open communication with the patient and assess their perceptions to individualize patient centered interventions. In utilizing a team-based approach to patient-centered care, the project looked to engage patients by opening dialogue, providing education and assessing the individual's unique perceptions about colorectal cancer screening. Support staff utilized motivational interviewing to identify the individual's perceptions to their own susceptibility to colorectal cancer, their understandings of the severity of the disease at various stages, and the benefits of screening and the identified barriers. The cue to action provided by the care team was be the initiation of the discussion with the staff followed by the provider's encouragement to complete screening. Patients also have their own cues to action, such as knowing someone who had cancer, the staff would identify these and use these to further provide encouragement.

The care team sought to understand the patient's perceptions about colorectal cancer screening using the Health Belief Model constructs. Some examples of applying the Health Belief Model constructs to this project included the assessment of perceptions such as:

- Does the patient understand the importance of asymptomatic screening? (Perceived susceptibility and Perceived benefit of screening)
- Does the patient understand the benefit to early identification in mediating cancer symptoms and minimizing aggressive therapy? (Perceived benefit of screening and Perceived severity)
- Does the patient understand the ease of collecting stool sample? (Perceived barrier and Self-efficacy)
- Is the patient fearful of discomfort and pain associated with colonoscopy prep and procedure? (Perceived barriers and Self-efficacy)
- Has the patient had a conversation with their provider regarding CRCS options? (External cues to action)

By targeting the above constructs effectively in the intervention, the project aimed to increase individual patient's compliance with colorectal cancer screening.

Synthesis of Evidence

To better understand the existing evidence in support of utilizing patient navigation to improve cancer screening rates, a literature review was completed. A search was completed on both PubMed and Cumulative Index of Nursing and Allied Health Literature (CINAHL). The following key words were used: cancer screening; patient navigat*; and navigation. The following related terms were used to narrow the search inclusion for the scope of the proposed project: colorectal cancer screening; underserved; health center; Hispanic; and Latino. The inclusion criteria were as follows: English language; published in the last 10 years; free full text available; and human subjects. A total of 76 articles were resulted. Of these articles, 13 were

selected which were closely related to the use of patient navigation in colorectal cancer screening to improve screening rates in underserved populations (Table 1). Studies which did not base screening protocols on the United States Preventive Services Task Force Recommendations were also excluded unless the quality of the research on effects of patient navigation was high. The literature review was primarily focused on assessing both associated screening rate increases with patient navigation, and key themes in patient navigation interventions.

Domingo and Braun (2017) completed a systematic review of the literature and found an increased colorectal cancer screening rate associated with patient navigation in federally qualified health centers to range from 9.7%-44%. Additional literature included in this review showed an associated increase from 11-20% screening rates in usual care to 33.6% -43% in the intervention groups (Lasser et al., 2011; Honeycutt et al., 2013). One randomized control trial found an increase in colorectal cancer screening rates at six months in a navigated group over usual care to be 84.9% compared to 40% (Baker et al., 2014). The higher screening rate associated with this study may be related to the navigation being continued over a three-month period regardless of patient participation, whereas other studies excluded patients after a pre-determined number of outreach attempts.

In underserved minority populations, such as Hispanic/Latino or African Americans in the federally qualified health center setting, patient navigation was shown to increase screening rates 9.7%-44% (Domingo & Braun, 2017). There was limited literature specifically addressing the use of patient navigation in the Latino population which shows increased value in the proposed project. The literature shows not only increased decision to complete colorectal cancer screening associated with navigation, but increased adherence to testing in patients who already

intended to screen (32.1% compared to 43.7%) (Enard et al., 2015). This is thought to be related to education increasing self-efficacy, patient reminders and assistance in overcoming barriers.

Screening rates were not shown to improve consistently with education alone, with evidence of decreased self-efficacy unless combined with patient navigation (Arnold, Rademaker, Liu, & Davis, 2017). This provides evidence to utilizing the patient navigation model described by Dr. Harold Freeman, where navigation is both education and assessment of barriers with individualized plan to assist patient in overcoming common barriers (Freeman & Rodriguez, 2011). Risk reduction associated with colon cancer screening was identified as the most important topic covered in education when patients made the decision to be screened (Brenner et al., 2014). Common themes were noted in interventions completed by patient navigators: education; assessment of barriers; motivation; overcoming barriers; language concordance, and reminders.

Patient navigation was found to be referenced in the literature as being proven to increase cancer screening rates, but the literature was limited in respect to the use of patient navigation in the Hispanic population despite the well-known disparities. The studies included large sample sizes and the majority reviewed are randomized control trials and, therefore, the evidence in favor of patient navigation is expected to be strong. A weakness found in the included literature was the variations in how patient navigation was defined, and in what context this was applied. For instance, some studies utilized primarily written education and mailings, while others focused on in-person and telephonic interventions. The frequency and number of interventions ranged significantly as well. Despite the variations, the literature provided support for the efficacy of patient navigation in increasing screening rates while providing a broad

understanding of the application of navigation in underserved populations. Despite the strong evidence in the literature, the organization does not formally implement colorectal cancer screening navigation. This project would investigate the effects of navigation on screening rates in a predominantly Hispanic population.

