EXPLORING THE INFLUENCE OF FAMILY HEALTH HISTORIES ON RISK PERCEPTION AMONG AFRICAN AMERICANS: A QUANTITATIVE ANALYSIS

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PURPOSE: The Center for Minority Health (CMH) in the University of Pittsburgh's Graduate School of Public Health established *The Healthy Black Family Project*, a program designed to increase awareness of the contribution of family health history to the development of chronic diseases. We assessed the impact of a family health history session on African American's risk perceptions for the development of chronic diseases, which result from interactions between genes and the environment. The public health significance of this study was to delineate how participants' perceived risks for developing chronic diseases (i.e., cancer, cardiovascular disease, etc.) would shape risk-reducing behavior modifications and utilization of preventive services.

METHODS: Participants (n=175) completed interviews to create a family health history (or *pedigree*), a schematic representation of health history information in a family. Of these individuals, a total of 125 participants completed surveys that assessed their perceptions of risk for nine chronic diseases. For the purpose of this study, statistical analysis was limited to colorectal cancer (CRC) and cardiovascular disease (CVD). Assessments of risk perception before and following the family health history sessions were calculated to assess changes in accuracy of risk.

RESULTS: Overall, participants appeared to understand the contribution of general risk factors (i.e., smoking) to disease development. However, participants were less knowledgeable about risk related to family health history. Of the 125 participants, sixty-nine percent (n=86) and eighty-five percent (n=107) overestimated the lifetime risks to develop colon cancer for women and men in the general population, respectively. Similar trends were observed for heart disease. More participants were accurate about their risk perceptions for colon cancer than for heart disease in both the pre- and post-family health history session. Among the participants whose perceptions changed, inaccurate perceptions for colon cancer and heart disease prior to the family health history interview were significantly more likely to become accurate for colon cancer (p=0.028) and heart disease (p=0.005).

CONCLUSIONS: The family health history is an effective tool in identifying at-risk individuals and promoting accurate risk perceptions. Encouraging the use of family health history and providing accurate risk perceptions can lead to healthy behavior modifications that may decrease racial and ethnic health disparities.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

DEDICATION

"God can dream a bigger dream than you can for yourself.
Set a vision for yourself and then surrender that vision.
You are co-creating your life every day.....
you do all you can do and then you surrender all." (Oprah Winfrey)

My dad's favorite saying: "Prevention is better than cure"

My thesis is dedicated to my beloved father, Sri Prabhakara K. Murthy
(1930-2003)

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Every individual has undergone events that have shaped his or her life. I could not begin to describe the numerous events and individuals who have influenced mine.

On January 6, 2003, my dad, Prabhakara K. Murthy, passed away. Before his passing, he had only one request of me—that I should meet someone and get married. He was always so proud of me. In a short time, my father's biggest dream for me would come true. I would meet and marry a remarkable individual, Venkatesh Krishna. I chose to discuss this because without him, I would be a different person. Venkatesh embodies many of the qualities that were so amazing about my dad. Because of him, I feel that my dad has never left me and will continue to be with us for the rest of our lives.

Venkatesh deserves special recognition because of his unconditional support, love, patience, and encouragement throughout the experiences of losing my father, wanting to pursue a career in genetic counseling, getting married twice in 2003, completing the genetic counseling program at the University of Pittsburgh, and now moving to a new city (Fresno, California) for my first job with Kaiser Permanente as a Genetic Counselor. I feel that this Master's degree is as much his as it is mine. I only hope that I can encourage and support him to pursue and achieve his dreams. I look forward to our incredible journey together, as we continue to shape each other's lives.

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1. INTRODUCTION

1.1. STATEMENT OF THE PROBLEM

"…quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (IOM, 1990)

Life expectancy and overall health, for a large number of Americans, have improved in recent years because of both an increased focus on preventive medicine and dynamic new advances in medical technology. According to the *Health, United States, 2004* annual report on the health status of the Nation, over the past 50 years the morbidity and mortality for many diseases have been substantially reduced. The life expectancy for Americans has increased to 77.4 years, up from 75.4 years in 1990 (Statistics, 2004). Public education campaigns that emphasize a healthy lifestyle and more effective medicines, in part, have resulted in improvements in overall health status. For example, the death rate for heart disease, a major cause of mortality among all Americans, has declined significantly because of public education and increased use of better cholesterol-lowering medications (Statistics, 2004).

However, not all Americans are benefiting equally from medical advances and public health campaigns. Specifically, minority Americans in the U.S. health care system do not fare as well as the majority population (Groman & Ginsburg, 2004). Racial and ethnic minorities, described as African Americans, Latinos, Native Americans, and some Asian/Pacific Islander

subpopulations, typically experience higher rates of illness, disability, and premature deaths than whites (Figure 1) (Commission, 2004; Report, 2002).

Life Expectancy At Birth, 2002[a]

(Bar chart showing life expectancy values:)
- All: 77.3
- All Females: 79.9
- All Males: 74.5
- White Females: 80.3
- Black Females: 75.6
- White Males: 75.1
- Black Males: 68.8
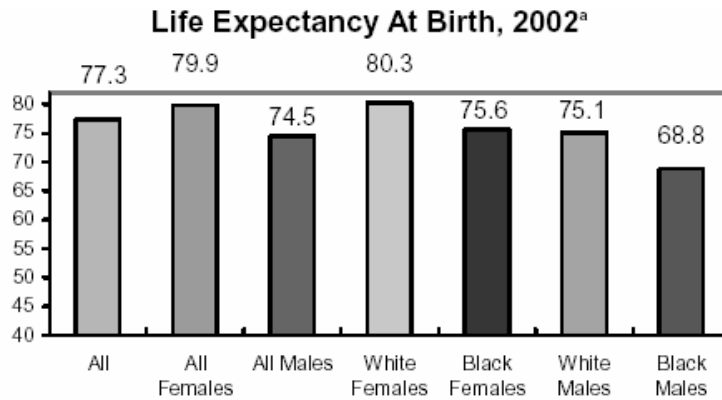
Note: Figure from Centers for Disease Control and Prevention (2002)

Figure 1. Life expectancy at birth by gender and selected race

The Commission report by the Secretary of Health (1985) should not have come as a surprise to the informed observer. From a historical perspective, the prevalence of disproportionate health status among racial and ethnic populations had been described for over 400 years (Byrd & Clayton, 2003). The existence and persistence of health disparities over time were attributed to the medical-social culture in the United States that Byrd and Clayton felt, "is heavily laden and burdened by race and class problems compounding continued social and economic deprivation. These factors interactively impact and contribute to the adverse health status and outcomes of African American and poor populations (Byrd & Clayton, 2003)."

The first comprehensive national study of the health status of black and minority populations in the U.S., the 1985 *Department of Health and Human Services (DHHS) Secretary's Task Force Report on Black and Minority Health*, documented the wide and persisting health disparities

between minorities and whites (Heckler, 1985). The study, which examined morbidity and mortality rates between 1979 and 1981, revealed that life expectancy of blacks was nearly 6 years less than whites; infant mortality among blacks occurred at a rate twice that of whites; and blacks suffered disproportionately higher rates of cancer, cardiovascular disease and stroke, chemical dependency, diabetes, homicide, and accidents. The scale and chronic nature of health disparities became broadly appreciated.

The six problem areas, which included cancer, cardiovascular diseases and stroke, chemical dependency, diabetes, homicides, suicides and unintentional injuries, as well as infant mortality, collectively accounted for more than 80% of the excess mortality during that time period (Heckler, 1985). Among the contributing factors were lack of access to health care, racism, poverty, and neglect.

This disparity in racial and ethnic health status has driven an increasing effort by the government to address the problem. In 1998, President Clinton announced a new initiative that set a national goal of eliminating longstanding racial and ethnic disparities in health status by the year 2010 (Ibrahim, Thomas, & Fine, 2003). *Healthy People 2010* have two major goals: to increase the length quality and years of life for all Americans and to eliminate racial and ethnic health disparities. The initiative is based on the premise that "the health of the individual is inseparable from the health of the larger community" (Satcher, 2000). The initiative focused on six areas: infant mortality, cancer screening and management, cardiovascular disease, diabetes, HIV infection, and child/adult immunizations (Disparities, 2000).

The Working Group on Health Disparities of the National Institute on Health was established to develop a strategic plan for tackling health disparities. The Working Group defined health disparities as "differences in the incidence, prevalence, mortality, and burden of diseases and other adverse health conditions that exist among specific population groups in the United States" (Disparities, 2000). The President's announcement and the subsequent DHHS initiative have focused public health leaders, professionals, and community groups to develop strategies to address and eliminate health disparities (Guttmacher, Collins, & Carmona, 2004).

Interventions for Reducing/Eliminating Racial and Ethnic Health Disparities

Numerous studies have explored ways to prevent the development of chronic conditions, such as type 2 diabetes, for all Americans. In 2002, a study published by The Diabetes Prevention Program Research Group (DPP) found that lifestyle changes or the use of medications to reduce blood glucose can significantly reduce an individual's chance of developing type 2 diabetes (Knowler et al., 2002). This study found that among participants randomized to an intensive lifestyle intervention, a moderate weight loss (5%-7% of body mass index) can reduce the risk of developing type 2 diabetes by 58 percent. The lifestyle intervention included a low-fat diet and an exercise regimen of 150 minutes per week. In addition, the DPP found that treatment with the oral diabetes drug metformin (Glucophage®) also reduces diabetes risk, though less dramatically (by 31%) in people at high risk for type 2 diabetes. Of the 3,234 participants enrolled in the DPP, 45% were from minority groups that suffer disproportionately from type 2 diabetes: African Americans (n=645), Hispanic Americans (n=508), Asian Americans and Pacific Islanders (n=142), and American Indians (n=171). The trial also included individuals known to

be at higher risk for type 2 diabetes, based on a family history of type 2 diabetes (n=2243). Identifying individuals who are at increased risk to develop type 2 diabetes and promoting healthy lifestyle decision-making can improve the quality of life and eliminate health disparities for all Americans.

Researchers have also targeted health improvement efforts at specific populations by partnering with community organizations and developing culturally-appropriate interventions. For example, numerous studies have been reported on African American church-based health promotion partnerships and the development of strategies and programs aimed at improving overall health status and reducing disease burden. Many of these programs have been successful at improving the consumption of healthy foods, promoting recommended health screenings, and spreading health promotion information, in general.

For example, Resnicow and colleagues (2000) developed the Eat for Life Program, which explored ways to increase fruit and vegetable uptake through black churches (Resnicow et al., 2000). A study by Resnicow et al. (2001), as part of this program, used telephone counseling and motivational interviewing to improve fruit and vegetable consumption (Resnicow et al., 2001). The authors found that individuals interviewed by motivational interview techniques have a significant increase in fruit and vegetable intake compared to individuals who were not interviewed using the same method. Individuals interviewed with motivational interviewing were more likely to follow through with positive health behaviors and develop more intrinsic motivation to partake in healthy diets.

These studies indicate that by researching strategies to prevent the onset of chronic conditions, through moderate weight loss or medications, and development of culturally-appropriate programs in partnership with community and church organizations, minority populations can be targeted for risk reduction interventions of specific health conditions. Unfortunately, there have been limited reports on the use of family health history as an intervention to identify at risk individuals, specifically in minority populations.

Despite enormous efforts since the implementation of *Healthy People 2010*, disparities in the burden of illness and death experienced by ethnic and racial minorities as compared to the U.S. population as a whole continue to exist (Prevention, 2005). In 2002, age-adjusted death rates for the black population exceeded those for the white population by 41 percent for stroke, 30 percent for heart disease, 25 percent for cancer, and more than 750 percent for HIV disease (Figure 2) (Prevention, 2004c; Statistics, 2004). Overall mortality was 31 percent higher for black Americans than for white Americans in 2002, compared with 37 percent higher in 1990. Large disparities in infant mortality rates among racial and ethnic groups continue despite the overall decline in infant mortality rates. In 2002, breast cancer mortality for black females was 36 percent higher than for white females, compared with less than 15 percent in 1990 (Health Status, 2004).

Death Rates* for Diseases of the Heart, by Race/Ethnicity, 2001

*Age adjusted rate per 100,000 population.

Source: National Health and Nutrition Examination Survey III, 1988–1994, National Center for Health Statistics, CDC.

Prevalence of Diabetes,* by Race/Ethnicity, 2002

*Age adjusted prevalence among U.S. adults age 20 or older.

Sources: 1999–2001 National Health Interview Survey and 1999–2000 National Health and Nutrition Examination Survey estimates, projected to 2002. Outpatient database of the Indian Health Service, 2002.

Note: Figures from the CDC REACH 2010 (2004)

Figure 2. Racial and ethnic health disparities for selected diseases

More recent efforts aimed at closing the gap and achieving the goals set forth in the *Healthy People 2010* initiative have been designed to identify at-risk individuals and populations and provide opportunities for education, prevention, and early diagnosis based on genetic information.

The Human Genome Project

In 1990, the Human Genome Project (HGP) constituted a revolutionary and stunningly successful attempt to understand one source of the disease burden in all populations – the genetic component. The HGP was an international effort that sought to understand the genetic basis of human disease. Among its many goals, the information generated by the HGP was expected to be "the source book for biomedical science and to be of immense benefit to the field of medicine" (US Department of Health and Human Services, 1990). The HGP was proposed to

aid in the understanding and eventually treatment of the more than 4000 genetic diseases that afflict all populations worldwide. Moreover, it was hoped that the HGP would have a major impact in *how* we understand and treat many common chronic diseases. Completion of the mapping of the human genome has immensely increased and enhanced our knowledge of the genetic component of diseases. Nearly every disease, with perhaps the exception of accidental trauma, has some genetic component that when combined with the certain environmental trigger(s) initiate the disease process, termed as *multifactorial disease*. Most common chronic conditions such as cancer, diabetes and heart disease are considered multifactorial diseases.

Several national agencies in public health and research, such as the National Human Genome Research Institute (NHGRI), a branch of the National Institutes of Health, and the Office of Genomics and Disease Prevention, a branch of the Centers for Disease Control and Prevention, have been organized following the establishment of the HGP. The overall mission of these agencies has been to understand the structure and function of the human genome and the role it plays in health and disease. Moreover, they have been involved in public health strategies to study the genetic factors that underlie health disparities among different groups (NHGRI, 2004).

The NHGRI developed a *Strategic Plan for Reducing Health Disparities*, with one of its major goals being to study the genetic factors that contribute to disease that disproportionately affect minority populations. The NHGRI in collaboration with other U.S. academic institutions developed a study in West Africa to explore the genetics of non-insulin dependent diabetes. They chose this population because of the presumed genetic similarity of West Africans with the

African American population and because of the presumed decreased contribution of environmental factors such as diet (NHGRI, 2004).

