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Abstract

Genetic counseling and testing for inherited cancer syndromes have the potential to save lives and may be an avenue for addressing health care disparities among African Americans newly diagnosed with colorectal cancer (CRC); and their close relatives. African Americans are more likely to be diagnosed with CRC at younger ages (under age 50 years), and diagnosed at later stages when cancer is more aggressive and difficult to treat, which are factors associated with hereditary cancers such as Lynch syndrome-related CRC. Considering the benefits of genetic testing for hereditary cancer syndromes - risk stratification, preventive surveillance, targeted treatment, and subsequent reduction in morbidity and mortality among patients by up to 60% - it appears that genetic testing may have a role in prevention, early intervention and reduction of CRC disparities in African Americans. Primary care physicians (PCPs), often the access point to the healthcare system, were anticipated to be at the forefront of genetic counseling and testing. However, a growing body of literature indicates that PCPs see genetic testing as the role of a specialist. This quantitative survey research study, based on the constructs of the Diffusion of Innovation Theory (Rogers, 2003), explored the factors which influence the likelihood of adoption of genetic counseling and testing for Lynch syndrome-related colorectal cancer among PCPs in Florida.

Keywords

Disparities; Lynch syndrome; Colorectal Cancer; African Americans; Genetic Testing; Primary Care Physicians

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ABSTRACT
Genetic counseling and testing for inherited cancer syndromes have the potential to save lives and may be an avenue for addressing health care disparities among African Americans newly diagnosed with colorectal cancer (CRC); and their close relatives. African Americans are more likely to be diagnosed with CRC at younger ages (under age 50 years), and diagnosed at later stages when cancer is more aggressive and difficult to treat, which are factors associated with hereditary cancers such as Lynch syndrome-related CRC. Considering the benefits of genetic testing for hereditary cancer syndromes - risk stratification, preventive surveillance, targeted treatment, and subsequent reduction in morbidity and mortality among patients by up to 60% - it appears that genetic testing may have a role in prevention, early intervention and reduction of CRC disparities in African Americans. Primary care physicians (PCPs), often the access point to the healthcare system, were anticipated to be at the forefront of genetic counseling and testing. However, a growing body of literature indicates that PCPs see genetic testing as the role of a specialist. This quantitative survey research study, based on the constructs of the Diffusion of Innovation Theory (Rogers, 2003), explored the factors which influence the likelihood of adoption of genetic counseling and testing for Lynch syndrome-related colorectal cancer among PCPs in Florida.

Keywords: Disparities; Lynch syndrome; Colorectal Cancer; African Americans; Genetic Testing; Primary Care Physicians

INTRODUCTION

African Americans develop colorectal cancer (CRC) earlier and are less likely to access screening than the general population. They are more often than other race/ethnicities, diagnosed at later stages of disease and present with more aggressive cancers, which are more difficult to treat and therefore more fatal (American Cancer Society, 2019; Williams et al., 2016). Research studies have found that developing CRC before age 50 is associated with Lynch syndrome (Shaikh, Handorf, Meyer, Hall, & Esnaola, 2018; Umar et al., 2004) and the trend of CRC among younger adults ages 20-49, a group not routinely screened for CRC, is increasing (Bailey, Hu, You, & Bednarski, 2015; Siegel at al., 2017; Simon, 2015). Genetic testing for Lynch syndrome-related colorectal cancer (LS-CRC) could be an avenue for addressing LS-CRC among persons newly diagnosed with CRC and for addressing disparities among African Americans.

Recognizing the potential of routine genetic testing for LS-CRC, Healthy People 2020 (HP 2020), included a new public health genomics goal to "improve health and prevent harm through valid and useful genomic tools in clinical and public health practices." Developmental objective G-2 aims to "increase the proportion of persons with newly diagnosed colorectal cancer who receive genetic testing to identity Lynch syndrome (or familial colorectal cancer syndromes)." (Office of Disease Prevention and Health Promotion, Healthy People.gov [HP2020], 2018). HP 2020 cites the Evaluation of Genomic Applications in Practice and Prevention (EGAPP) Working Group's recommendations to offer counseling and educational materials about genetic testing to people newly diagnosed with colorectal cancer, and offering genetic testing for Lynch syndrome to reduce their risk from other cancers, and reduce morbidity and mortality in relatives. (EGAPP Working Group, 2009) EGAPP's recommendations have also gained support from other scientific organizations and appear in medical guidelines: the National Comprehensive Cancer Network Guidelines Version 1.2017; the American College of Medical Genetics and Genomics (position statement on the clinical utility of genetic and genomic services, 2015, the National Academy of Medicine, The American College of Gastroenterology Clinical Guideline (Hamilton, 2017; Hampel et al., 2008; Shaikh et al., 2018; Syngal, 2015).