TABLE 2. *Synthesis of evidence.*

Reference	Research Question	Study Design	Sample and Setting	Methods for data collection and analysis	Conclusion
Arnold, C. L., Rademaker, A., Liu, D., & Davis, T. C. (2017). Changes in colorectal cancer screening knowledge, behavior, beliefs, self-efficacy, and barriers among community health clinic patients after a health literacy intervention. <i>Journal of Community Medicine and Health Education</i> , 7(1). doi:10.4172/2161-0711.1000497.	Compare effectiveness of health literacy-directed intervention	Quasi experimental intervention; pre-post survey assessment	Sample: n=428 Usual care: n=97 Education: n=120 Nurse support and navigation: n=211 Mean age 58.5 years 54% limited health literacy 69% African American Setting: 8 federally qualified health centers in Louisiana	Data collection: orally administered 15-minute survey at enrollment and 15 months later Self-efficacy scale Barrier scale Data analysis: Generalized estimating equations for clustering by clinic Bowker's test for symmetry	Screening rate improved by >83% Decreased self-efficacy to get FOBT (p=0.001) in education only group compared to an increase significantly in the nurse support group (p<0.0001); education arm alone had increased perceived barriers while nurse support group reported less barriers (p<0.0001)
Baker, D., Brown, T., Buchanan, D. R, Weil, J., Balsley, K., Ranalli, L., ... Wolf, M. S. (2014). Comparative effectiveness of a multifaceted intervention to improve adherence to annual colorectal cancer screening in community health centers. <i>Journal of the American Medical Association</i> , 174(8), 1235-1241.	Reminders and navigation intervention effects on FIT completion	Randomized control trial	Sample: n: 450 Intervention/control n=225 87.5% Latino/Hispanic 83.6% Preferred language Spanish Setting: Network of family health centers in Illinois	Data collection: EHR query Data analysis: Differences in groups compared, bivariate analyses using X ² Multivariate logistic regression for demographic 2-sided P=.05 significance	Intervention more likely to complete stool test (82.2% vs 37.3%) p<.001 Median time to complete FIT 13 days (intervention) and 83 days (non-intervention) By 6 months, 84.9% intervention group and 40.0% usual care received CRCS (P <.001)

TABLE 2 – Continued

Reference	Research Question	Study Design	Sample and Setting	Methods for data collection and analysis	Conclusion
				<p>Considered stopping early due to significant improvement in screening rates (O'Brien Fleming method to determine stopping criteria) ($p < .044$)</p> <p>Interim analysis showed 78.8% intervention vs 36.5% control screening completion rate</p>	<p>Estimated cost of outreach \$34.59 per patient and \$43.13 with FIT</p> <p>Speaking to a navigator at 3 month call increased FIT completion (50% vs 21.6% $P = .04$)</p> <p>39.6% completed within 2 weeks of initial intervention; greatly affected adherence</p>
<p>Brenner, A., Howard, K., Lewis, C., Sherida, S., Crutchfield, T., Hawley, S., ... Pignone, M. (2014). Comparing three values clarification methods for colorectal cancer screening decision-making: A randomized trial in the US and Australia. <i>Journal of General Internal Medicine</i>, 29(3), 507-513.</p>	<p>Participants self-reported most important attribute in choosing to screen; test preference</p>	<p>Randomized control trial</p>	<p>Sample: n=920 United States 49% Australia 51% 87% white</p> <p>Setting: Online panel Survey Sampling International Excluding non-English speakers</p>	<p>Data collection: Online study questions Decisional Conflict Scale</p> <p>Data analysis: Chi Square Anova Logistic regression</p>	<p>Most important attribute was risk reduction (57.9%)</p> <p>55.9% preferred stool based test</p> <p>9.2% preferred no screening in US</p> <p>70% intended to screen</p> <p>#1 most important feature when choosing to screen was risk reduction (69.8%); both countries FOBT was preferred test (55.9%)</p>

TABLE 2 – *Continued*

Reference	Research Question	Study Design	Sample and Setting	Methods for data collection and analysis	Conclusion
<p>Domingo, J. B. & Braun, K. L. (2017). Characteristics of effective colorectal cancer screening navigation programs in federally qualified health centers: A systematic review. <i>Journal of Health Care for the Poor and Underserved</i>, 28, 108-126.</p>	<p>What navigation activities increase screening? What challenges are there to implementing navigation? What clinic supported protocols increase screening?</p>		<p>PubMed, CINAHL and PsychINFO 2005-2014; search terms: colorectal cancer, early detection and screening, patient navigat*, community health centers, fecal occult blood test, colonoscopy</p> <p>PRISMA Guidelines</p> <p>Experimental or quasi-experimental designs;</p> <p>Total of 8 articles met criteria</p>	<p>PubMed, CINAHL and PsychINFO 2005-2014; search terms: colorectal cancer, early detection and screening, patient navigat*, community health centers, fecal occult blood test, colonoscopy</p> <p>PRISMA Guidelines</p> <p>Experimental or quasi-experimental designs;</p> <p>Total of 8 articles met criteria</p>	<p>African American or Latino/Hispanic primarily; FQHC Midwest and east coast; 6 good quality, 2 fair quality</p> <p>Navigation increases CRC screening prevalence 9.7%-44% in FQHC</p> <p>Three navigation activities essential: Assessment of barriers, educating regarding CRC procedures, reminders that they were due with motivation and support</p> <p>Mediating language and cultural barriers; fostering trust</p> <p>When coupled with screening protocols, navigation had greatest success</p>