Public health researchers and health care providers have recognized the value of the translation of genomic information for public health, particularly in understanding diseases in the context of epidemic settings (e.g., HIV, SARS), where interventions could be more effectively targeted, or genomic tools more efficiently utilized (Prevention, 2003). While "genomic profiling," described as tailoring interventions based on an individual's genotype, is not currently available in the general population, public health and medicine have had to identify and utilize other strategies for "personalized medicine", in particular, by exploring the value and utility of family health history to identify people who could be at increased susceptibility to diseases that are often preventable.

The Family History Initiative

Family health history is not a new concept in public health. A history of disease in families is known to be a risk factor for most chronic diseases of public health significance including coronary heart disease, diabetes, several cancers, osteoporosis, and asthma (Prevention, 2003). However, new genetic information combined with knowledge about environmental triggers has given family health histories a new power to identify at risk individuals and help them to take preventative action. In 2004, the U.S. Surgeon General, Dr. Richard H. Carmona, in collaboration with the National Institutes of Health, the Centers for Disease Control and Prevention and other federal agencies, announced *The Surgeon General's Family Health*

Initiative, a national campaign to promote the use of family health history for disease prevention and health promotion (Services, 2004).

The initiative had three major objectives: 1) to encourage all Americans to become more aware of their family health history, 2) to educate health care professionals about the importance of family history, and 3) to promote genomic literacy. The first aim of the initiative was to develop web-based tools that the general public could use in order to gather, understand, evaluate, and use family history information to improve their health status, as well as to provide the information to their health care provider(s). Second, the initiative focused on educating health professionals on the availability and familiarity of family history tools to gather, evaluate, and integrate family history as part of routine health care management. Lastly, the initiative aimed at promoting genomic literacy, so as to prepare both the American public and their health care providers for uses of genetic technologies in medicine. Through these efforts, genomic technologies can be more efficiently and effectively used to target preventive strategies to appropriate individuals and populations. Thus, they can be used to reduce and eliminate health disparities.

The Healthy Black Family Project

Even before the announcement of *The Surgeon General's Initiative*, efforts were being made to use this powerful tool to help alleviate racial and ethnic health disparities. For example, The University of Pittsburgh Graduate School of Public Health (GSPH) Center for Minority Health (CMH) launched the Healthy Black Family Project (HBFP) in 2003. The HBFP, a multi-year

effort, is a community-based health promotion and disease prevention initiative and is part of the

African American Health Promotion Campaign: Countdown to 2010. The main focus of the

HBFP is to use public health strategies to eliminate racial and ethnic health disparities in

Pittsburgh, Pennsylvania. The efforts have been focused on developing interventions to prevent

diabetes and hypertension among the black community in Pittsburgh. This exploratory study,

The Healthy Black Family Project: Assessing the Response of African Americans to Family

Health Histories, is part of the HBFP and was designed to explore the utility of family health

histories in identifying and targeting at-risk individuals in the African-American communities in

Pittsburgh.

The increasing knowledge in human genetics has been predicted and indeed has already begun to

shift the priorities in some areas of medicine, particularly in preventive medicine, internal

medicine, and oncology practice toward a genetically based, individualized preventive medicine

(Collins, 1999; Prevention, 2003). Currently, hundreds of genetic tests are now available to

confirm a suspected underlying genetic predisposition to a particular disease. Health care

providers are being "re-educated" and trained to incorporate genetic information in their delivery

of health care. Moreover, the general public is becoming more aware of how an underlying

genetic susceptibility can be a major contributing factor of illness (Prevention, 2004a). To date,

however, DNA-based genetic testing is limited for the most part to analysis of highly penetrant

single gene disorders that account for about 5%-10% of the total disease burden in the general

population (Yoon et al., 2002). The application of genetic medicine to understanding the

interplay of environment, lifestyle, and genetic factors may be better understood through the

family health history.

Family health histories can provide important clues as to how traits are clustered within families and how they are passed through generations. Family health histories can also be used to document other important individual risk factors, such as smoking, unhealthy diets, and physical inactivity by recording information on these risk factors. The family health history is an evolving record that can be used to keep track of the health information in a family across multiple generations and variations among and within people from different racial and ethnic backgrounds. More importantly, family health history can play a critical role in early diagnosis, lay the foundation for accurate risk perception, and appropriately identify at-risk individuals for targeted, risk-reducing interventions (Guttmacher et al., 2004).

The knowledge and number of multiple affected family members who have chronic conditions may raise questions and/or increase awareness of other family members about their own risks. Apart from the emotional issues related to the occurrence of a serious disease in a family, questions related to the cause of the disease, the risk of developing the disease, and the ways to prevent disease, are of increasing importance to individuals and their families (Collins, Halliday, Warren, & Williamson, 2000). Risk perception can be a significant factor in an individual's compliance with recommended screening behaviors and other risk-reducing strategies for moderate- to high-risk populations.

The purpose of this study was to investigate risk perceptions of African Americans for several common conditions, including type 2 diabetes, heart disease, Alzheimer's disease, and cancers of the breast, colon, ovary, prostate and lung. The study tested the null hypothesis of no difference in risk perception after completion of family health history. We considered demographic

characteristics that may influence risk perception, including gender, age, education, and income as well as several other factors including self-reported health status, self-reported knowledge of genetics, provider status, and insurance. The educational intervention of conducting a family health history (a one-to-one interview of the participant's family health history), reviewing the patterns of disease in the family, and providing an objective assessment of risk provided participants with information about the value and importance of family health history and other risk factors in disease susceptibility. The alternative hypothesis was that following the family health history, participants would have a more accurate perception of their risk for chronic disease.

An added advantage is that the family health history also provided an opportunity to discuss with participants the availability of prevention services. Identifying moderate- and high-risk individuals through the family health history may be a motivating factor for individuals to take action on lifestyle changes. For example, participants may be more likely to consider the importance of modifying risky behaviors, such as smoking or physical inactivity, and to become engaged in risk reduction programs. As a result, participants who share their health history information with family members and their health care providers may be more motivated to engage in health promotion and lifestyle changes as a way to avoid developing the same diseases that affected their family members. This form of community engagement and health education can make an important contribution in the *Healthy People 2010* objectives to improve the quality of health for all Americans and eliminate health disparities. This paper focused on identifying at-risk individuals in the African-American community through the use of family health histories

and assessing changes in disease risk perception brought about by informing these individuals of their family health histories.

1.2. BACKGROUND AND SIGNIFICANCE

1.2.1. Racial and Ethnic Health Disparities

According to the 2000 U.S. Census, African Americans account for about 12.7% of the country's population, while whites account for the majority (84%). Other populations, such as Asians, American Indians, and Pacific Islanders, account for a significantly smaller percentage (6.3%) (Census, 2000). In Pennsylvania, African Americans account for 10.4% of the population. In the city of Pittsburgh, located in Allegheny County, blacks account for the city's largest minority population of 24.7% (Pittsburgh, 2002). There are neighborhoods within the city of Pittsburgh, in which the percentage of the population that is African American is well over 50% (Pittsburgh, 2002). For many health conditions, blacks bear a disproportionate burden of disease, injury, death, and disability. Although the top three causes (heart disease, cancer, and stroke) and seven of the ten leading causes of death are the same for blacks and whites, the risk factors and incidence, morbidity, and mortality rates for these diseases and injuries often are greater among blacks than whites (Prevention, 2004b, 2004c, 2005).

In 2002, the State Department of Health in Pennsylvania released their *State Health Improvement Plan: Special Report on the Health Status of Minorities in Pennsylvania, 2002,* its first report on minority health, which utilized both epidemiological and qualitative data to document whether disparities exist in Pennsylvania (Department of Health, 2002). The report, in particular, noted

that African American women in Pennsylvania have higher death rates for breast cancer (43.2 per 100,000 for black women compared to 28 per 100,000 for white women). The prevalence rate for diabetes among adults in the state was reported as 12% for blacks compared to 7% for whites. However, African Americans with diabetes had more significant complications related to their disease compared to whites. In Pittsburgh, Pennsylvania, the diabetes death rates for African American male and females is almost twice as high as it is for whites. These figures underscore the differences in health status and the unequal burden of disease among African Americans in Pennsylvania, including in Allegheny County and the city of Pittsburgh, as compared to whites. While access to medical care may be a significant contributing factor to these health differences, the awareness among African Americans of risk factors, such as family history, as well as the preventability of many of these diseases may be lacking.

1.2.2.   Family History as a Screening Tool

"The family history is the gateway to identify individuals at risk

for genetic disorders" (Bennett, 2004)

The Human Genome Project has produced immense amounts of important genetic information and has taught us much about why some populations/groups live longer and in better health than others. In addition, the Human Genome Project has provided invaluable information of use in improving health disparities among minority populations. However, this topic of genetically-based racial or ethnic differences has been controversial because of the long and troublesome history of race in America (Anderson & Nickerson, 2005). Despite the controversy, the potential

value of the family health history screening tool, which takes into account racial and ethnic background, is two-fold: people can make more informed decisions about their health and the family health history has the potential to provide ethno-specific predisposition information (Bonham, Warshauer-Baker, & Collins, 2005).

The scope of family history information ranges from knowing that a parent, sibling, or child (first-degree relatives or FDRs) had a particular disease to a detailed pedigree analyses about specific diseases and ages at onset, and ages and causes of death for first-, second-, and even third-degree relatives. Second-degree relatives (SDRs) are described as half-siblings, nieces and nephews, grandparents, aunts and uncles, and grandchildren. Third-degree relatives (TDRs) are described as first cousins, great aunts and uncles, and great grandparents. A detailed family health history should include a three-generation *pedigree*, or family tree, including ages of family members, specific disease and ages at onset for affected family members, and ages and causes of death (Bennett, 2004).

Arguably, both the general public as well as many health professionals may not be aware of the risks associated with family history. For specific diseases, family health history reflects the consequences of underlying genetic susceptibilities, shared environment between family members, and common behaviors (Yoon et al., 2002). The interactions between genes and environment place many individuals and ethnic groups - including Africans Americans - at increased risk for multifactorial conditions such as diabetes, cardiovascular disease, and cancer.

Generally, a family history of a common, chronic disease is associated with relative risks ranging from 2 to 5 times those of the general population (King, Rotter, & Motulsky, 1992; Scheuner, Wang, Raffel, Larabell, & Rotter, 1997; Yoon et al., 2002). Relative risk increases with an increased number of affected relatives and earlier ages of disease onset (King et al., 1992). Epidemiological evidence suggests that family health history by itself is most useful for predicting disease when there are multiple family members affected, there is early onset of disease, and the relationship of relatives is close (Table 1) (Yoon et al., 2002).

Table 1. Prevalence and relative risk estimates due to family history for selected diseases

Disease	U.S. Prevalence of the disease	Risk due to family history
Cardiovascular disease	38 million	OR=2.0 (one FDR)
		OR=5.4 (2 or more FDR with onset < 55 years)
Breast cancer	3 million women	RR= 2.1 (one FDR)
		RR=3.9 (3 or more FDR)
Colorectal cancer	Yearly incidence = 130,000	OR =1.7 (one FDR)
		OR=4.9 (2 FDRs)
Prostate cancer	Yearly incidence = 200,000	RR=3.2 (one FDR)
		RR=11.0 (3 FDRs)
Type II diabetes	13 million	RR=2.4 (mother)
		RR=4.0 (maternal and paternal relatives)
Hypertension	65 million*	Data not available
Alzheimer's disease	4.5 million **	Data not available

Note: Table adapted from Yoon et al, 2002. Statistics reported from American Heart Association* and the Alzheimer's Association**

It has been shown that knowledge of family history and associated risk factors for chronic diseases may improve the efficacy of existing screening programs. The identification of individuals at increased risk to develop common diseases may result in increased participant compliance with recommended screening guidelines and therapies (Scheuner et al., 1997). Many

community-based programs throughout the United States that screen for chronic diseases or risk factors tend to target only a single disease (e.g., heart disease or diabetes) or a single risk factor (e.g., cholesterol or glucose) at a time. Hunt and colleagues (2003) noted that because an estimated 45% of families have a positive family history of one or more common chronic diseases, taking a family health history can capture information about multiple diseases and risk factors simultaneously (Hunt, Gwinn, & Adams, 2003).

1.2.2.1.   Family health history and classification into risk groups

Family history of disease is important not only because it is an independent predictor of future disease incidence, but also because it defines the relatively small subset of families within the population that account for most of the cases (Hunt et al, 2003). A number of methods have been proposed for quantifying the risk associated with family history of disease (Yoon et al., 2002). The family history score (FHS) developed by Hunt and colleagues compared a family's age- and sex-specific disease incidence to that expected in the general population in order to predict the future disease incidence in unaffected family members (Hunt, Williams, & Barlow, 1986; Yoon et al., 2002).

In another approach, Scheuner and colleagues (1997) proposed a classification system that stratifies risk into three groups: high, moderate, and average (general population risk) (Table 2) (Scheuner et al., 1997). This method of assigning risk takes into consideration the age at onset of a disease, the number of affected relatives, and their relationship to the patient. Scheuner et al. (1997) collected family history data on 400 healthy individuals for 8 chronic conditions: heart

disease, stroke, diabetes, and cancers of the colon, breast, endometrium, ovary, and prostate.

They found that most individuals had an average (general population) risk for these conditions.

Approximately 5%-15% of the individuals were found to be at moderate risk and 1%-10% were

found to be at high risk. In this study, we used the classification system developed by Scheuner

and colleagues to identify participants who would fall into these risk strata (high, moderate, and

average).

Table 2. General guidelines for risk stratification

High Risk	Moderate Risk	Average Risk
1. Premature disease* in a FDR. 2. Premature disease in a SDR (coronary artery disease only). 3. Two affected FDRs. 4. A FDR with late/unknown onset of disease and an affected SDR with premature disease from the same lineage. 5. Two SDRs (maternal or paternal) with at least one having premature onset of disease. 6. Three or more affected maternal or paternal relatives. 7. The presence of a "moderate risk" family history on both sides of the pedigree.	1. A FDR with late or unknown disease onset. 2. Two SDRs from the same lineage with late or unknown disease onset.	1. No affected relatives. 2. Only one affected SDR from one or both sides of the pedigree. 3. No known family history. 4. Adopted individual with unknown family history.

Note: Table adapted from Scheuner et al., 1997. *Premature disease: coronary artery disease onset ≤ 55 yrs in males, ≤ 65 yrs in females; stroke, noninsulin-dependent diabetes, colon and prostate cancer onset ≤ 50 yrs; breast, ovarian and endometrial cancer onset premenopausal onset ≤ 50 years. Pedigrees demonstrating clustering of different primary cancers consistent with a family cancer syndrome were high risk.