Primary care physicians are a patient's first contact for health care in an ambulatory setting and it is therefore important to understand their perceptions of genetic counseling and testing (GCT) for LS-CRC. This exploratory study examined the perceptions and likelihood of primary care physicians in Florida to adopt GCT for LS-CRC. The research question asked was: Which construct (s) in the theoretical framework are associated with the likelihood to adopt GCT for LS-CRC?

METHODS

The population of interest for this study was primary care physicians licensed to practice medicine in the state of Florida. Primary care physicians in this study were defined as those who practice Internal Medicine, Family Medicine, and Obstetrics/Gynecology.

Survey Instrument

The study is based on the Diffusion of Innovation theory (Rogers, 2003). The sub-scales of interest from this theory were characteristics of an innovation: *relative advantage, compatibility, complexity, trailability and observability*. The survey instrument consisted of 43 questions based

on the Diffusion theory, with the exception of six questions that explored professional environment and professional values. All questions were answerable on a five-point Likert scale. Nine additional demographic questions were also included. The instrument used for this study was adapted from two surveys validated by Marzuillo et al., (2013) and Suther (2003). In the context of this research study, diffusion of innovation was operationalized as the adoption of GCT for LS-CRC. The dependent variable was likelihood to adopt GCT.

Procedures

The study was conducted in two time periods, August 2017 to October 2017 and November 2017 to April 2018. The surveys were distributed by mail and SurveyMonkey using a modified Dillman (2006) strategy. A list of 25,414 physicians was obtained in May 2017, from the state health department directory of physicians. These physicians were classified as medical doctors (profession code 1501) or doctors of osteopathy (code 1901). The database was sorted into the target primary care specialties. The obstetrics and gynecology group included physicians who specialized in obstetrics, gynecology or both. The internal and family medicine group included geriatrics and preventive medicine subspecialties. It was then filtered to exclude all records of physicians that were not listed as *clear and active* in practice. Records that did not show Florida as the practice state were also eliminated. This resulted in an adjusted sample frame of 1l, 572 primary care physicians meeting the inclusion criteria. A proportional sample was randomly selected from each stratum (family medicine, internal medicine, obstetrics, and gynecology) using the Microsoft Excel randomization function; for a total study sample (N=1240). This represented 10.7% of the sample population. Using Raosoft sample size calculator (http://www.raosoft.com/samplesize.html), approximately 372 completed surveys were required for 95% confidence interval (CI) and a 5%, sampling error. The sample size for this study was 317 physicians, which represents a 26% response rate.

Data Analysis

Data from the paper surveys and SurveyMonkey were entered into SPSS 26. Descriptive analysis was used to assess frequencies, measures of central tendency, and measures of dispersion, inferential statistics were used to draw inferences from the sample population on study results. Cronbach's Alpha reliability test was conducted to determine if perceived attribute items clustered as expected; while linear regression analysis was performed to test the proposed theoretical model, to determine which of the variables were best associated with the likelihood of physician adoption of GCT for LS-CRC. Statistical calculations were performed using SPSS version 26 (IBM Corporation, 2019).

RESULTS

The study included 317 PCP respondents. Table 1 provides the number and percent responding to specific physician characteristics. The majority of respondents were male (62.8%), were between the ages of 40 to 69 years (74.5%), identified as White (68.8%), had practice areas in family (40.7%) or internal medicine (29.3%) and practiced in solo or small group settings (43.5%).

Table 1: Characteristics of Study Respondents

Characteristic (Number responding to item)	**Number**	**Percent**
Gender (303)		
Male	199	62.8%
Female	104	32.8%
Age Range in years (305)		
20-29	1	0.3%
30-39	37	11.7%
40-49	68	21.5%
50-59	88	27.8%
60-69	80	25.2%
70-79	27	8.5%
80 and above	4	1.3%
Race (300)		
White	218	68.8%
Non-White	82	25.8%
Practice Area (313)		
Family Medicine	129	40.7%
Internal Medicine	93	29.3%
General Practice	5	1.6%
Obstetrics	3	.9%
Gynecology	25	7.9%
Obstetrics/Gynecology	27	8.5%
Other	31	9.8%
Practice Type (313)		
Solo or Small Group (five or fewer physicians)	138	43.5%
All Others	175	55.2%

Cronbach's alpha coefficients established the reliability of each scale at 0.8 or higher. The mean and standard deviation for each scale for the entire sample were also calculated (Table 2).

The scores were collapsed into three categories of responses measured by percentages. The categories varied depending on the scale:

- Disagree, neutral, agree
- Not important, neutral, important
- Disagree, not sure, agree
- Difficult, neutral, easy
- Not likely, likely, already incorporated

Compatibility importance scale, had a higher relative mean (smaller standard deviation), indicating that physicians who thought it important that GCT for LS-CRC be easy to incorporate into current medical practice were most likely to adopt GCT (Table 2).