TABLE 2 – *Continued*

Reference	Research Question	Study Design	Sample and Setting	Methods for data collection and analysis	Conclusion
<p>Enard, K. R., Nevarez, L., Hernandez, M, Hovick, S. R., Moguel, M. R., Hajek, R. A., ... Torres-Vigil, I. (2015). Patient navigation to increase colorectal cancer screening rates among Latino Medicare enrollees: A randomized control trial. <i>Cancer Causes Control</i>, 26, 1351-1359.</p>	<p>What is the effectiveness of navigation to increase CRCS adherence in Latinos</p>	<p>Medicare fee for service Eligible for USPSTF recommended CRCS</p> <p>Sample: n=135 intervention, n=168 control 54.5% Spanish only language, 51.2% not US born</p> <p>Setting: University of Texas Anderson Cancer Center</p> <p>Large Latino population (41% vs 17% in US average)</p>	<p>Data collection: Research staff collected self-reported data by phone Interviewers were not blinded to participants' group assignments Surveys for general health, history Barriers and navigation codes recorded</p> <p>Data analysis: Descriptive statistics to summary study sample Differences between groups assessed using Chi-Square tests Logistic regression models to estimate PN effects on CRCS adherence Logistic models to estimate odds of stool versus colonoscopy 80% power, significance 0.05 level</p>	<p>Data collection: Research staff collected self-reported data by phone Interviewers were not blinded to participants' group assignments Surveys for general health, history Barriers and navigation codes recorded</p> <p>Data analysis: Descriptive statistics to summary study sample Differences between groups assessed using Chi-Square tests Logistic regression models to estimate PN effects on CRCS adherence Logistic models to estimate odds of stool versus colonoscopy 80% power, significance 0.05 level</p>	<p>Intervention tailored patient navigation including education, counseling and logistical support in language of choice in comparison to receiving mailed education only.</p> <p>Navigated adherence to screening: 43.7% Non-navigated adherence to screening: 32.1%</p> <p>Significant differences in methods selected only for colonoscopy (navigated 35.6% vs. 23%)</p>

TABLE 2 – Continued

Reference	Research Question	Study Design	Sample and Setting	Methods for data collection and analysis	Conclusion
Honein- AbouHaidar, G. N., Kastner, M., Vuong, V. ... Baxter, N. N. (2016). Systematic review and meta-study synthesis of qualitative studies evaluating facilitators and barriers to participation in colorectal cancer screening. <i>Journal of the American Association for Cancer Research</i> . doi:10.1158/1055-9965.EPI-15-0990.	Facilitators and Barriers to Colorectal cancer screening	MEDLINE, EMBASE, CINAHL, PsychINFO “colon/rectal/colorectal cancer” “screening” “participation” in subject heading Of 514 articles in full text, 94 articles selected for analysis	Two stage synthesis; Critical Appraisal Skills Programme tool	Two stage synthesis; Critical Appraisal Skills Programme tool	Facilitators: awareness of screening and purposes, positive attitude, motivation for screening Barriers: lack of awareness, negative view of cancer, negative attitude about screening modalities, lack of motivation, socioeconomic barriers; PCP inadequate explanation Modifying factors: public education, PCP recommendation, interpersonal communication with PCP, emotional support.
Honeycutt, S., Green, R., Ballard, D., Hermstad, A., Brueder, A., Haardorfer, R., ... Arriola, K. J. (2013). Evaluation of a patient navigation program to promote colorectal cancer screening in rural Georgia, USA. <i>Cancer</i> , 119, 3059-66.	Effects of patient navigation on screening rates	Sample: n= 809 62.9% Minority black Setting: 4 community health centers in Georgia	Data collection: Trained data abstractors, double abstracted fields Data analysis: Frequency distributions of descriptive statistics	Data collection: Trained data abstractors, double abstracted fields Data analysis: Frequency distributions of descriptive statistics	43% intervention group guideline compliant versus 11% of control Intervention patients were 5 times more likely to receive a colonoscopy compared to control patients