The Scheuner risk stratification can be used to guide and inform prevention activities (Figure 3)

(Yoon, Scheuner, & Khoury, 2003). Yoon and colleagues (2003) developed a proposed

framework for using family health history to guide and inform prevention activities. While this

preliminary model has yet to undergo an extensive scientific review and validation process, it

provides some insight as to how family health history information may be used by clinicians and public health professionals.
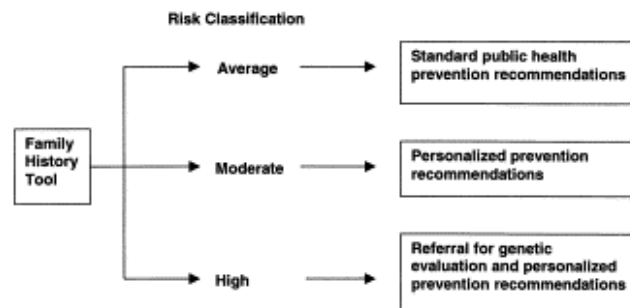
Note: Figure from Yoon et al, 2003

Figure 3. Proposed scheme for using family history to guide and inform prevention activities

Individuals who have a risk equal to the general population (average risk) would be advised to follow the standard public health recommendations for maintaining good health. Individuals with an increased risk to develop disease (i.e., moderate and high risk) would be provided with personalized prevention recommendations, based on their family health history, that might include an assessment and modification of risk factors, lifestyle changes, early detection strategies, and chemopreventive therapies (e.g., aspirin for cardiovascular disease or oral contraceptives for ovarian cancer) (Yoon et al., 2003). For those individuals found to be at high risk, based on their family health history, genetic consultation to discuss an inherited disorder might be recommended. These individuals could well benefit from genetic counseling, education, and genetic testing, as well as appropriate screening and preventions. Such individuals would be well advised, in most cases, to inform their relatives as to the results of such counseling and testing and to have their family histories re-evaluated periodically.

1.2.2.2.   Validation and utilization of family health history

Because complex and complicated tools are generally prone to fail, a family health history

screening tool designed for public health use should be simple, easily applied, and inexpensive.

Yoon and colleagues (2002) suggested that criteria for inclusion of diseases would include the

accuracy with which the disease could be recalled, the prevalence of the disease in the

population, the risk associated with family history, and the availability of effective early

detection and prevention measures (Yoon et al., 2002).

<u>Accuracy of Reported Family History</u>

Family health histories depend heavily on the accuracy of reported information and for that

reason, the actual accuracy of reported family histories has been measured repeatedly. Several

studies have reported on the accuracy of recall of family health history for a variety of different

conditions, such as coronary heart disease, diabetes, and several cancers. Moreover, multiple

approaches have been used to examine the reliability of reported family health histories. Kee

and colleagues (1993), for example, performed a case-control study involving 174 cases, in

which reported histories of FDRs were validated using death certificates, physician records, and

hospital records. The sensitivity, positive predictive value, and specificity of a reported history

of myocardial infarction in FDRs were 67.3%, 70.5%, and 96.5%, respectively (Kee et al., 1993;

Scheuner et al., 1997). The reported figures for the cases did not differ significantly from the

corresponding figures for the 175 controls (68.5%, 73.8%, and 97.7%, respectively).

In another study, Kahn and colleagues (1990) assessed the accuracy of family history reporting for diabetes among Hispanic and non-Hispanic white cases and controls interviewed at clinic visits. The reported family histories were validated by interviewing family members. Kahn et al. found that there was complete agreement between the information given by the proband (patient/individual providing the family history information regarding diabetic status and answers provided by family members (Kahn, Marshall, Baxter, Shetterly, & Hamman, 1990; Scheuner et al., 1997).

In the case of cancer many screening and prevention strategies, providers rely on accurate family health history information since inaccurate information could potentially result in inappropriate care. In 1985, Love et al. (1985) assessed the accuracy of a family history of cancer. In order to assess the accuracy of a family history of cancer, Love and colleagues (1985) compared pathology and operative reports, hospital admission and discharge summaries, death certificates and autopsy reports to patient reports. The accuracy of cancer site identification by the participant was 83.7% in FDRs, 71.3% in SDRs, and 71% in TDRs (Love, Evans, & Josten, 1985; Scheuner et al., 1997). Verification of negative family histories was not performed.

More recently, Murff and colleagues (2004) performed a meta-analysis on the accuracy of family cancer history. This meta-analysis focused specifically on cancers commonly encountered by primary care physicians and whose management might be altered based on family health history information (Murff, Byrne, & Syngal, 2004). Murff et al. reviewed articles between 1966 and 2004, with a verified positive family history of cancer for several specific cancer sites (breast, colon, ovarian, endometrial, and prostate cancers). Verification methods performed included a

review of identified relatives' medical records, physician records, or death certificates, and/or verification within a population cancer registry. Based on the evaluation of 15 studies, Murff et al. found that individuals with personal histories of cancer tended to report family histories with a greater positive predictive value (Murff et al., 2004). The findings suggested that for cancers with an identified gene or genetic susceptibility, such as breast/ovarian and colon cancers, the cancer family histories are likely to represent true positives and true negatives for the disease. However, it should be noted that for other cancers with a familial disposition reporting may be less accurate.

In addition to recollection about diseases in the family, ages of onset of those diseases for affected family members can provide important clues with regard to hereditary transmission. Parent and colleagues (1997) evaluated the accuracy of reports of ages at diagnosis of breast cancers in first-degree relatives (Parent, Ghadirian, Lacroix, & Perret, 1997). They confirmed diagnoses by pathology records and compared reports of breast cancer events among 125 FDRs by 68 women with breast cancer and 37 women without the disease. The accuracy of reported ages of onset was remarkable. Both groups reported greater than 90% accuracy of the reports of the occurrence of breast cancer in relatives. Moreover, nearly 89% of the reports of age at diagnosis were correct within 5 years. The average error in the reports was 2.0 years. This study suggested that accuracy of reports of both diagnoses and ages of onset in FDRs are sufficient to assess breast cancer risks for family members (Parent et al., 1997).

In the aggregate, these studies suggest that the accuracy of family health history tends to be better when concerning FDRs compared with SDRS and TDRs. But, overall, these studies have

suggested that a family health history report can generally be used with a high degree of accuracy for the identification of individuals in the population who may be at increased risk for developing disease (Scheuner et al., 1997).

Utility of Reported Family History

As with any scientific tool, the use and application of the family health history must be clinically and scientifically valid as well as socially ethical. In 2000, the Secretary's Advisory Committee on Genetic Testing (SACGT) recommended a process for assessing the benefits and risks relative to genetic tests. [Note: In 2004, this committee was reformed and is now known as the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS)]. The four components included analytic validity, clinical validity, clinical utility, and ethical, legal, and social issues that influence both validity and utility. These factors have also been considered when developing and implementing a screening tool based on family health history in the general population (Bowen, Ludman, Press, Vu, & Burke, 2003; Rich et al., 2004; Yoon et al., 2003; Yoon et al., 2002).

Analytic validity refers to how accurately and reliably the family health history tool identifies disease among a person's relatives. Analytic validity involves two specific measurements: *sensitivity* and *specificity*. Sensitivity is a measure of how well the family health history identifies relatives who [verifiably] have the disease, and specificity is a measure of how well the tool identifies the relatives who do not have the disease. As described, several studies have attempted to measure the sensitivity and specificity of family health history instruments or the accuracy of family health history reporting by interviewing relatives and conducting medical

24

record interviews, and have shown that reported family histories in general have both good sensitivity and specificity, particularly for FDRs and SDRs.

Clinical validity refers to how well family health history can be used to stratify disease risk and to predict future disease in a person. The important elements of clinical validity are positive and negative predictive values. These measures refer to the probability that a person will develop or not develop disease given that they have a positive or negative family history, respectively. Like predictive genetic testing, a family health history tool is used to estimate the probability that a person will develop disease.

For many of the common conditions where the causative genes are less penetrant, a positive test means that there is an increased probability of disease but that development of disease may be influenced by other genes and environmental factors. Likewise, with a positive family history, a person may be at an increased risk for disease greater than that of the general population, but the interaction of genetic and environmental factors will ultimately determine whether or not the person develops a disease. The present study examines how the family health history can be used in the African American population to detect patterns of disease. The Scheuner risk classification system is utilized as the basis for clinical validity in this study (Scheuner et al., 1997).

Clinical utility of family health history information depends on the impact and usefulness of the family health history tool for individuals, families, and society. Family health history information can be used to, not only to identify at-risk individuals, but also raise awareness of

risk and positively influence health behaviors. With clinical utility, perhaps the most important issue is whether family health history information can be used as a motivator to change behavior. One factor that may influence health-related behavior change is risk perception. Risk perception will be discussed in more detail in the following section.

Finally, the *ethical, legal, and social issues* refers to an assessment of the effect of knowledge of disease risk may have on people, particularly whether or not it may negatively impact individuals, families, and society. An example of *ethical, legal, and social issues* might include labeling a person as high or moderate risk for disease, which may have important psychological, social, legal, and economic costs.

Examples of potential psychosocial issues raised by family health history information may include fatalism, anxiety, depression, blame associated with collecting family health history information and stigmatization. These issues have been discussed in relation to genetic testing. However, no data are available to suggest that these unintended behaviors or feelings result from obtaining family health history or how commonly they may occur (Yoon et al., 2003).

Indeed, legal precedents relating to the failure of a physician to warn family members of a known family history of a hereditary condition have already been established. To date, three lawsuits, *Pate v Threlkel* (1995), *Safer v The Estate of Pack* (1996), and *Molloy v Meier* (2004), have been filed against physicians who did not inform a patient's family members of their increased risk for a disease based on a positive family history (McAbee, Sherman, & Davidoff-Feldman, 1998; "Molloy v Meier," 2004; Offit, Groeger, Turner, Wadsworth, & Weiser, 2004;

"Pate v. Threlkel," 1995; "Safer v. Estate of Pack," 1996).   In the genomic era, family health history and clinical testing will provide health care providers with the information necessary to predict disease occurrence. However, improved patient-provider communication and education is essential to maximize the benefits of genetic information and minimize the ethical, legal, and social complications that can potentially result.

1.2.3.   Family health history and its influence on risk perception

Risk perception is a very complex cognitive process influenced by a variety of factors and is unique to each individual (Yoon et al., 2003). Although there have been numerous studies on the relationship between risk perception and disease they have been general in nature. A review of the literature was performed to identify studies that discussed the influence of family history of hereditary conditions on risk perception. Table 3 summarizes several studies including the study purpose, disease of interest, participant characteristics, and findings.

In general, most of the studies identified drew from a sample of well-educated, Caucasian participants, with a family history of different conditions. And, many studies identified focused on individuals who had a family history of breast cancer. Other studies discussed risk perception of individuals with a family history of heart disease, colon cancer, or diabetes. Several of the studies are discussed in more detail about breast cancer, which reflects a general pattern of the effect of family history of common conditions on risk perception. There were relatively fewer studies on risk perception and family history of common diseases among African Americans (Green & Kelly, 2004; Royak-Schaler et al., 2002).

Table 3. Exploratory studies on impact of family history and risk perception

REFERENCES	STUDY POPULATION	PURPOSE OF STUDY	FINDINGS
(Royak-Schaler et al., 2002)	141 participants; 71 African American and 70 Caucasian FDRs with breast cancer	To investigate the relationship between breast cancer risk communication delivered by providers as well as patient knowledge, perceptions, and screening practices	Levels of perceived risk increased with conversations about family history and personal risk with providers; community-based FDRs had moderate levels of perceived risk
(Jacobsen et al., 2004)	176 males; 93% Caucasian 83 males had (+) family history; 83 males had (–) family history of prostate cancer	To explore whether men with a family history of prostate cancer perceive themselves to be more vulnerable to the disease and if they are more likely to undergo screening than men without a family history	Overall, men with (+) family history had heightened risk perceptions (50%), especially compared to men without family history, and were more likely to undergo prostate cancer screening
(LaRusse et al., 2005)	56 females with 29% lifetime risk estimates of developing Alzheimer's disease (AD) 36 (89% were Caucasian) in family history group and 30 (97% were Caucasian) in genotype group, APOE3 homozygous)	To explore the impact on risk perception of incorporating negative genetic test results into a risk assessment for late-onset AD compared to a family history-based risk assessment	The genotype group reported lower perceived risk and lower anxiety of developing AD as compared to the family history group; despite having the same lifetime risk estimates (29%)

Sagi and colleagues (1998) reported on the effect of genetic counseling in the hereditary breast cancer setting on knowledge and perceptions of risk (population, genetic contribution, and personal risks) (Sagi, Kaduri, Zlotogora, & Peretz, 1998). They found that prior to genetic counseling, most women tended to overestimate risks for breast cancer. After completing a genetic counseling session, they found that the risk estimates of participants were reduced; however, personal risk remained relatively high as compared to the risk assessments provided by the genetic counselor. The authors discussed that, "preconceptions that were changed by the counseling were affected only to a limited degree" (Sagi et al., 1998). Many women tended to overestimate their risks even after counseling. They described that "the phenomenon could be a

result of anxiety, or reflect the participant's inability to estimate risk figures." In addition, they suggested that many of the FDRs accompanied the individual to the oncology clinic and therefore may influence the participants' perceived risks (Sagi et al., 1998).

In another study, Watson et al. (1999) investigated the perceptions of genetic risk in women with a family history of breast cancer (Watson et al., 1999). This study also utilized genetic counseling with pre- and post-counseling assessments of risk perception. Similarly, Watson and colleagues determined that the majority of women were inaccurate in their estimates of the population risk of breast cancer and tended to overestimate their personal risk. They found that the risk estimates improved post-genetic counseling because women were provided estimates that were closer to the correct figure; however, after a 1-year follow-up, the correct risk figures were poorly retained since about half of the women tended to regress to inaccurate risk perceptions. The authors expressed concerns that a substantial minority did not benefit from genetic counseling because they continued to over-estimate their risk (Watson et al., 1999).

Other studies involving participants with a family history of breast cancer, colon cancer, or heart disease have arrived at similar conclusions in finding that individuals with a family history tend to overestimate risks. Hopwood et al. also investigated risk perception and cancer worry among women with a family history of breast cancer (Hopwood, Shenton, Lalloo, Evans, & Howell, 2001). They found that women who lost their mother before the age of 10 years were less likely to overestimate their personal risk. These studies demonstrate that risk perception can be influenced by family health history in specific hereditary conditions. Moreover, under certain

circumstances, risk perceptions can be closer to the correct risk figure, while in other cases, such perception may be either inflated or underestimated.