Table 2: Mean, Standard Deviation and Cronbach's Alpha for Independent Variables

Independent Variables Scale	Mean	Std. Deviation	Cronbach's Alpha
Relative Advantage Belief	15.91	3.230	.86
Relative Advantage Importance	16.04	3.526	
Compatibility Belief (practice environment and professional values)	15.09	3.471	.85
Compatibility Importance (practice environment and professional values)	8.20	1.841	
Compatibility Belief (ease of incorporation)	10.67	2.701	.85
Compatibility Importance (ease of incorporation)	11.64	2.643	
Complexity Belief	8.44	3.288	.86
Complexity Importance	11.71	2.671	
Trialability Belief	9.72	2.226	.85
Trialability Importance	10.77	2.869	
Observability Belief	8.79	2.554	.85
Observability Importance	9.19	3.344	

Our regression analysis model demonstrated significant relationships between likelihood to adopt GCT, and six independent variables associated with the study model: *Compatibility Importance* based on practice environment and professional values (Beta = .338, p <.05), *Compatibility Belief* based on ease of incorporation (Beta = .202, p < .05) *Complexity Belief* (Beta = .316, p <.000), *Trialability Belief* (Beta = .320, p < .005), *Trialability Importance* (Beta = .274, p <.005), and *Observability Belief* (Beta = .230, p <.01). The overall model fit was Adj. R^2 = .65. Not significant among the theory constructs were: *relative advantage belief and importance*, *compatibility belief* associated with practice environment and professional values, *compatibility*

importance measuring ease of incorporation, *complexity importance*, and *observability importance*.

Table 3: Regression Model: Independent Variables Associated with Likelihood of PCPs to Adopt Genetic Counseling and Testing for Lynch Syndrome-related Colorectal Cancer

Independent Variables	Unstandardized Regression Coefficients β	95% CI (Lower, Upper)	Std. Errors	*P*-value
Compatibility Importance (practice environment and professional values)	.39	(.06, .62)	.14	.018
Compatibility Belief (ease of incorporation)	.20	(.01, .40)	.10	.041
Complexity Belief	.32	(.18, .45)	.07	.000
Trialability Belief	.32	(.11, .53)	.11	.003
Trialability Importance	.27	(.10, .45)	.09	.003
Observability Belief	.23	(.07, .39)	.08	.005

Multiple regression (Adjusted R^2=.65).

DISCUSSION

The findings of this exploratory study suggest that the Florida PCPs included in this study on the likelihood of adopting GCT for LS-CRC are influenced by select characteristics of the innovation in the research model. Most significant effects on likelihood to adopt, were the constructs of c*omplexity belief* (p <.001), followed equally by *trialability belief, trialability importance, and observability belief* (p<.01), then *compatibility importance* measuring practice environment and professional values, and finally *compatibility belief* related to ease of incorporation (p<.05).

Complexity belief addresses the "degree to which an innovation is perceived as relatively difficult to understand and use" (Rogers, 2003, p. 257). While complex issues may be simple in nature, they are not easily solved because there is no formula that can be applied to reproduce success from the past; rather, the past and one's experience, knowledge or knowledge of experts can only serve as a starting point (Plsek, 2003). Prior studies (Acton et al., 1997; Cremin et al., 2009; Shields, Burke & Levy, 2008; Suther & Goodson, 2003) congruent with this assertion, demonstrated physicians' perceived difficulty to understand and use genetic testing on several levels – awareness, knowledge, incomplete family history, insufficient training, low confidence in explaining test results and in tailoring recommendations. It is therefore not surprising that PCPs in this study believed it is difficult to locate available GCT services, to stay updated on guidelines, to interpret results and provide follow-up care recommendations. All these factors can be perceived as complex and ever-changing. Another factor affecting complexity is the influence of systems on behavior and outcomes. Plsek (2003) notes that physicians are embedded within multiple systems. For example, physician practices may be the first layer of the system, organized as a solo, small

or large group practices. Another layer of the system that the physician practice operates within is the context of a statewide or nationwide health care delivery system. That broader delivery system is itself embedded in social and political systems. These systems influence and are influenced by innovation and it is difficult to know if a small change will have a large effect, or if a seemingly large change will have little effect (Plsek, 2003). Such inability to predict the outcome with complex innovations, could lend itself to inaction and maintaining the status quo among PCPs in relation to genetic testing for LS-CRC.