TABLE 2 – Continued

Reference	Research Question	Study Design	Sample and Setting	Methods for data collection and analysis	Conclusion
			Multilevel analyses logistic model to investigate effectiveness of intervention, .05 statistical significance	Multilevel analyses logistic model to investigate effectiveness of intervention, .05 statistical significance	
Lasser, K. E., Murillo, J., Lisboa, S., Casimir, N., Valley-Shah, L., Emmons, K. M., ... Ayanian, J. Z. (2011). Colorectal cancer screening among ethnically diverse, low-income patients: A randomized controlled trial. <i>Archives of Internal Medicine</i> , 171, 906-912.	Does patient navigation increase CRCS rates?	Sample: n:465; 1 year; 52-74 years due for colonoscopy Setting: 4 community health centers and 2 public hospital clinics	Data collection: Study investigator masked records review Data analysis: Intention to treat basis Sample size calculated with a power of 80% and a 2-sided significance level of .05 X ² and Fisher exact tests 95% CI	Data collection: Study investigator masked records review Data analysis: Intention to treat basis Sample size calculated with a power of 80% and a 2-sided significance level of .05 X ² and Fisher exact tests 95% CI	Random assignment to up to 6 hours of navigation; education on screening options; motivation; education on completion; scheduling and transportation. Language concordant navigators 33.6% of intervention patients and 20% control completed screening by 1 year; larger portion of intervention screened with colonoscopy (26.5% t/t 13.0%); increased benefit for non-English speaking patients; barriers to reaching patient migrant (P <.001)

TABLE 2 – Continued

Reference	Research Question	Study Design	Sample and Setting	Methods for data collection and analysis	Conclusion
Levy, B. T., Xu, Y., Daly, J. M., & Ely, J. W. (2013). A randomized controlled trial to improve colon cancer screening in rural family medicine: An Iowa Research Network (IRENE) study.	Effects of interventions provider reminder, + mailed education, magnet and FIT test, + structured telephone navigation	<p>Sample: n=743 (randomized into 4 groups – usual care, chart reminder, mailed education and mailed education/FIT + Phone call) 99% White 37% High school education or less</p> <p>Setting: Iowa Research Network (IRENE) – 16 family medicine offices</p>	<p>Data collection: Medical records review</p> <p>Data analysis: Intention to treat Pearson X² test compare discrete outcomes</p> <p>One-way analysis of variance to compare continuous variables</p> <p>Wilcoxon rank-sum test for ordinal variables and continuous variables that did not follow a normal distribution</p> <p>Odds ratios for differences</p>	<p>Data collection: Medical records review</p> <p>Data analysis: Intention to treat Pearson X² test compare discrete outcomes</p> <p>One-way analysis of variance to compare continuous variables</p> <p>Wilcoxon rank-sum test for ordinal variables and continuous variables that did not follow a normal distribution; odds ratios for differences</p>	<p>No effect from chart reminder, FIT and colonoscopy significantly increased with mailed education.</p> <p>Odds of being screening significantly higher in mailed education groups compared to usual care (odds ratio 6.0, 95% confidence interval)</p> <p>No outcome difference between electronic vs. paper reminders</p> <p>Colonoscopy completion significantly higher in the mailed education groups (22% vs. 11.9% P=.009)</p> <p>No statistical difference in completion in the chart reminder group</p>
Percac-Lima, S., Lopez, L., Ashburner, J., Green, A. R., & Atlas, S. J. (2014). Longitudinal impact of patient navigation on equity in colorectal		<p>Sample: n=3115 Intervention vs. n=43, 905</p> <p>Setting: Community health center predominant</p>	<p>Data collection: EMR CRCS data and characteristics</p> <p>Data analysis: Descriptive statistics 2-tailed chi-square tests</p>	<p>Data collection: EMR CRCS data and characteristics</p> <p>Data analysis: Descriptive statistics 2-tailed chi-square tests</p>	<p>Same college educated, Spanish/English Latina woman navigated during the entire study period and additional staff added speaking six other languages were trained</p>

TABLE 2 – Continued

Reference	Research Question	Study Design	Sample and Setting	Methods for data collection and analysis	Conclusion
cancer screening in a large primary care network. <i>Cancer</i> , 120, 2025-2031.		Latino and immigrant population compared to other primary care centers without navigation in the same network	1-way analyses of variance logistic regression models	1-way analyses of variance logistic regression models	<p>Language appropriate reminder letter of due service + education; a week later they were called; 7 telephone attempts over 3 months; repeated annually for the 5-year study; Phone call educated and assessed barriers; tailored interventions to overcome barriers</p> <p>Colonoscopy preferred study at center (both ordered)</p> <p>Before intervention: 49.2% versus 62.5% After intervention: 69.2% versus 73.6%</p> <p>Before intervention Latinos had lower screening rates than non (47.5% vs 52.1%); higher after (73.5% vs 67.3%)</p> <p>After intervention, non-English speaking patients had higher screening rates than English (70.6% vs 58.6%)</p>