It is important to note that only a limited number of studies have focused on individuals in the African American population in order to explore their risk perceptions for hereditary conditions. Lipkus and colleagues (1999) reported on the risk perceptions of African American women with and without a family history of breast cancer (Lipkus, Iden, Terrenoire, & Feaganes, 1999). They found that women with a family history had greater perceived breast cancer risks than women without a family history of breast cancer.

Green and Kelly (2004) explored colorectal cancer (CRC) knowledge and perceptions of African American participants (n=100) (Green & Kelly, 2004). Although family history was not a primary criterion for participation, the study was guided by the Health Belief Model. Questions on risk perceptions were discussed in terms of "perception of threat." In general, Green et al. found that the majority of individuals had an inadequate knowledge about CRC. Men tended to believe that they were more susceptible to threat of CRC than did women; while women tended to perceive CRC as more severe than did men. The study did not determine the influence of family history independent of other factors on participant's perceptions of CRC disease threat. Nonetheless, it provided some insight as to how certain African American men and women perceive the threat of developing CRC. These perceptions have important implications for individuals' willingness to participate in recommended screening behaviors as well as their willingness to modify unhealthy lifestyles.

2.   SPECIFIC AIMS OF STUDY

This study explored risk perceptions of African Americans toward several chronic diseases. The specific aims of the study were: 1) to develop the family health history study and determine the demographic characteristics of our study participants, 2) utilize survey data and family health histories to determine how risk perception is influenced by knowledge of family health history information, 3) to explore the clinical utility of family health history to identify individuals who have a moderate and high risk to develop chronic diseases using the Scheuner classification system, and 4) to determine the accuracy of an individual's risk perception compared to objective risk assessment (Scheuner et al., 1997).

The study design compared pre and post family health history intake risk perceptions to the Scheuner risk classification scheme. Participants were provided with public health information and opportunities for screenings of chronic diseases identified through their family health history. This study will focus on a subset of the overall study information. The scope of this paper focused primarily upon participants' risk perceptions of heart disease and colon cancer because of the disproportionate morbidity experienced by African Americans in relation to these conditions, as well as the overwhelming opportunity to educate participants about screening and prevention opportunities.

3. STUDY DESIGN AND METHODS

3.1. FAMILY HEALTH HISTORY INTERVIEW

In 2003, The Center for Minority Health in the University of Pittsburgh's Graduate School of Public Health established the *Healthy Black Family Project* (HBFP), a program designed to promote health and prevent disease in the black community. Our strategy was to use the family health history to increase awareness of the disease patterns in the family and identify individuals who may be at increased risk to develop those conditions.

The structure of the family health history interview was based on peer-reviewed recommendations of The Pedigree Standardization Task Force (PSTF), a committee formed through the National Society of Genetic Counselors (NSGC), which also involved the Pacific Northwest Regional Genetics Group, and the Washington State Department of Health, Maternal Infant Health and Genetics. They developed standardized human pedigree nomenclature and guidelines on recording a family health history (Table 4) (Bennett et al., 1995). The family health history sessions involved genetic counseling students interviewing participants in one-to-one conversations about their family health history. During the interview, participants were asked a series of questions about the people who are members of their families, what health conditions do/did these individuals have, what ages they were diagnosed, the ages and causes of death, and ethnic background for both maternal and paternal families (**Appendix A**).

Table 4. Recommended factual and health information to include in a pedigree

- Age/birth date or year of birth
- Age of death
- Cause of death
- Pregnancy with gestational age (LMP) or estimated date of delivery (EDD)
- Pregnancy complications with gestational age noted (i.e. 6 wk, 34 wk), miscarriage (SAB), stillbirth (SB), and pregnancy termination (TOP)
- Infertility vs. no children by choice
- Relevant health information (i.e. height, weight)
- Affected/unaffected status (define shading of symbol in key/legend)
- Testing status ("E" is used for evaluation on pedigree and defined in key/legend)
- Ethnic background
- Consanguinity (note degree of relationship if not implicit in pedigree)
- Date pedigree taken or updated
- Name of person who took pedigree and credentials (MD, RN, MSW, CGC)
- Key/legend

Genetic counseling students hand drew and recorded the family health history information as provided by the participants. Upon completion of the family health history intake, the genetic counseling students reviewed and assessed the participant's pedigree. The students' risk assessments were based on the guidelines developed by Scheuner and colleagues for stratifying risk based on family health history information for specified conditions. The students discussed with participants what their modified risks were based on the family health history assessment.

After the interview, participants were provided a copy of their hand-drawn pedigree. They were encouraged to share the information with their family members and to verify the accuracy of the information. Participants were offered the option of also receiving a PROGENY® computer-generated copy of their family health history by mail. The participants had to give contact information to the research team in order to receive a computer-generated copy of their family health history. Participants were also encouraged to contact the research team if any information changed in their family health history and if they wanted additional copies of the family health

history to share with family members and/or their health care providers. Those participants who requested a computer-generated copy of their family health history were also mailed a certificate of completion (**Appendix B**). In addition, individuals who provided their contact information received educational materials developed by various organizations, such as the American Cancer Society (ACS), American Heart Association (AHA), National Institutes of Health (NIH), and other organizations, as related to their family histories (**Appendix C**). Finally, information on free local health screenings, health fairs, health insurance assistance programs, and weight management programs were mailed to individuals who provided their contact information.

The family health history interview process was pilot-tested at a CMH-sponsored community event in April, 2004 during National Minority Health Month. The event focused on cancer genetics and was targeted to the African American community. A total of 43 registrants attended the event, of which 25 individuals completed the family health history interview. Of those individuals who participated in the family health history interview, 17 (68%) individuals had a history of cancer and three individuals (12%) were found to be at significantly increased risk for different hereditary cancers (one for breast/ovarian cancer, one for prostate cancer, and one for colon cancer) based on review of participants' family health histories (Thull & Vogel, 2004). Subsequently, these individuals were referred to a certified genetic counselor that specialized in cancer genetics. The remaining individuals (n=5) did not have a significant family history of cancer.

Based on the experiences with the pilot test, refinements were made and a survey instrument was developed to explore participant's perceptions of their risk for different conditions. In addition,

the survey explored the effects of providing an accurate assessment of individuals' risks as well as participants' interest in enrolling in a recruitment database to receive information on clinical research studies that would pertain to their family health history. The University of Pittsburgh's Institutional Review Board (IRB) approved the family health history questionnaire that was used to gather family health history information from participants (**Appendix A**). Genetic counseling students did not ask certain questions on pregnancy history (e.g., any pregnancy complications or terminations of pregnancy).

3.2.   SURVEY INSTRUMENTS

In the absence of a validated risk perception survey instrument, a literature review was performed to identify common themes and questions related to self-reported relative and absolute risk perception. The databases PUBMED and PSYCINFO were queried from 1994 onward using the key words *risk perception*, *family* history, and *questionnaire* and *risk perception* and *African Americans* in combination. Limitations of the query were English language and human subjects. Articles were identified that involved the administration of questionnaires. Additional references were identified through bibliography searches. Several authors were contacted via email and asked if they would be willing to provide a copy of their survey instruments (Hopwood, Howell, Lalloo, & Evans, 2003; Hopwood et al., 2001; Royak-Schaler et al., 2002). The research team reviewed the survey instruments and developed a set of questions based on consensus. The survey was pilot-tested among staff within the Center for Minority Health among 10 individuals, and refinements in wording, organization, and structure were made by the research team.

3.2.1.   Pre-session Survey

The pre-session survey was designed to collect demographic characteristics, general family health history information, and data about participant's perceptions of risk for selected chronic diseases in the general population as well as personal risk (**Appendix E**). The pre-session survey also explored participants' beliefs about risk factors for disease and included a history of smoking, poor diet, physical inactivity, and family history. The pre-session survey had a total number of 20 questions and took approximately 15-20 minutes to complete.

3.2.2.   Post-session Survey

The post-session survey included two questions on participants' perceptions of personal risk. The post-session survey was designed to assess whether there were any changes in the participant's risk perception by using the identical [two] questions asked in the pre-session survey (**Appendix F**). The post-session survey also explored factors contributing to participants' interest in participating in research and willingness to be included in a research recruitment database. However, the exploration of factors relating to an individual's willingness to participate in the research recruitment database is not reported in this study. The scope of this study is limited to risk perception. The post-session survey took approximately 15 minutes to complete and had a total of 15 questions.

3.3. PARTICIPANTS AND PROCEDURE

Participating individuals were volunteers recruited at forums from the general population of the greater Pittsburgh, Pennsylvania area, in Allegheny County. Based on the demographic characteristics of Allegheny County, we attempted to recruit 300 participants, stratified by gender and race; however we recruited 134 participants. Efforts were made to over-sample for African Americans (Table 5). Participants were eligible if they were 18 years or older, spoke and read English, and were able to provide meaningful informed consent (i.e., able to articulate study purpose and the risks and benefits of study participation).

Table 5. Recruitment sampling plan

Participant Stratification	Male	Female
Caucasian/White	50	50
African American/Black	100	100

The research team, including the genetic counseling students who served as interviewers on the study, conducted the family health history interview and administered the surveys by working through the network developed by the CMH. Interviewers contacted and attended meetings with church leaders and health ministries of local black churches, organizers of community health fairs, and owners of barbershops and beauty salons, in neighborhoods throughout the greater Pittsburgh area with predominantly African American populations. The individuals were informed about family health histories and potential participants were offered the opportunity to have their family histories completed. Participation in the survey study was offered, and those who were interested completed the pre- and post-session surveys as described. There were a number of individuals (n=9) who completed the family health history interview, but who

declined to participate in the study. Data from those who completed the family health history interview only are not included in this study; therefore, the study population consisted of 129 individuals.

Upon completing these family health history session and surveys, church leaders and health ministries began to offer their congregations the opportunity to participate in the study. Many organizers of health fairs had not been offered the opportunity to complete the family health history because of the lack of opportunity to meet with them prior to the health fair event. In these cases, the genetic counseling students were participating on behalf of the CMH, as part of pre-committed opportunity for the CMH. The research team would request the opportunity to set up a recruitment table at church health fairs, in which the organizers had already completed their family health histories. Finally, owners of barbershops and beauty salons allowed the research team to distribute IRB-approved flyers and brochures at their shops. Additionally, brochures and flyers were distributed at Sunday church services and community fairs (**Appendix H**).

Brochures were developed by the genetic counseling students to emphasize the importance of family health history information (**Appendix H**). The brochures were distributed to individuals at black churches, health fairs, and barbershops and beauty salons. The brochures included a case example of colon cancer, contact information for the research team, and additional resources. The flyers described the opportunity to complete a family health history and "identify what you may be at risk for;" however, no particular health condition was emphasized in order to avoid recruiting individuals who had been diagnosed with particular conditions or who had an

interest in certain diseases. Participants were offered a $5.00 gift card for a local grocery store upon completion of the pre- and post-session surveys.

3.3.1.   Informed Consent

All study procedures, including the pre and post session questionnaires and format of the family health history interview, were reviewed and approved by the Human Subjects IRB of the University of Pittsburgh in May, 2004 (**Appendix D**). The informed consent procedure and research practices involving human subjects conformed to the ethical guidelines of the 1975 Declaration of Helsinki.

Genetic counseling students met with interested individuals to explain the aims of the study and the format of the family health history interview. Potential participants were informed of the risks and benefits of participation in the family health history interview and the optional two questionnaires. Individuals were informed that they had the right to refuse to answer any questions which were uncomfortable. In addition, potential participants were informed that the questionnaires were optional and informed that they would receive compensation for their time. Individuals were told that it would take approximately 30 minutes to complete the family health history interview. Participants would begin the pre-session survey following the informed consent process. The post-session survey was administered following the family health history interview and risk assessment. The entire process including the informed consent, pre-session survey, family health history interview, and post-session survey in total took approximately 1 hour.

Those participants who were willing to allow the research team to re-contact them were mailed education materials relevant to their family health history. For example, individuals who were at increased risk for stroke were provided materials from the American Heart Association on how to recognize the signs of stroke, the risk factors of stroke, etc. We mailed out individual information based on their family health history to all participants. In addition, when other programs, such as a weight management programs and free cancer and health screenings, became available, we would mail this information to those participants who agreed to allow us to re-contact them.

A phone follow-up questionnaire was designed to assess the extent to which participants shared their family health history information with their family members and/or health care provider(s) (**Appendix G**). Participants were asked if they would be willing to allow a member of the research team to contact them by phone one time, one month later for a post-family health history interview; however, the results of the phone follow-up were not analyzed for this study.

At the recruitment sites, sign-up sheets were available. Interested individuals signed up by providing their contact information and dates and times of availability. The genetic counseling students contacted these individuals up to a total of five times to schedule an initial appointment. The appointment was scheduled for an agreed upon day, time, and meeting place. Interviews took place at various locations including churches, the University of Pittsburgh campus, coffee shops, libraries, and occasionally at health fairs. In addition, family histories were also performed on-site at health fairs.

Based on the sign-up sheets from multiple recruitment locations, approximately 165 individuals had indicated an interest in meeting with a genetic counseling student to have their family health history recorded. Of these individuals who initially signed-up, forty-three were males and 119 were females. Three individuals had only provided their first and last name initials; therefore, we could not determine their sex. Of those who signed up, we were unable to contact 78 individuals. We were unable to contact twelve individuals because of a disconnected phone number and we attempted to contact sixty-six individuals but they were unreachable by phone.

An initial appointment was made with eighty-seven individuals who signed up at the recruitment site. For those scheduled, the genetic counseling students attempted to confirm appointments with participants one day in advance. Approximately 27 individuals had to be recontacted to reschedule their initial appointment because of "no-shows" or cancellations. Up to two attempts were made to reschedule these individuals. If these individuals did not show or had a history of canceling or rescheduling appointments repeatedly, they were provided with the research team's contact information and asked to call when they were available.

The remaining sixty individuals (11 males and 49 females) completed their family histories. Of those 60 individuals, 56 people completed the pre- and post-session surveys. Fifty-three of the 56 provided us with their contact information, so that we could do the phone follow-ups and also mail them health education materials. The remaining individuals completed their family histories at the recruitment site or had contacted us through referrals and were not listed on the sign-up sheets.

3.4. MEASURES

3.4.1. Demographic Characteristics

Socio-demographic information. The pre-session survey included socio-demographic questions to assess age, ethnicity, education, income, general perceived health, health insurance status, and whether or not the individual had a personal health care provider.