Trialabilty belief and *trialability importance* address the ability to try out the innovation on a limited basis without total commitment and with minimal investment (Rogers, 2003, p. 258). In this study, most physicians agreed and indeed felt it was important for the ordering of GCT to lend itself to gradual incorporation into their practices and be incorporated on a trial basis. However, a notable percentage of respondents were neutral, indicating their uncertainty about their ability to try out the innovation. This ambivalence is supported by Cain & Mittman (2002) who found that trying out an innovation or new technology allows potential adopters to reduce their uncertainty about its risks and benefits and physicians are more likely to adopt an innovation if it is easy to try without having to fully commit to it or give up an existing practice.

Observability belief, describes whether PCPs in this study noticed other physicians use genetic testing and observed its outcomes or benefits (Rogers, 2003, p. 258). The majority of physicians in this study had neutral responses related to the practice habits of their colleagues, which seem to indicate that study PCPs did not know if their colleagues were adopting genetic counseling, testing, or assisting patients with making decisions regarding genetic services. Other studies in this area demonstrated that physician integration among his or her colleagues is positively related to acceptance and adoption of an innovation into professional practices (Winick, 1961). Therefore, it is not surprising that the relative unawareness of the practices of other physicians and not being able to observe such practices by their colleagues, related to GCT for LS-CRC limits the likelihood of PCPs adopting it.

Compatibility belief and *compatibility importance* embody the physicians' concept of how well the innovation fits with established ways of accomplishing the same goal (Rogers, 2003, p. 240) in the primary care practice. While genetic testing has delivered a product for physicians needing to delve deeper into their patients' cancer etiology, it's adoption into the practice environment is limited by the degree to which an innovation is perceived as consistent with existing values, past experiences and the needs of potential adopters. In this study, physicians felt that it was important that ordering GCT for patients with a genetic predisposition to LS-CRC be consistent with both their professional values and practice environment and be easily incorporated into primary care practice. They felt that genetic testing was best left to specialist "who already had a streamlined evaluation and treatment process." This finding was supported by the literature which found that primary care physicians thought the responsibility for ordering genetic counseling and testing rests with other specialists (Crowther et al., 2018; Schroy et al., 2002; Tan et al., 2014). Other studies offer additional insights to the physicians' perceived importance of *compatibility*. Likely prohibitive are the many tasks associated with genetic counseling and testing as defined by the National Society of Genetic Counselors' Definition Task Force et al., (2006), which include: additional time required to interpret family and medical histories to assess the chance of disease occurrence or recurrence; education about inheritance, testing, management, prevention, resources and research; and counseling to promote informed choices and adaptation to

the risk or condition. Similarly, Jaen, Stange and Nutting (1994) found that 87% percent of physicians agree with the U.S. Preventive Service Task Force's recommendation that all medical encounters should include preventive services for its ability to reduce many common causes of morbidity and mortality. However, given the busy nature of PCPs' offices, much fewer (20% to 60%) in practice, performed the recommended preventive services during the medical encounter. The challenge then becomes the willingness to learn about the actual clinic flow of the primary care physicians' office and devising ways to catalyze both the physician and patients toward the implementation of genetic testing. We hope that given the opportunity, this sample of PCPs will implement genetic-testing protocols within their patient population.

Study Limitations

While this exploratory statewide study utilized a randomized survey design, a limitation is that the response rate fell short of the level needed to achieve generalizability. Thus, there is the risk of nonresponse bias. The inability to determine PCP-patient mix in terms of race, is also a study limitation. Another limitation is that it focused on the likelihood of adopting GCT. We know that the likelihood of use and actual use may vary.

CONCLUSION

GCT for LS-CRC reduces morbidity and mortality through increased colonoscopy screening, individualized medical management and surgery (Strafford, 2012). Increasing PCP use of GCT for LS-CRC among persons newly diagnosed with colorectal cancer, particularly African Americans, has the potential to reduce disparities in morbidity and mortality of patients with Lynch syndrome and their relatives.

Clinical and public health scientist are aware that health disparities have persisted between African Americans and Caucasians for decades and are eager to explore new technologies that hold promise for ending disparities. We are aware that disparities for CRC have been tenacious for many reasons as documented by Crowther, et al. 2018 based on research by Gwede et al., 2015; Jones, Devers, Kuzel & Woolf, 2010. Some of the reasons for the low CRC screening rates among African Americans include less access to care, late entry into care, mistrust of the medical system, denial, cancer fears, living with the burden of cancer, inconvenience or lack of time, transportation, insurance and cost.

The newly diagnosed CRC patient, particularly African American patient, presents the primary care physician with an opportunity to order or refer the patient for genetic testing, which will enable better PCP and patient decision-making. If tests show no mismatch repair deficiency, further testing of relatives is unnecessary; however, if positive for Lynch syndrome variants, primary care physicians seizing upon this opportunity, can be the catalyst for treatment and secondary prevention for their patients and advocate for genetic testing of relatives and subsequent primary prevention if indicated. Further research is needed to identify ways to increase the likelihood of adopting genetic counseling and testing in the primary care setting.

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