TABLE 2 – Continued

Reference	Research Question	Study Design	Sample and Setting	Methods for data collection and analysis	Conclusion
<p>Rice, K., Gressard, L., DeGroff, A., Gersten, J., Robie, J., Leadbetter, S., ... Butterly, L. (2017). Increasing colonoscopy screening in disparate populations: Results from an evaluation of patient navigation in the New Hampshire colorectal cancer screening program. <i>Cancer, 123</i>, 3356-3366.</p>		<p>Sample: n= 131 intervention n=75 non intervention</p> <p>Setting: Community health center in New Hampshire</p>	<p>Data collection: Abstracted from EHR Purposive sampling</p> <p>Data analysis: Descriptive statistics (chi-square test) Fisher exact test of independence for association between PN and study outcome measures</p>	<p>Data collection: Abstracted from EHR Purposive sampling</p> <p>Data analysis: Descriptive statistics (chi-square test) Fisher exact test of independence for association between PN and study outcome measures</p>	<p>2 trained register nurse navigators gave detailed education regarding colonoscopy via telephone, operating external to clinic Language translation for non-English 6 topic specific contacts (education, barriers, appointment setting/reminders) Intervention group completed colonoscopy 96.2% versus 69.3% 11.2% more likely to complete colonoscopy compared to control 5.9% more likely to have adequate bowel prep, no missed/no show appointments compared to 15.6% in control group</p>

TABLE 2 – Continued

Reference	Research Question	Study Design	Sample and Setting	Methods for data collection and analysis	Conclusion
Rohan, E., Slotman, B., DeGroff, A., Morrissey, K. G., Murillo, J., & Schroy, P. (2016). Refining the patient navigation role in a colorectal cancer screening program: Results from an intervention study. <i>Journal of National Comprehensive Cancer Network</i> , 14(11), 1371-1378.		2012-2014 n: 423 Control arm; n:420 Navigation 39% Hispanic; 55% language other than English; 89% Public Insurance Boston Medical Center	Data collection: Survey, open ended questions; average time spent; consensus; grouped themes; Data analysis:	Data collection: Survey, open ended questions; average time spent; consensus; grouped themes; Data analysis:	education about colonoscopy most common barrier; followed by scheduling; out of pocket expenses and transportation (order of frequency); average 44 minutes per patient navigation; assessment and planning most frequent intervention (89%) with education second. Nearly all patients recommended navigation services (96%);
Singal, A. G., Gupta, S., Tiro, J. A., Skinner, C.S., McCallister, K., Sanders, J. M., ... Halm, E. A. (2015). Outreach invitations for FIT and colonoscopy improve colorectal cancer screening rates: A randomized controlled trial in a safety-net health system. <i>Cancer</i> , 122(2), 456-463.		Sample: n=5999 48.9% Hispanic 39% Spanish speaking primary Setting: Texas hospital based safety net institution, 12 community based primary care clinics	Data collection: Electronic health system laboratory data Data analysis: Intent to treat Pre-specified alpha of .05 Pearson chi-square test Interaction analysis	Data collection: Electronic health system laboratory data Data analysis: Intent to treat Pre-specified alpha of .05 Pearson chi-square test Interaction analysis	Mailed outreach FIT outreach: 58.8% FIT completed Colonoscopy outreach: 42.4% colonoscopies completed (12.4% missed appointment for colonoscopy) Usual care: 29.6% screenings completed Screening participation significantly higher in both outreach arms (P<.0001), and significantly higher in the FIT outreach versus the colonoscopy (P<.001)

METHODS

Setting

The quality improvement project was piloted in a federally qualified health center in Southern Arizona. As the purpose of this project was to expand upon current literature in support of patient navigation for colorectal cancer screening in the Hispanic population, the pilot project was completed at one of the health center's clinics located on the Arizona-Mexico border.

Participant Selection

The electronic health record pre-visit planning tool was used to alert when patients were due for colorectal cancer screening prior to a face-to-face encounter with a provider. The tool utilized the United States Preventive Services Task Force (USPSTF) inclusion criteria: a) age 40-75 years old; b) asymptomatic; c) average risk for colorectal cancer (no family history); d) no personal history of inflammatory bowel disease; e) no personal (formatting is off here) history of colorectal cancer; and, f) no previous adenomatous polyp (USPSTF, 2016). The project aimed to include a minimum number of 15 patients.

Intervention

Training of Staff

An existing partnership with the American Cancer Society (ACS) was utilized to provide training to the medical support staff on how to educate patients about colorectal cancer and screening, motivational interviewing, and the role of patient navigation. Additional navigation-specific education was provided, to include cultural competency, communication, motivational interviewing, establishing a list of barriers, and mapping resources (Esparza, 2013). The ACS has been helping federally qualified health centers overcome barriers to accessing screening and

cancer treatment in areas with health disparities for many years. One example was their Community Health Advocates Implementing Nationwide Grants for Empowerment and Equity (CHANGE) grant program in 2013 (Riehm, Stephens, Henry-Tanner, & Brooks, 2017). One of the key evidence-based interventions for quality improvement utilized by the ACS is patient navigation. In fact, the ACS funded the pilot program for patient navigation done by Dr. Freeman (Esparza, 2013).