Family history. All participants were asked if they had a blood relative (mother, father, sister, brother, uncle, aunt, grandmother, grandfather) who had or has a health condition that the participant was concerned about developing sometime in his/her life. The number of affected first-degree relatives (FDRs) and second-degree relatives (SDRs) were determined based on the Scheuner risk classification system (Table 2) (Scheuner et al., 1997).

Recruitment setting. Participants were recruited through community settings or health-related events. Community settings included churches, senior centers, community fairs, barbershop/beauty salons, or word-of-mouth. Health-related events included health fairs.

3.4.2. Participant Characteristics

Knowledge of genetics. Each participant was asked to rate his or her knowledge on genetics. Options were: excellent, very good, good, fair and poor.

Discussions with health care provider. Participants were asked whether they had one individual whom they considered their personal doctor or health care provider. The options were: yes only one, more than one, no, or don't know. Since they were asked whether they had ever talked to a doctor or nurse about their concerns for developing a disease, responses were summarized as a binary variable (yes, no). Once an answer was selected, participants had the option of providing specific information about the health condition (qualitative assessment).

3.4.3.   Measured Perceptions of Risk

Knowledge of risk factors. Participants were asked how often they believed certain risk factors, smoking, poor diet, lack of exercise, and family history (described as other family members with a disease) contributed to an individual's chance or risk of developing a disease such as diabetes, heart disease, and cancer. Respondents had the option of choosing: never, sometimes, always, or don't know.

Perceptions of general population risks. In order to assess the knowledge about risks for specific conditions in the general population, participants were asked to provide their perceptions about the chance of a healthy woman and healthy man, the same age as the participant, to develop a particular condition some time in their life.

Pre-risk assessment perceived risks. Participants were asked to rate their perceived risks for nine chronic conditions (eight of which can have a significant genetic contribution in high risk families). These two questions were based on previous research questionnaires of others (Hopwood et al., 2001; Royak-Schaler et al., 2002). Participants indicated the extent to which

they believed themselves to be at risk for these conditions using a Likert-type scale ranging from 1 (Low=<10%), 2 (Moderate=10-50%), to 3 (High=>50%). Participants were also provided with the option to answer "don't know."

Post-risk assessment perceived risks. As described above, participants were provided with a post-session survey and asked to answer the same questions on relative and absolute risk perceptions for nine chronic conditions. The scale described previously (ranging from 1 to 3) was used. Participants were also provided with the option to answer "don't know."

Objective risk stratification. Based on the guidelines of Scheuner and colleagues, the research team used the objective criteria to stratify participants into average (general population risk), moderate, and high risk categories using their family histories. The guidelines were modified as two conditions were added, Alzheimer's disease (AD) and hypertension. Individuals were considered to be at high risk if they met the criteria for high risk based on a premature age of disease for AD $\leq$ 65 years. This definition of premature disease was based on the Alzheimer's Association and Alzheimer's Society descriptions of early-onset disease. Similarly, participants were stratified into risk categories for hypertension based on the guidelines and having an early-onset of disease cut-off of $\leq$ 50 years of age. This was a conservative estimate based on the guidelines for premature disease for non-insulin dependent diabetes and coronary artery disease. Two reviewers independently stratified the participants for the ten conditions using the guidelines. The reviewers reviewed all responses for which there were any discrepancies (57/1548), and a third reviewer stratified all responses for which there were any remaining

discrepancies (2/57). The final stratification of participants into each of these risk categories was determined by consensus among the three reviewers.

Pre- and post-correct risk assessment. Variables were created for each of the diseases of interest (cancers of the breast, ovary, colon, and prostate, coronary artery disease, type 2 diabetes, and Alzheimer's disease) in which participants correctly identified their risk as compared to the objective risk classification by Scheuner et al. Pre-correct risk assessment and post-correct risk assessment were assigned if an individual correctly identified their objective risk prior to and following the family health history interview and risk assessment, respectively. For example, individuals who correctly assessed their risk prior to the interview were "correct." Similarly, those who correctly identified their risk post interview were "correct." These risks were then compared to determine accuracy of risk perception pre and post family health history interview.

3.5. STATISTICAL ANALYSIS

Descriptive statistics were used to characterize the study population based on age, ethnicity, educational level, income, insurance coverage, knowledge of genetics, and perceived health status. Variables hypothesized to be associated with risk perception included perceived health status, education, insurance coverage, knowledge of genetics, perceptions of general population risks, and discussions with health care providers regarding concerns for developing a disease.

The total sample included 129 participants. Because of the overwhelming majority of African American participants, a total of four individuals were excluded from these analyses. Two of the

individuals excluded reported themselves to be Caucasian only, one individual was Asian, and one individual did not report his ethnicity or race. Therefore, these analyses will only focus on the African American participants. The research team's attempts to recruit Caucasian participants based on the recruitment plan were not met, although efforts were made to recruit individuals of any racial or ethnic background. The final study population included 125 African American men and women.

The demographic characteristics were tabulated using *Intercooled STATA Versions 8.2* (STATA, College Station, TX, 2004). As described, pre and post family health history risk perceptions were tabulated and categories were developed to assess how individuals' perceptions compared to the objective risk stratification by Scheuner and colleagues (Scheuner et al., 1997). Binomial tests were used to assess changes in risk perception pre and post family health history interview and to determine whether individuals' perceptions became more or less accurate following the family health history intervention and risk assessment.

<u>Exclusion Criteria for Specific Questions</u>

Participants were excluded from pre and post risk perception questions based on any of the following criteria: 1) gender, if the condition was sex-specific; 2) whether they responded to the question or responded "don't know"; or 3) personal history of a particular disease. All men and women were excluded from risk perception questions for ovarian and prostate cancer, respectively. Individuals who did not answer a question on risk perception or who had answered "don't know" were excluded from the analyses for those particular diseases. In the pre- and post-correct risk assessment categories, participants who did not answer both the pre and post

interview risk perception questions were excluded. Finally, participants were excluded for a particular risk perception question if they reported during the family health history that they had been diagnosed with a particular disease.

Forty-two individuals reported either on the pre/post surveys or during the family health history interview that they had been diagnosed with hypertension. However, two individuals did not identify themselves as having hypertension during the family health history interview. Therefore, forty individuals were excluded from the risk perception questions on hypertension. As described for hypertension, individuals who had been diagnosed with cancer of the breast, prostate, or colon, heart disease, or Alzheimer's disease were excluded from respective risk perception questions for those conditions. No individuals reported having a diagnosis of ovarian cancer. Participants' answers were included for all other diseases, unless they were diagnosed with any of the other specified conditions. For example, an individual could be excluded for more than one condition if he or she had more than one diagnosis. Table 6 summarizes the number of participants' (n=45) who reported being diagnosed with the any of the above conditions. Of the 45 participants with chronic conditions, 16 participants (36%) had more than one condition listed below. The remaining 29 individuals (64%) had only one of the specified conditions.

Table 6. Number of participants diagnosed with health conditions

Disease (n=45)	Affected (n)
Breast cancer	3
Ovarian cancer	0
Colon cancer	1
Prostate cancer	3
Heart disease	3
Type 2 diabetes	14
Alzheimer's disease	1
Hypertension	40

Table 6 illustrates that the majority of participants in this study had been diagnosed with hypertension (n=40) and type 2 diabetes (n=14). There were fewer individuals who had been diagnosed with certain types of cancer, including breast cancer. All of the affected individuals were excluded from pre and post risk perception analyses for diseases involving their specified diagnoses. The results section will focus on participants' risk perceptions for cardiovascular disease and colon cancer. We included only these two diseases for comparative purposes. However, all of the data for the participant's perceptions of risk have been summarized (**Appendix I**).

4.   RESULTS

4.1.   PARTICIPANT CHARACTERISTICS

The data reported here are from 125 study participants in the greater Pittsburgh area. All

personal characteristics were self-reported. Table 7 presents the participants' demographic

characteristics, general health, and knowledge of genetics.

Table 7. Characteristics of study participants

Participant characteristics (n = 125)	n (% of participants)
Sex	
Male	26 (21%)
Female	99 (79%)
Ethnicity	
African American Only	117 (94%)
Multiracial (African American And Other)	8 (6%)
Age	
≤ 50 years	67 (54%)
> 50 years	58 (46%)
Education	
High School Graduate Or Less Than High School	21 (16%)
Some College (1 To 3 Years)	52 (42%)
Bachelor's Degree	29 (23%)
Post-Graduate Education (MS, PhD)	24 (19%)
Income	
< $20,000	27 (22%)
$20K To $35K	29 (23%)
$35K To $50K	23 (18%)
$50 To 75K	16 (13%)
> $75,000	26 (21%)
General Health	
Good / Very Good / Excellent	98 (78%)
Fair / Poor	27 (22%)
Knowledge Of Genetics	
Good / Very Good / Excellent	52 (42%)
Fair / Poor	73 (58%)

Note: Percentages may not add to 100% because some participants did not provide answers for
certain characteristics.

All of the participants (n=125) described their race as African-Americans, with only 8

individuals (6%) describing themselves as multiracial. The median age of participants was 49

years with an age range from 22 to 88 years. Of the 125 participants, the vast majority of

participants were women (79%), had at least some college education (84%), and were in good

health (78%). Six individuals (5%) reported having less than high school education. The

household income for many participants (66%) was less than $50,000 annually, with 27

individuals (22%) being below the federal poverty-level. Most participants' (n=73) reported

their knowledge of genetics as fair to poor (58%), with only four individuals (3%) reporting their

knowledge of genetics to be excellent.

Participants were recruited through various settings. Figure 4 summarizes the recruitment sites

of participants. The majority of participants (n=87) were recruited through church locations

(70%), twenty individuals were recruited through health fairs (16%), and seven were recruited at

a long term care facility for the elderly (6%).
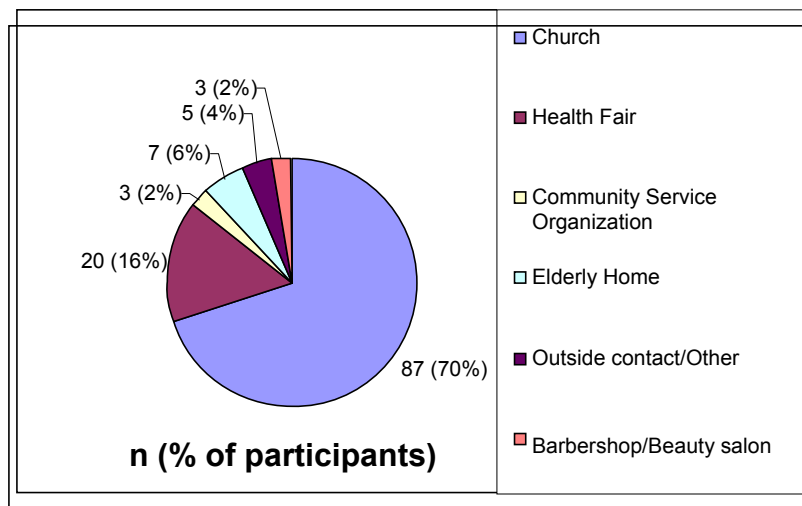
Figure 4. Recruitment Location

The long term care facility used as the recruitment site was the oldest continuously operated African American sponsored long term care organization for the elderly in the United States. Attempts were made to recruit more individuals from African American barbershops and beauty salons, but uptake was low (3%).

Table 8 summarizes the participant's insurance status and interactions with health care providers. Of the 125 participants, the majority (90%) reported having health insurance, had at least one individual whom they considered as their primary care provider (90%), and were not prohibited from seeing a doctor in the past 12 months because of costs (90%). Fifty-six participants (45%) reported that they discussed their concerns about developing a health condition with their health care provider in the past. Of these individuals, fifty-three participants reported discussing concerns about the following conditions with their doctors: diabetes (23%), cancer (26%) with reference to cancers of the colon, breast, and prostate, hypertension (11%) as well as related kidney complications, heart disease (7.5%) and stroke (4%). Other conditions that participants had concerns about were multiple sclerosis, sarcoidosis, mental illness, rheumatoid arthritis, polycystic ovary syndrome, and thyroid conditions.

Table 8. Participant's insurance and health care provider status

Characteristic	n (% of participants)
Health insurance	
Yes	113 (90%)
No	12 (10%)
Have primary care physician	
Yes, only one	75 (60%)
Yes, more than one	38 (30%)
No	12 (10%)
Did not see doctor due to cost	
Yes	12 (10%)
No	112 (90%)
Talked with doctor about concern for developing a disease	
Yes	56 (54%)
No	68 (45%)

Table 9 summarizes the stratification of patients based on their family history and the Scheuner objective risk guidelines. All of the parents were classified into one category for each of the specified conditions listed below. Among the conditions considered, participants were at increased risk for hypertension, coronary artery disease, and type 2 diabetes. For the majority of the conditions, most participants had risks comparable to the general population. The next section on risk perception will focus on the results from participants' perceptions of risk for heart disease and colon cancer.