The education provided by the ACS included two separate training sessions, one for medical support staff and one for patient navigators (also referred to as care coordinators). The patient education module included the following information: education on colorectal cancer, guidelines, screening recommendations, identifying and overcoming objections, and 1:1 education (Ramos, 2018). The 1:1 education provided the support staff with basic facts about screening options, how screening options are completed, and the approximate costs. Navigation is presented as a service where patients are linked within the healthcare system to needed services, advocacy, empowering of individuals in their health, assessment of needs, informal support, and culturally appropriate care (Ramos, 2018). Navigation tasks include outreach, follow up and tracking.

Education and Navigation

Patient navigation began with identification of eligible patients for colorectal cancer screening during pre-visit planning by the medical assistance. The medical assistant verified patient and family past medical history during the face-to-face encounter. They identified any history of previous CRCs and facilitated the request of results where indicated. If any exclusion

criteria are met, they notified the provider for further discussion with the patient. Patients who meet exclusion criteria were not included as a participant in the project.

If eligible for CRCS, the medical assistant provided education and motivational interviewing regarding colorectal cancer screening. The provider was notified by the medical assistant of the patient's initial CRCS type chosen, or the need for further reinforcement of screening recommendations. If patients opt out of screening despite education and provider recommendation, the noted this in the visit summary and continued to offer at each visit.

A standing order for fecal immunochemical testing was utilized if the patient selected that option. The provider ordered the specialist referral for consultation regarding colorectal cancer screening. Medical assistants followed up with the patient at the end of the visit providing education regarding the selected screening and notified the patient of what the steps were complete the screening. The medical assistant discussed with the patient the role of the care coordinator in the navigation process and what they can expect regarding follow up. A task was then sent to the care coordinator in the electronic health record if patient required immediate navigation assistance, such as scheduling of specialist appointment and/or transportation to specialist.

Clear guidelines were provided for patient navigators to follow as to type (i.e., transportation arrangement, scheduling of appointment, further education, reminders) and frequency of contact. All encounters with patient or outside entity in efforts to navigate the screening were documented in the electronic health record. Education and navigation were provided to patients in their preferred language.

TABLE 3. *Tasks related to interventions.*

Pre-visit	During visit	Post-visit
<ul style="list-style-type: none"> • Pre-visit planning utilizes population management software to identify missing colorectal cancer screening 	<ul style="list-style-type: none"> • Cue given to patient that colorectal cancer screening is due • Inclusion/exclusion criteria is assessed based on guidelines • Assistance in obtaining records of past screening completed if applicable • Education and motivational interviewing given by medical assistant • Provider notified of patient's initial screening tool selected and if screening declined. Further motivational interviewing and education given • Patient educated on next steps based on screen tool selected • Offered navigation (i.e. scheduling, arranging transportation, stamp for returning stool-based test) at time of visit or how to reach at later time. 	<ul style="list-style-type: none"> • Follow up navigation offered by phone if stool based testing not completed within 2 weeks • If colonoscopy not completed based on institution outstanding referral policy, care coordination calls and offers further motivational interviewing, education and navigation if accepted

Study of the Intervention

The purpose of the project was to generate evidence of patient navigation for colorectal cancer screening in the Hispanic population. The desired outcome was completion of USPSTF recognized CRCS, with a health center-identified focus on FIT testing due to cost and availability. The site that was selected to pilot the navigation project was in part selected due to strongly established provider practices around the recommendation of colorectal cancer screening at each visit. The intent in utilizing this site is to strengthen validity of assessments of improved colorectal cancer screening rates with navigation.

The patients were tracked by the care coordinators utilizing population management software at the health center. The initiation of navigation started when the pre-visit planning tool was utilized to identify CRCs due and was completed when either the negative screening results were obtained in the chart and the patient is notified of the recommended screening plan, or when definitive diagnosis is obtained with the specialist.

All information was extracted from the electronic health record and collected as nominal data. Care was taken to assure all patient identifiers are removed, following Health Insurance Portability and Accountability Act (HIPAA) guidelines. Data extraction was completed by the student systematically. A clear data collection guide was created in Excel to organize data, with a “person by item” table utilized to track trends (Bonnell & Smith, 2018). Data extracted included demographics; preferred language; screening type selected; timeframe from order to completion of screening; and results of screening. The patients were then tracked for 6 weeks as part of this rapid cycle quality improvement project, and then the data was gathered.

Methods of Evaluation

This project is a quantitative descriptive design in that the participants were not chosen at random to receive the intervention. Rather all eligible patients received the intervention unless they declined. After systematically collecting the data, analysis of the data was completed utilizing descriptive statistics. Descriptive statistics was used for sample demographics, and for comparing pre-and post-intervention screening rates.

Ethical Considerations

To assure that the project met all ethical requirements, the project was reviewed by The University of Arizona Institutional Review Board (IRB) (Appendix A). The purpose of the

Institutional Review Board was to evaluate the proposed project to assure the rights and welfare of human research subjects are protected. Additionally, the Chief Medical Officer of the community health center is on the project committee, assuring that both the institution and its patient's rights were protected.

The project is a quality improvement project where evidence-based interventions were applied to improve colorectal cancer screening rates, and data was gathered to show the magnitude of the effects of the intervention on the patient population. The data collected is part of routine clinical performance measurement and was used to validate the intervention. By definition, the data does not represent human subjects research and is exempt to the criteria defined by the United States Department of Health and Human Services (HHS) (United States Department of Health and Human Services, 2018).

Respect for Persons

One of the main goals of was project is to provide education to assure patients' informed decision making regarding colorectal cancer screening. Patients' autonomous decision to complete or decline CRCS was respected. A chart review was completed, and all patient identifiers were removed from the project information in protection of confidential health information.

Beneficence

As a quality improvement project, it is expected that there be no harm to patients above and beyond what is routinely found in daily clinical practice. The purpose of the project was to maximize benefits of colorectal cancer screening by providing education and navigation,

increasing the quality of care to patients subsequently reducing possible harms of omission of screening.

Justice

All patients eligible for colorectal cancer screening were included in this project, despite the intention to quantify effects in the Hispanic population. The intervention of education and navigation is part of evidence-based practice and therefore should be applied to patient care regardless of ethnicity.

RESULTS

Study participant selection began on September 11, 2018. In a review of all face to face encounters during the final two weeks of September, there were 22 patients identified in pre-visit planning as due for CRCS. When reviewing the chart, or speaking to the patient, evidence of previous colorectal cancer screening or medical exclusions were found in seven patients.

In four visits CRCS was not discussed. The missed opportunities to address screenings due were all in visits scheduled the same day for acute concerns. The pre-visit planning tool was found to not populate same day appointments. This finding in review of the data helped identify new workflows to address missing screenings in visits scheduled the same day.

All 11 patients without exclusions were receptive to medical support staff education and provider reinforcement, there were no documented refusals of CRCS. The 11 participants chosen for this quality improvement project included 55% men and 45% women. All participants were white, with 82% Hispanic ethnicity. The preferred language was Spanish in 73%, with the remainder preferring English. All but one patient had insurance.

The provider participating in this pilot quality improvement project had a preference of utilizing colonoscopy as a screening tool, therefore he ordered both FIT and colonoscopy screens where patients were receptive. This practice was to assure that patients would obtain the FIT test while waiting for the often-lengthy time before colonoscopy, allowing for identification of positive FIT tests and expediting referral to colonoscopy where applicable.

TABLE 4. *Participant data.*

Ethnicity	Preferred Language	Insurance	Sex	Test Ordered	FIT completed	GI Appointment Completed
H /L	S	Medicaid	F	Colonoscopy		10/30/2018
H /L	S	Medicaid	M	Fit/Colonoscopy		
H /L	S	Medicare	M	Fit/Colonoscopy	09/13/18	10/03/18
Not H/L	S	Medicaid	F	colonoscopy		09/26/18
Not H/L	E	Commercial	M	FIT/Colonoscopy	09/13/18	09/26/18
H /L	S	Medicaid	M	FIT	09/13/18	
H /L	E	Dual	M	Fit/Colonoscopy		10/04/18
H /L	S	Uninsured	F	FIT		
H /L	E	Commercial	M	FIT	09/15/18	
H /L	S	Dual	F	Colonoscopy		09/15/18
H /L	S	Medicaid	F	FIT	09/13/18	

H/L=Hispanic/Latino S=Spanish; E=English Dual =Medicare/Medicaid

Colorectal cancer screening was addressed in 82% of the patients who were initially identified as having a gap in care. This is compared to the previous year's rate of 38%. Five patients elected to have FIT screening, three elected colonoscopies, and four patients with screening colonoscopies ordered agreed to FIT testing as well. The practice of ordering both testing was preferred by the participating provider, given evidence existing that colonoscopy is the preferred screening by some respected organizations

Of the FIT tests ordered, there was a 63% completion rate with all being done within 3 days of the visit. Completion of FIT tests increased nearly 30% over the previous year. There were no positive FIT screenings in this study. Of the six patients whose initial GI appointment

was scheduled during the six-week project time, all attended their visit. All colonoscopies were scheduled for greater than two months after the initial primary care visit therefore the data for completion of colonoscopies is yet to be determined. Using the available data during the project evaluation, the screening rate for this participant group was 45% which is significantly increased over the previous year's rate (19%). This is only including those FIT tests, as the colonoscopies had yet to be completed. The provider participating in this pilot study encouraged colonoscopy as the first line tool based on the United States Multi-Society Task Force (Rex et al., 2017). The Task Force does also state that both FIT and colonoscopy are preferred screening tools, and FIT testing should be offered to patients who decline colonoscopy.