Table 9. Participant risk stratification based on Scheuner guidelines (All conditions)

Disease	High risk (n, %)	Moderate risk (n, %)	Average (general population) risk (n, %)
Breast cancer	8 (6%)	8 (6%)	109 (87%)
Ovarian cancer	5 (4%)	1 (0.8%)	119 (95%)
Colon cancer	1 (0.8%)	7 (5.6%)	117 (94%)
Prostate cancer	0	12 (10%)	112 (90%)
Heart disease	52 (42%)	22 (18%)	51 (40%)
Type 2 diabetes	38 (30%)	25 (20%)	62 (50%)
Alzheimer's disease	3 (2%)	5 (4%)	117 (94%)
Hypertension	60 (48%)	24 (19%)	41 (33%)

4.2. RISK PERCEPTION

Participants' perceptions on general risk factors for disease, general population disease risk, and personal disease risk were explored. First, we explored participants' perceptions about general risk factors for disease. Figure 5 illustrates the results of participants' perceptions of smoking, poor diet, physical inactivity, and family history as risk factors that contribute to disease development. Overall, participants appeared to have a good understanding that smoking, poor

diet, physical inactivity, and having affected family members contribute in some way to the development of disease. Of the 125 respondents, the majority of participants perceived that smoking (73%), poor diet (62%), and physical inactivity (58%) *always* increase or contribute to the development of disease. Participants appeared to be less knowledgeable about family history as a risk factor for disease. Forty-four percent of participants (n=55) perceived that family history *always* increases the chance for the development of disease. Very few participants reported that smoking, poor diet, physical inactivity, or family history as risk factors *never* increase the risk for the development of a disease.
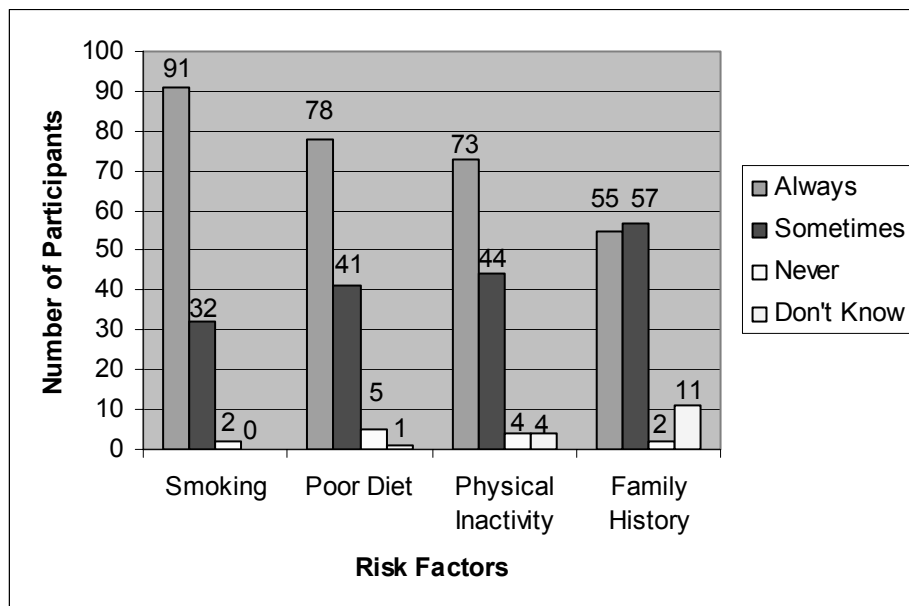
Figure 5. Participant's perceptions of known disease risk factors

4.2.1.   General Population Perceived Risks

All participants were asked to estimate the general population risks for men and women to develop cardiovascular disease (CVD) and colon cancer using a 3-point Likert. Table 10

describes the perceptions of participants on men and women to develop heart disease and colon cancer.

Table 10. Participant's Perceptions of General Population Risks for Men and Women

Disease	Men (n, % of Participants)	Women (n, % of Participants)
Colon cancer		
Actual General Population Lifetime Risk	**3-6%**	**3-6%**
Low (<10%)	14 (12%)	23 (18%)
Moderate (10-50%)	60 (48%)	63 (51%)
High (>50%)	47 (37%)	23 (18%)
Don't Know	3 (2%)	16 (13%)
Cardiovascular Disease		
Actual General Population Lifetime Risk	**35%**	**24%**
Low (<10%)	13 (10%)	16 (13%)
Moderate (10-50%)	46 (37%)	45 (36%)
High (>50%)	62 (50%)	51 (41%)
Don't Know	3 (2%)	13 (10%)

In the absence of a personal or family history, the general population lifetime risk for colon cancer in both men and women is 3-6% (Allen & Terdiman, 2003). Of the 125 participants, sixty-nine percent of participants (n=86) overestimated the risk of developing colon cancer for women in the general population, placing them at a moderate (10%-50%) or high (>50%) risk. A higher proportion of participants (85%) overestimated the lifetime risk of men in the general population to develop colon cancer.

Similarly, in the absence of a personal or family history of cardiovascular disease (CVD), the general population risk for men and women to develop CVD by age 70 is 35% and 24%, respectively (Wilson & Culleton, 2005). Approximately three-quarters (n=96) of participants perceived that women in the general population had a moderate to high risk of developing heart

disease in their lifetime and more individuals (n=108) perceived that men in the general

population had a moderate to high lifetime risk of developing CVD (Table 10).

4.2.2. Pre-and Post-Family History Session Risk Perceptions

Participants' perceptions on personal risks for the same chronic disease were also assessed in the

pre- and post-session surveys. The pre- and post-session responses were compared to the

Scheuner risk classification system. Table 11 summarizes participant's perceptions of their risks

to develop heart disease and colon cancer prior to and following the family health history

interview and risk assessment. Participants' responses were excluded if they had the condition,

if they responded d*on't know*, or did not answer the question. Therefore, the number of

participants will vary for each disease based on these exclusion criteria.

Table 11. Pre- and Post-Family History Session Risk Perceptions

Disease	Scheuner risk assessment	Pre-session	Post-session	% of participants changed from pre to post session
Colon cancer	N=125	N=112	N=119	
Low (<10%)	117 (93.6%)	57 (51%)	73 (61%)	+ 10%
Moderate (10-50%)	7 (5.6%)	43 (38%)	38 (32%)	- 6%
High (>50%)	1 (0.8%)	12 (11%)	8 (7%)	- 4%
Cardiovascular disease	N=125	N=117	N=119	
Low (<10%)	51 (40.8%)	32 (27%)	38 (32%)	+ 5%
Moderate (10-50%)	22 (17.6%)	58 (50%)	46 (39%)	- 11%
High (>50%)	52 (41.6%)	27 (23%)	35 (29%)	+ 6%

Prior to the family health history session, most participants perceived themselves to have a low

or moderate risk to develop colon cancer (low risk, n=57; moderate risk, n=43) and

cardiovascular disease (low risk, n=32)). After the family health history session, the majority of

individuals still perceived themselves to be at low or moderate risk for these disease. More

participants believe they were at low risk for both colon cancer (low risk, n=73) and

cardiovascular disease (low risk, n=38) than before the session. Fewer participants perceived

themselves to be at high risk for colon cancer; conversely, more participants perceived

themselves to be at high risk for CVD following the risk assessment.

4.2.3.   Correct Risk Perception

Participants pre- and post-session risk perceptions were compared to the Scheuner objective risk.

Accuracy of participants' responses were assessed to determine whether individuals had an

accurate perception of their risk to develop CVD and colon cancer prior to and following the

family health history interview. In addition, among those whose perceptions changed, responses

were assessed to determine whether their perceptions became more or less accurate following the

intervention (Table 12).

Table 12. Correct Risk Perception

Disease	Accurate (Pre & Post)	Inaccurate (Pre & Post)	Number of participants whose perceptions changed	Inaccurate to Accurate	Proportion	95% Confidence Interval
Colon cancer	53	30	26	19*	0.731	0.522, 0.844
Heart disease	28	49	38	28**	0.737	0.569, 0.866

Note: [a] Binomial tests were performed based on the null hypothesis that among participants whose perceptions changed, they were equally likely to become inaccurate or accurate; [b] Participants whose perceptions changed from inaccurate to accurate: $*p < 0.05$; $**p \leq 0.005$.

In general, more participants were accurate about their risks pre and post family history for colon cancer than heart disease. Among the participants who changed their perceptions (CRC, n=26; CVD, n=38), we found that individuals who were inaccurate prior to the family health history interview and risk assessment were significantly more likely to become accurate for colon cancer (p=0.028) and heart disease (p=0.005) following the intervention.

5. DISCUSSION

"One of the greatest challenges of preventive medicine is

conveying the notion of risk so that people can make informed

decisions about their health behaviors" (Yoon et al., 2003)

The unique value of these data lies in the interactions and discussions between participants and interviewers. This study explored the risk perceptions of African Americans for chronic diseases, specifically colon cancer and heart disease. The targeted population in this study were blacks because of the higher mortality rates of heart disease and colorectal cancer among other conditions experienced by this population compared to whites in Allegheny County (Department of Health, 2002). We examined whether family health histories could provide individuals with more accurate perceptions of risk for the development of such diseases. We were interested in raising awareness about family history as a risk factor for chronic diseases and empowering individuals with information on prevention strategies and recommended guidelines for preventive screening.

In this large cross-sectional study, we found that individuals were interested in learning *how* family history influences risk for the diseases found in their families. Our participants' perceptions of known risk factors for disease (i.e., smoking, poor diet, and physical inactivity) combined with the fact that they appeared to be less knowledgeable about the role of family history in disease highlighted the effects of public health education. The participants' lack of knowledge about family history as a risk factor may stem from a lack of public health and/or medical messages about family health history and disease, in general. Public health campaigns have generally focused attention on the negative effects of smoking, the importance of a healthy diet, and the necessity of moderate physical activity; however, public health has only begun to educate both medical professionals and the public on the relevance of a genetic family history as a contributor to disease (Services, 2004).

Assessment of family health history and identification of at risk individuals can be a powerful tool for both public health and medicine because of the clinical implications in early detection and management of many preventable diseases. Petersen and colleagues (1999) reported that those with a family history of a given disorder have been more likely to engage in disease prevention behaviors for that disorder (Petersen et al., 1999). Codori et al. (1999) found that a strong family history of colorectal cancer was associated with better adherence to sigmoidoscopy screening (Codori et al., 1999; Yoon et al., 2003).

There is empirical evidence which suggests that both primary (e.g., diet and physical activity) and secondary (e.g., screening and early detection) prevention strategies are effective means of reducing colorectal cancer and heart disease incidence and mortality (Hunt et al., 2003; James,

Campbell, & Hudson, 2002). Despite national recommendations and positive evidence, colon

cancer screening, for example, has not been widely adopted by the American public, and a

majority of people do not adhere to the guidelines (James et al., 2002). In Pennsylvania, the

2002 Behavioral Risk Factor Surveillance Study data showed that of respondents $\geq$ 50 years of

age, 20% had a fecal occult blood test (FOBT) within the year preceding the survey and 48.0%

indicated that they have had a sigmoidoscopy or colonoscopy (Prevention, 2004d).

Similarly, existing education and risk factor screening programs for heart disease prevention are

becoming less effective, which is evident in the leveling of downward trends of cardiovascular

disease in the U.S. (Wilson & Culleton, 2005). Public health and medicine need to become more

innovative at identifying ways to encourage individuals to utilize prevention programs.

From a public health perspective, our study is relevant because we provided participants in the

general public with knowledge about the importance of family history in disease development.

We emphasized that individuals should share their family health histories with family members

and health care providers. Sharing family health history information would subsequently

provide physicians with the opportunity to evaluate the information and focus the clinic visit on

screening, management, or recommendations for genetic counseling for those individuals

identified to be at moderate or high risk for multifactorial conditions (Frezzo, Rubinstein,

Dunham, & Ormond, 2003). In this study, based on the Scheuner risk assessment of family

health history, we found 8 individuals (7 moderate and 1 high risk) at elevated risk for colon

cancer and 74 individuals (22 moderate and 52 high risk) at elevated risk for heart disease.

Several studies have found that a health care provider's recommendation to undergo screening

has been shown to be one of the strongest predictors of completing a colorectal screening test, for example (Katz et al., 2004). The individuals identified in our study who were at increased risk could benefit from sharing their family health history information with their health care providers and following recommended screening practices for moderate and high risk populations.

In addition, understanding patients' perceptions of risk is another potential indicator for screening practices. Several studies have found that perceptions of elevated risk in diseases such as with breast and colon cancers were also positively associated with increased screening practices (McCaul, Schroeder, & Reid, 1996; Yoon et al., 2003). A meta-analytic review of 19 studies by McCaul et al. compared breast cancer screening among women with and without a family history of breast cancer (McCaul et al., 1996). They found that women were more likely to be screened if they had a family history. This study also evaluated risk perceptions related to breast cancer and engaging in breast cancer screening and found that elevated perceptions are also positively associated with breast cancer screening. Perceptions of risk related to family history have also been found to influence participation in risk-counseling programs. Documenting a family health history and making individuals more aware of their risks and providing them with information regarding available screenings and risk-reducing behaviors, may be more likely to increase screening practices (Scheuner et al., 1997) and reduce the disease burden.

Despite emphasis on collecting family health history data in family medicine and the more recent emphasis on taking a genetically-informed family history in internal medicine, physicians often

have barriers in obtaining family health history information (Rich et al., 2004). Often, discussions about family health history with patients may be limited, inaccurate, or nonexistent. When physicians have discussed family history with their patients, Watt et al. discussed that lay perceptions of family history can differ from clinical definitions (Watt, McConnachie, Upton, Emslie, & Hunt, 2000). Therefore, individuals in the general population may not fully understand the role of family history and disease development or may have a different understanding than the medical community, leading to inaccurate risk perceptions.

Prior to the family health history intervention, many of our participants tended to overestimate both the risk to develop common diseases in the general population and their own risk to develop heart disease and colon cancer. Our findings are consistent with reports that individuals in the general population tend to overestimate or misinterpret risks for the development of disease (Hopwood et al., 2003; Watson et al., 1999). However, a number of participants (n=19 for colon cancer and n=28 for heart disease) adopted a more accurate risk perception following the family health history interview. Our study highlighted that family health history can be a valuable tool for health care practitioners to identify individuals at elevated risk for certain diseases and is an effective tool in providing accurate risk perceptions.

Incidentally, we observed through brief examination of the data involving the one-month phone follow-ups with participants that many individuals have shared the family histories with other family members, and even some with health care providers (data not available in this thesis). This finding suggests that participants' want to learn more about their risks through dialogues with family members and health care providers, and are motivated to inform others.

As genetic information becomes widely used in clinical and public health settings, the onus will fall upon health care and public health professionals to communicate risks and promote acceptable prevention strategies to at-risk individuals or populations, respectively. Gradually, the clinical utility and validity of family health history in disease prevention is becoming more evident as observed by the ever-increasing discussions of its role in medicine and public health. However, the challenge still remains to identify ways in which to motivate individuals to engage in risk-reducing behaviors.

5.1. STUDY LIMITATIONS

Our study has several limitations. One limitation stems from the fact that our participants were self-referred and therefore did not represent a population-based sample. Our study focused its efforts on over-sampling African Americans in Pittsburgh by advertising the study as *The Healthy Black Family Project*. Recruitment efforts were targeted at locations primarily within the black community. Consequently, our study population is not reflective of the demographics of the greater Pittsburgh area.

Second, the study population may represent interested individuals who were highly motivated to record their family health histories. The individuals who agreed to complete the family health history interview and surveys may have had more family history knowledge than individuals who declined the study. Although the interview team of genetic counseling students informed all potential participants that knowledge of one's entire family health history was not a prerequisite,

the study may not have included individuals who were concerned, but had a lack of family history information.

Interestingly, we found that the proportion of individuals at high risk for colon cancer (0.8%) and cardiovascular disease (42%) were elevated compared to previous reports by Scheuner et al. (e.g., 0.2 % for colon cancer and 11.2% for cardiovascular disease). In the Scheuner study, approximately 22 individuals (or 6%) were African American. Scheuner and colleagues reported that depending on the specific disease, 5% to 15% of at-risk individuals had a moderately increased risk (2 to 5 times the population risk), and approximately 1% to 10% had a high risk (Scheuner et al., 1997). One explanation for our assessment of the study population is that verification of family health history information was not performed. The objective risk assessment may be altered if verification processes were performed in this study. Nevertheless, these potentially high risk individuals should be followed by their physicians and be encouraged to follow the recommended screening guidelines.