Of the seven specialist referral for colonoscopies ordered, five accepted assistance with scheduling and two with arranging transportation with insurance. The patients who did not complete the FIT test within the first week did not have accurate contact information and/or did not respond to efforts to follow up. One patient who was homeless had required phone calls and letters to family to provide further assistance and had a pending FIT and colonoscopy at the end of the project period.

DISCUSSION

Consistent with the Health Belief Model, the patients in the pilot study showed an increase in screening rates when provided a cue to complete screening; education to increase colorectal cancer and screening knowledge; and increased efficacy by providing tools to overcome barriers. Implied by the increased completion of FIT testing within days of the visit is that patients had been given cues to action and were engaged in completing the screening. These patients required no further navigation or follow up to aid in completion of testing. Patients who

did not complete the FIT within the first three days did not complete the testing with added navigation after the visit. The reason for this patient engagement cannot be proven to be directly linked to the intervention task in this pilot study, although a qualitative study on patient feedback may provide insight into what motivated them.

Patient navigation for colonoscopy was highly utilized. Contact with patients by navigators was documented clearly, as were the tasks associated with navigation. Overcoming barriers of language in scheduling appointments, access to long distance phone services and transportation assistance appear to have improved patients attending their initial specialist visit. Rates of completion of initial specialist appointments from the previous months was not collected but is a potential area of future focus. There is the perception that a significant number of patients fail to complete the colonoscopy after the initial visit with the specialist. Clinical leadership is working with a local hospital to consider direct referral to colonoscopy, eliminating one visit for patients and possibly increasing screening rates.

The literature review identified the largest screening increases to be in programs where multiple interventions were applied when combined across three areas to increase patient engagement: through education; access through reducing structural barriers; and provider assessment and feedback (Community Preventive Services Task Force, 2017). While the interventions in this study were patient focused through education and navigation, the health center had been providing data on screening rates to providers for several months.

Strengths

One of the strengths of the project was institutional support in improving quality of care and provider engagement. The provider who agreed to participate in this project was a strong

advocate for improving colorectal cancer screening rates. Providers had recently met attended a meeting focused on the data and evidence around FIT based screening. While completion rates of all CRCS was poor, as stated above FIT based testing had been shown to be higher. This resulted to an increase in number of FIT based testing ordered by the provider during this study.

The health center had purchased population management software just prior to this study, which allowed for identifying gaps in colon cancer screening during pre-visit planning and to pull comprehensive data. This data was presented several times over the three months prior to the project being implemented. Presenting accurate data to the providers on their own screening rates with transparency to allow comparison with other providers within the same health center provided both accountability and friendly competition.

Weaknesses

The study design did not allow enough time to show the medical support staff fully participating in educating patients, although with the successful increase in screening rates this may not be a concern. To better assess education effects on adherence, data should be gathered as to who provided the patient education and was able to engage the patient to agree to screening. As a rapid cycle small scale quality improvement project, more time is needed to see how the education and navigation effected completion of colonoscopies.

Recommendations for Further Study

There were likely multiple factors which effected this increase aside from education and navigation given that this study ran concurrent to the new workflows. This project did not assess who was able to gain the participants initial agreement for screening, the medical assistant or the

provider on follow up. It is also possible that the team-based approach to educating patients contributed to increased patient buy-in.

To fully understand the effects of navigation on completion of colonoscopy in this vulnerable population the data will continue to be gathered and assessed for effects of completion of testing. Patient acceptance of navigation in other populations across the county may be different, as the population in this study had higher rates of language, transportation and education barriers. In conclusion, while this study cannot show conclusively whether education and navigation alone improved colorectal cancer screening it is consistent with previous research which shows multi-component interventions are successful in improving screening rates.

APPENDIX A:
THE UNIVERSITY OF ARIZONA INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL
LETTER



Human Subjects
Protection Program

1618 E. Helen St.
P.O. Box 245137
Tucson, AZ 85724-5137
Tel: (520) 626-6721
<http://hgw.arizona.edu/compliance/home>

Date: August 01, 2018

Principal Investigator: Dia Cherie Madden

Protocol Number: 1807818128

Protocol Title: Improving Colorectal Cancer Screening Rates in the Hispanic Population Utilizing Education and Navigation

Determination: Human Subjects Review not Required

Documents Reviewed Concurrently:

HSPP Forms/Correspondence: *Advisor Confirmation Email.pdf*

HSPP Forms/Correspondence: *IRB Non determination form D. Madden FInal.pdf*

Other Approvals and Authorizations: *Site Letter of Support D Madden (1).pdf*

Regulatory Determinations/Comments:

- Not Research as defined by 45 CFR 46.102(d): As presented, the activities described above do not meet the definition of research cited in the regulations issued by U.S. Department of Health and Human Services which state that "research means a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge."

The project listed above does not require oversight by the University of Arizona.

If the nature of the project changes, submit a new determination form to the Human Subjects Protection Program (HSPP) for reassessment. Changes include addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the study activity. Please contact the HSPP to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

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