Another limitation is the fact that our data relies on participant recall rather than medical documentation. As discussed, verification of family health history information by medical record exam or interviews with family members may have altered the results of the Scheuner risk assessment.

Our study was not grounded in a major cognitive health behavior model. The questions used in our study were obtained from researchers identified in the risk perception literature, in future studies we could consider cognitive health behavior models, such as the Health Belief Model and

Common-Sense Model, to guide the research questions. This study may provide support for further exploration of a new model that utilizes family health history as a motivation for risk-reducing behavior modifications.

Lastly, we identified extraneous wording in some of the questions, which may have influenced participant responses. In the example provided below, the extraneous wording is bolded:

> "In your opinion, how often do you believe each of the following factors increases (or contributes to) an individual's chance or risk for developing a disease **such as diabetes, heart disease, and cancer?**"

We consider that the wording of the above question, in which we have provided a list of diseases, could have confused participants or altered their responses for this question. For example, some individuals may have responded to this question, with the notion that smoking *always* contributes to cancer, but is not related to the development of heart disease. Therefore, it would be equally important to recognize the limitations posed in certain questions by wording choices, as these have the potential to influence response rates.

5.2.   FUTURE PLANS

Decisions about health-related behaviors and the influences of risk perception and family history are complex. In the future, we would like to expand our study. This study design did not include a long-term follow-up of risk perception recall. Many studies have described short-term improvements in risk perception, in which individuals often revert to their initial misperceptions over a period of time. We could explore risk recall and whether participants' perceptions

remained accurate over time. Reversion of participants' risk perceptions would not undermine the importance of improvements in risk-reducing behaviors.

Additionally, we would like to explore the potential success that knowledge of family health history may have in generating risk-reducing behavior modifications, such as improved diet, increased physical activity, smoking cessation, and increased disease screening.

We will evaluate the follow-up questionnaires to determine the influences of whether individuals were likely to share their family health histories with family members and health care providers. For example, we would like to explore whether an individual's objective risk based on Scheuner et al. (average, moderate, or high) influenced his or her willingness to share the information with others.

Finally, we intend to revise the format and wording choice of the surveys to include cognitive health belief models that consider risk perception, health beliefs, and health behaviors. As well, we will consider the potential for how the methodology used in this exploratory study can be used to develop a novel cognitive health behavior model, which incorporates family health history information as an intervention to modify health behaviors and beliefs.

6. CONCLUSION

This exploratory study was conducted in a non-clinical environment within a targeted community, but had important clinical and public health implications. We had the opportunity to complete family health histories, provide clinical assessments, and discuss public health

interventions in a targeted population. We explored the perceptions of African American participants on risk for several multifactorial diseases and how they are influenced by family health history information.

Our study engaged the African American community in Pittsburgh, through established Center for Minority Health networks, to discuss the importance of family history as a risk factor for disease. As part of the study, we completed 134 family health histories within an 8-month time period and had more than 90% compliance in the completion of the pre and post-session surveys. Based on the uptake of our study in the African American community, it appeared that individuals were interested in understanding the contribution of family history to explain the disease history in their families. As the dialogue and education process continues with public health campaigns and patient-provider communications, the public will become more aware of family history as a risk factor, which will most likely influence decisions about health-related behaviors.

Based on the Scheuner risk classification, we identified individuals who would be at elevated risk for colon cancer and heart disease, as well as several other conditions, including hypertension, type 2 diabetes, and breast cancer. Moreover, we found that the family health history can influence individuals' perceptions of risk for diseases and provide them with a more accurate perception of their risk. These individuals would benefit from sharing their family health histories with their physicians and following recommended screening practices for moderate and high risk populations.

As part of our study, we also encouraged participants to share their family histories with family members. Because perceptions of risk are often influenced by the experiences of family members, screening practices and health behaviors can also improve with sharing risk information. An individual's accurate risk perception can influence the willingness to participate in recommended preventive screening.

A detailed family health history can be used to identify individuals in the general population who may be at increased risk to develop chronic diseases and targeted for prevention strategies. Many participants commented that the experience of documenting the family health history and seeing the information on paper "opened their eyes." This unique form of community engagement and health education can make an important contribution in the *Healthy People 2010* objectives to improve the quality of health for all Americans and eliminate health disparities. "Our greatest opportunities for reducing health disparities are in empowering individuals to make informed health care decisions and in providing the skills, education, and care necessary to improve health," said Dr. Satcher (Satcher, 2000). Family health histories may serve as the bridge between patients and providers by improving health communication and increasing preventive measures, in order to reduce the disease burden for all Americans.

EPILOGUE

When I first joined the University of Pittsburgh, Graduate School of Public Health in 2003, I involved myself with the Center for Minority Health to work on project(s) that would allow me to utilize many aspects of my training and experience in public health and as a new genetic counseling student. I wanted to work in underserved communities. The experiences of working on the Family Health Histories aspect of the *Health Black Family Project* exceeded any expectations I may have had.

This project engaged the African American community in a manner that was respectful and empowering to the participants. I may have been the expert at taking family health histories, but the participants were certainly experts on the knowledge and information they provided. The interactions that took place between many of the participants and me were ones in which many genetic counselors or health care providers may not experience. I developed a relationship with the participants that extended beyond a clinical encounter, because we [CMH] followed up with them through phone calls, health fairs, and an appreciation dinner. It provided an opportunity to greatly impact the quality of an individual's life because I had the opportunity to promote public health messages. As a genetic counselor, I had the opportunity to provide participants with resources and information.

As I explore new opportunities and continue to work in both a public health and genetic counseling capacity, I will find myself reflecting fondly on my experiences in Pittsburgh, particularly with the *Healthy Black Family Project*. I feel as if I was part of something BIG and hope that I can have an even greater impact in my career.

APPENDIX A

Family History Interviewer Questionnaire

Pedigree Questions: Taking a Family Health History
1. Gather information on immediate family (individual, spouse, children, parents, brothers, and sisters)
    A. How old are you? How would you describe your health?
    B. Are you married? If so, how old is your wife or husband?
    C. Do you have any children? If so, how many? What are their ages?
    D. Do you have any brothers or sisters? If so, how many—please give them in the order by age (oldest to youngest).
    E. Does your husband/wife have any brothers/sisters? If so, how many—please give them in the order by age (oldest to youngest)?
    F. Do you have any nieces and/or nephews?
    G. Are both of your parents still living? How old are they? Ages and cause at death?
    H. Are there any health conditions that you, your children, parents, or brothers/sisters have that you are aware of?
2. Gather information on parents' family
    A. Focus on mother's brothers/sisters
        i. How many brothers and/or sisters does your mom have? (Please give them in the order by age, if you have that information)
        ii. Do you have any cousins on your mother's side of the family? (Please give them in the order by age, if you have that information)
        iii. Are there any health conditions on this side of the family that you are aware of?
    B. Focus on father's brothers/sisters
        i. How many brothers and/or sisters does your father have? (Please give them in the order by age, if you have that information)
        ii. Do you have any cousins on your father's side of the family? (Please give them in the order by age, if you have that information)
        iii. Are there any health conditions on this side of the family?
3. What is your ethnic background? (For example, Black, African American, Native American, German, Irish, Italian?)
4. Follow checklist of disease
    A. Diabetes
    B. HTN
    C. CVD/CAD
    D. Stroke
    E. Blindness
    F. Kidney disease
    G. Cancer
    H. MR
    I. SAB
    J. Consanguinity
    K. Birth Defects
    L. Unexpected deaths <40
    M. Sickle cell anemia

APPENDIX B

Progeny-Generated Family History and Participant Certificate
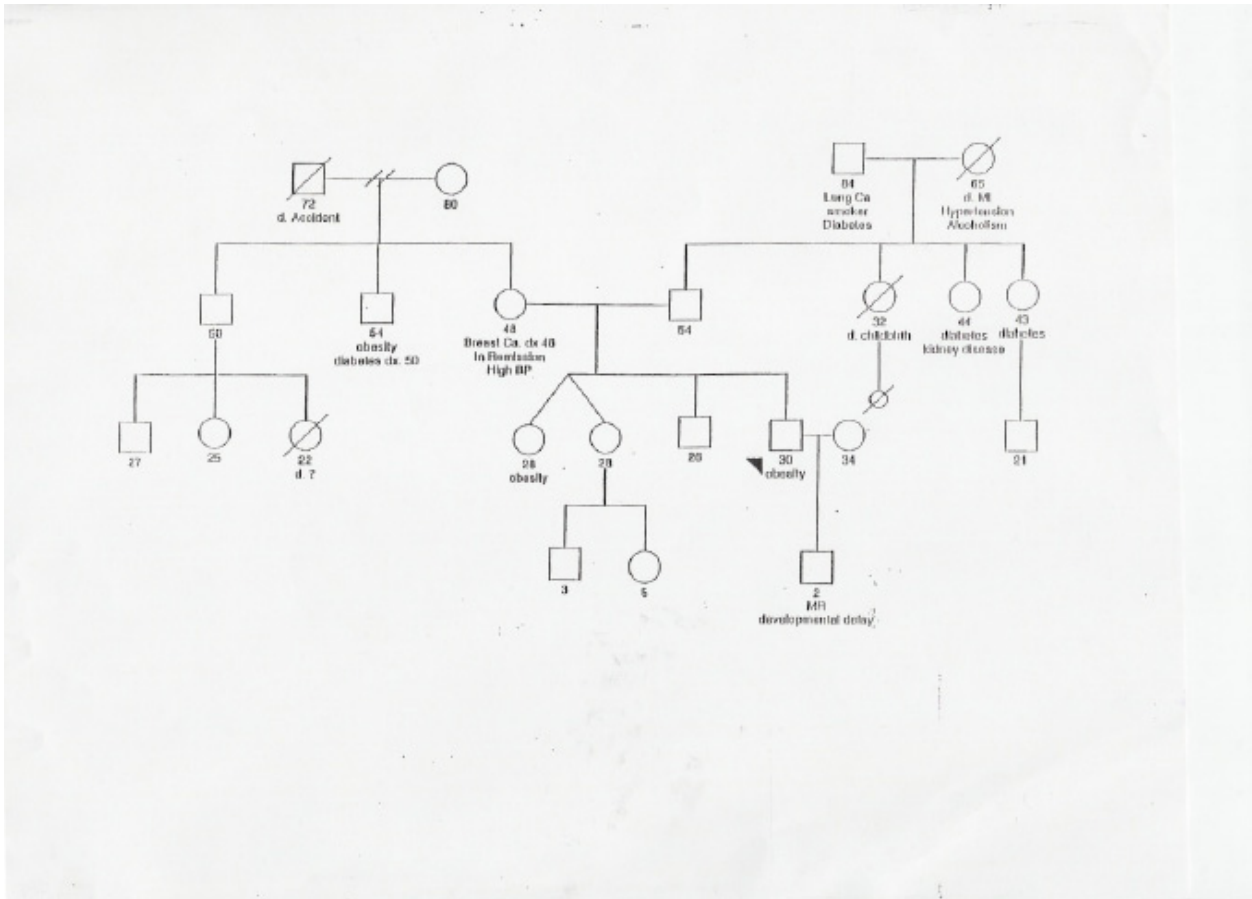
Progeny®-Generated Family History
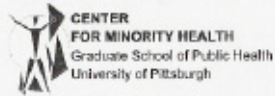
Sample Participant Certificate

APPENDIX C

Participant Health Education Materials: An Example

"5 A Day Challenge"
By National Cancer Institute and the Centers for Disease Control and Prevention
(May, 1998)
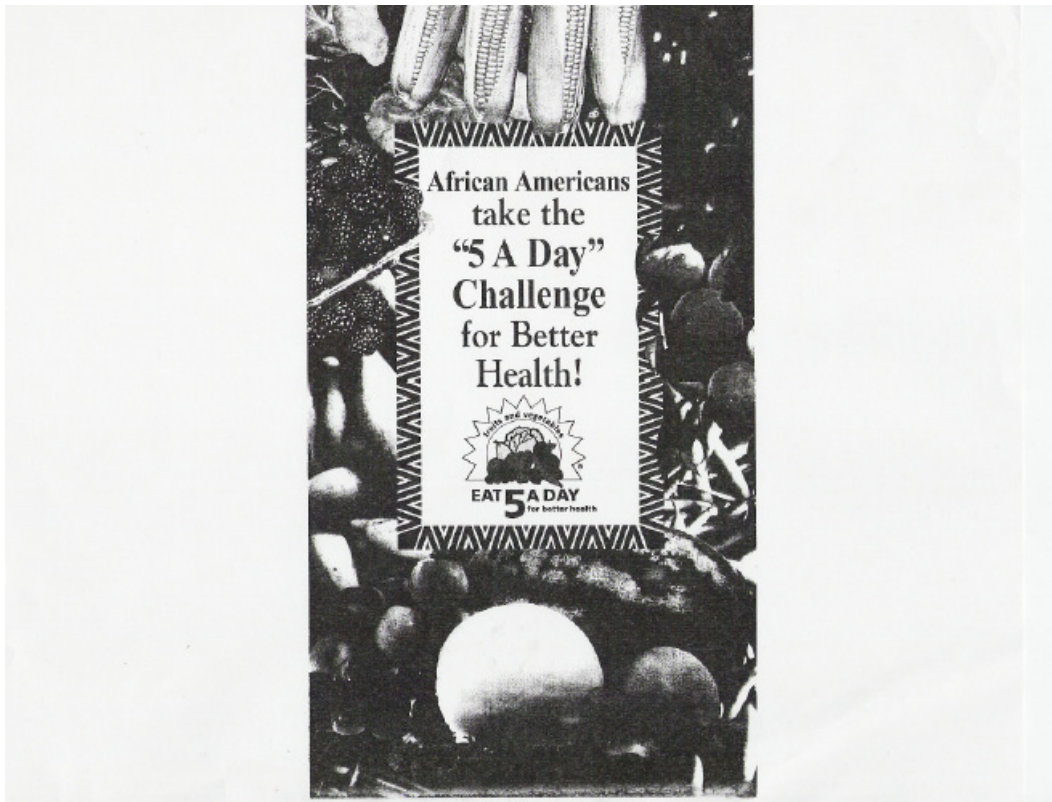
$\mathcal{A}$frican Americans are at high risk for serious diseases like cancer, diabetes and stroke. Many people can avoid these diseases by making simple diet, health and lifestyle changes.

That's right! You can start making these changes **RIGHT NOW** by taking the "5 A Day" Challenge. That means eating any mix of five servings of fruits and vegetables everyday, like three vegetables and two fruits. Fruits and vegetables are an important part of a healthy diet. They are low in fat, and good sources of vitamins, minerals, and fiber.

Read on to learn how people are making changes in their lives to look better, feel better and live longer. Learn how YOU can do it too!

WHY Take The
"5 A Day" Challenge

"I almost died on my job from a stroke. My pressure was high, I ate greasy food everyday, and I wasn't willing to change my ways. When I woke up in the hospital and didn't have any feeling on my left side, I *knew* I had to make some changes. It took me nine months to get back on my feet. Now I get regular check-ups, try to exercise, eat plenty of fruits and vegetables and cut out the grease. Believe me, these changes have made a difference in my life!"

"I've known Joe for a long time. When he had a stroke on the job, it shook me up. I learned from my doctor that Black men have more strokes than anyone else. I'm young, but I know the things I do now will help me to be healthier later on. I learned a lot from Joe and my doctor and I'm making changes."

Here are some fast and easy tips to help you meet the "5 A Day" Challenge!

BREAKFAST
- Drink a glass of juice.
- Add fruit to your waffles or pancakes.
- Add fruit to your hot or cold cereal.

LUNCH
- Have vegetable soup or a salad.
- Eat a piece of fruit like an apple, banana or a peach.
- Add lettuce and tomatoes to your sandwich.

SNACK
- Snack on grapes or raisins instead of candy.
- Have a bowl of your favorite fruits.

DINNER
- Eat beans cooked with non-fatty seasonings.
- Add fresh, sliced tomatoes or cucumbers to your dinner.
- Add vegetables to your rice or casserole.

To make sure you get "5 A Day" follow the serving guide below.

A serving is:
- 1 medium fruit or 1/2 cup of small or cut-up fruit
- 3/4 cup of 100% fruit juice
- 1/4 cup of dried fruit
- 1/2 cup of raw or cooked vegetables
- 1 cup raw leafy vegetables (lettuce, spinach)
- 1/2 cup cooked beans or peas (black-eyed peas, lima beans)

| 1/4 CUP | 1/2 CUP | 3/4 CUP | 1 CUP |

For more information on nutrition and diet, or to learn more about chronic diseases, contact: your local health department, your doctor or the organizations listed below.

National Cancer Institute 1-800-4-CANCER (1-800-422-6237)
American Cancer Society 1-800-ACS-2345 (1-800-227-2345)
American Heart Association 1-800-AHA-USA1 (1-800-242-8721)
American Diabetes Association 1-800-DIABETES (1-800-342-2383)
American Lung Association 1-800-LUNG-USA (1-800-586-4872)

APPENDIX D

Institutional Review Board Approval Letter & Documentation
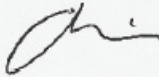
University of Pittsburgh

Institutional Review Board

3500 Fifth Avenue
Ground Level
Pittsburgh, PA 15213
(412) 383-1480
(412) 383-1146 (fax)

MEMORANDUM:

TO: Stephen B. Thomas, Ph.D.

FROM: Christopher Ryan, Ph.D., Vice Chair

DATE: May 4, 2004

SUBJECT: IRB#: 0403125 HEALTHY BLACK FAMILY PROJECT: Assessing African Americans' Response to Family Health Histories

The above-referenced proposal has received expedited review and approval from the Institutional Review Board under 45 CFR 46.110 (7).

Please note that the advertisement that was submitted for review has been approved as written.

If applicable, please include the following information in the upper right-hand corner of all pages of the consent form:

Approval Date: 05/03/2004
Renewal Date: 05/02/2005
University of Pittsburgh
Institutional Review Board
IRB# 0403125

Adverse events which occur during the course of the research study must be reported to the IRB Office. Please call the IRB Adverse Event Coordinator at 412-383-1145 for the current policy and forms.

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month prior** to the expiration date noted above for annual renewal as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center) and FWA00000600 (Children's Hospital of Pittsburgh).

Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.

CR:ky

IRB Approval Letter

THE HEALTHY BLACK FAMILY PROJECT:
Assessing the Response of African Americans to Family Health Histories

PROTOCOL

1.0 Objective and Specific Aims

In 2002, the University of Pittsburgh was awarded a five year grant (P-60) from the National Institutes of Health (NIH), National Center for Minority Health and Health Disparity (NCMHHD) to establish The Center for Excellence in Partnerships for Community Outreach, Research on Health Disparities and Training (Project EXPORT HEALTH). Administratively housed in the Center for Minority Health (CMH) at the University of Pittsburgh's Graduate School of Public Health (GSPH) Project EXPORT, investigators are focused on building research infrastructure around the following theme:

> **"increasing community capacity for participation in health promotion and disease prevention research and interventions**."

Project EXPORT addresses the seven health disparity priority areas identified by the Department of Health and Human Services and described in **Healthy People 2010**.

1. cancer screening and management;
2. infant mortality;
3. cardiovascular disease;
4. diabetes;
5. HIV/AIDS;
6. adult and child immunization and
7. mental illness

Project EXPORT Health provides the infrastructure needed to launch the Healthy Black Family Project which is designed as a pilot demonstration to examine how knowledge of family health histories influence risk perception and willingness to participate in clinical trials research. The priority population for this pilot includes individuals aged 18 and older, residing in Allegheny County, PA, who report a family history of at least one chronic illness known to have genetic risk factors. The chronic diseases include, but are not limited to: cancer, cardiovascular disease, diabetes, Alzheimer's disease, and hypertension.

Specifically, we propose to:

1) describe the extent to which individuals with a family history of cancer demonstrate higher levels of awareness regarding their increased risk compared to individuals without a family history of cancer

2) develop a better understanding of how knowledge of family health histories influence perceived risk for cancer compared to other chronic diseases

3) describe the extent to which knowledge of a personalized family health history (pedigree), including review of the genetic pedigree chart, shapes "information seeking" and other behaviors associated with health promotion and disease prevention

4) describe the extent to which knowledge of a personalized family health history, including review of the genetic pedigree chart, shapes willingness to participate in clinical trials research

5) describe demographic characteristics of individuals who agree to receive information on clinical research studies

2.0 Background and Significance
2.1 Background

Cancer, diabetes, and cardiovascular disease are among some of the diseases that represent preventable causes of premature illness and death among ethnic and racial minority populations. The development of these conditions is often the combination of many factors, including genetics and the environment. Family history may be a good predictor of risks for certain diseases because it takes into account both of these factors (Scheuner, Wang, Raffel, Larabell, & Rotter, 1997). A family health history is a useful tool for understanding if a disease runs in a family (Frezzo, Rubinstein, Dunham & Ormond, 2003).

The knowledge and occurrence of multiple affected family members who have chronic conditions such as cancer, cardiovascular disease, and diabetes raise many questions for family members about their own risk. Apart from emotional issues related to the occurrence of a serious disease in a family, questions related to the cause of the disease, the risk of developing the disease, and what can be done to prevent it are likely to be of concern to individuals and their families (Collins, Halliday, & Williamson, 2000). The awareness of family history to improve early detection and disease prevention for individuals found to be at increased risk may be important, but is not sufficient to improve disease prevention strategies. Other factors such as perceived risk, psychological implications, risk comprehension, recruitment biases, and cultural variables can provide important information as to whether risk information based on family history is an effective tool to promoting healthy behavior changes (Audrain-McGovern, Hughes, & Patterson, 2003).

In addition to identifying individuals based on family history for improving disease prevention, the identification of moderate- to high-risk individuals based on family history may be an important strategy for recruiting and increasing enrollment of minority participants into clinical research studies. Yet, little evidence exists to assess the use of family history information as a recruitment strategy for research studies involving ethnically diverse groups.

The significance of including ethnically diverse groups in research studies has been discussed in the context of drug evaluation and research, for example. Over the years, numerous investigations have documented substantial racial differences in drug response and disposition; such is the case with the antihypertensive effects of ß-blockers (Svensson, 1989). Variations in drug response and metabolism have been observed with the use of ß -blockers, in which Blacks were less likely to respond to the antihypertensive effects of ß -blockers compared to white hypertensive patients (Svensson, 1989). In this example, it would be important to understand why a drug to treat hypertension is less effective in the African American population. Similarly, for any new drug development, an underrepresentation of minority subjects would result in insufficient data for the optimal use of new drugs in these patients. Family health histories may be an important criterion to identify eligible participants for clinical research studies, particularly in minority populations.

2.2 Significance

Family health histories may be an important risk assessment tool to identify individuals, who are at moderate- to high-risk for developing chronic diseases, particularly in minority populations. By identifying these individuals, it would be possible to increase their awareness of risk for chronic conditions, to offer them information to improve disease prevention, and to discuss the importance of participating in clinical research studies.

3.0 Research Design and Methods

3.1 Drug/Device Information

   N/A

3.2 Research Design and Methods

(1) This is a qualitative descriptive study.

(2) The pilot study involves a one time in-person questionnaire administration (pre-session and post-session) and a family health history interview to be delivered either in the church, barbershop/beauty salon, at a community event, or in a mutually agreed upon location. Four weeks post-interview, there will be a one-time follow-up by phone. The questionnaires and family health history session together will take approximately 45 to 60 minutes, depending on the information the participant is able to present. The phone follow-up should take approximately 5 minutes.

   The questionnaire is administered in three phases: In Phase 1) the pre-session questionnaire (Appendix A) is designed to collect data about the participant's perception of risk for selected chronic diseases. The family health history session will be conducted immediately following the completion of the pre-session questionnaire. The family health history session will be conducted by a genetic counseling student/counselor from the Department of Human Genetics, Graduate School of Public Health at the University of Pittsburgh. In Phase 2) a post-session questionnaire (Appendix B) will be administered to collect data on changes in risk perception. The post-session questionnaire will also include questions about willingness to participate and receive information about clinical research studies. If participants express an interest in receiving information on clinical research studies (Appendix C) related to chronic diseases as identified in their family health history, the CMH will maintain a database with their contact information and will periodically send out health information (i.e., health education materials, health fair announcements, etc) and up-to-date information on how participants can contact relevant studies. In addition, participants can contact the CMH for information on clinical research studies. The participants' contact information will be kept with the Center for Minority Health. No outside investigators will have access to any of the participants' health or contact information. In Phase 3) individuals who have provided their contact information will be contacted over the phone to complete a brief follow-up questionnaire (Appendix D) to assess whether participants shared their family health history information with their health care provider and/or family members.

   The family health history session involves having a genetic counseling student/counselor hand draw a family health history (or pedigree) for participants (Appendix E). The pedigree will be professionally redrawn using a software program called Progeny (Appendix F). Participants will be asked a series of questions about who is in their families, what health conditions do/did these individuals have, and at what ages they were diagnosed (Appendix G). This information will allow the genetic counseling student/counselor to assess the participant's risk associated with a condition in his/her family, if any. Not every participant will be determined to be at-risk for a chronic condition. Participants will be recruited on a voluntary basis.

(3) Participants will be identified and invited to participate through community-based recruitment efforts, including local churches, barbershops, beauty salons, and community events. We will obtain a letter of permission for each site we identify as a recruitment location. These letters of permission will be submitted to the IRB in advance before recruitment begins.

As sites are added, we will submit the letters of permission under the "Modification" of the IRB Cover Sheet. In addition, a brochure about the importance of family health history (Appendix H) will be used as recruitment tool and distributed through community-based organizations, the Center for Minority Health website, social networks and local businesses. The brochure will contain information on how to contact the study coordinators of the Healthy Black Family Project. We may also post fliers in advance of participating at community health fairs (Appendix I). Additionally, potential study participants can contact the research team via telephone and e-mail.

3.3 Data Collection and Statistical Methods
(1) This is a pilot demonstration study using qualitative research methods. The proposed sample of convenience will include approximately 300 individuals. This sample size will generate sufficient data to determine reliability of the methods being used and will generate hypotheses to be tested in a more rigorous design in the future. Data from this study will be used by the two genetic counseling students (interviewers) to complete requirements for their master theses.
(2) The data collected in this study will enable investigators to measure changes in risk perception, and willingness to receive information on and participate in clinical research studies.
(3) All data will be collected in person using self-administered questionnaires (pre- and post) and follow-up phone interview conducted by genetic counseling students/counselors. Survey data will be analyzed using Stata 8.0 or SAS. The Statistical approach will be limited to descriptive analysis (means, standard deviations and t-test). Follow-up phone interviews will be recorded on a pre-formatted questionnaire (Appendix D). The analysis will be limited to identification of narrative threads and relevant quotes which illustrate common themes across the interviews.

4.0 Human Subjects
4.1 General Characteristics
(1) The pilot study will attempt to recruit 300 participants. We will attempt to over-sample for African-American participants. Only those who agree to participate in the pilot and sign the informed consent will be asked to participate in this one-time in-person session and questionnaire.
(2) No exclusion criteria shall be based on race, ethnicity, gender, or HIV status.
4.2 Inclusion of Children in Research
       N/A
4.3 Inclusion/Exclusion Criteria—Pregnancy and Birth Control Statements
       N/A

4.4 Recruitment Procedures
(1) Initially, study participants will learn about the importance of family health history information and of how it relates to disease prevention. The participants will be offered the opportunity to learn more about their own family health history by speaking with a genetic counseling student, who will gather information provided by the participants, draw out the participants' family health histories, and review the information obtained. The student will discuss with the participant how the information relates to the participant's risk for any diseases identified in the family during the session. The participant will receive a copy of his/her family health history (pedigree) and may share this information with family members, physicians, and other health care providers. In addition, the student will discuss two questionnaires, pre- and post-session surveys. The student will explain that the surveys explore the participant's risk perception and interest in improving health promoting behaviors as well as their interest in participating in a family health history recruitment registry for future research studies. Following the introduction to the study

and family health history session, if participants are agreeable, they will be presented with the informed consent, given time to review the consent form with the student, and a written signed consent form. The written signed consent form will be obtained <u>BEFORE</u> any information is obtained, questionnaires are filled out, sessions are conducted, or family history is taken.

(2) None of the involved study investigators will attempt to identify or contact specific family members based on the relationship information.

(3) Participants will be told there will be no adverse effects on health care if they do not participate.

(4) In addition to the Principal Investigator, Vinaya Murthy and Kristen Vogel, two genetic counseling students, will be responsible for obtaining informed consent.

(5) The direct benefit to the participant will be to have a copy of their family health history to share with other family members and their health care providers. In addition, the results of this study could lead to benefits regarding improved public health and health care services to future generations.

4.5 Risk/Benefit Ratio

(1) There may be a risk of discomfort when answering questions about family health history. The direct benefit to the participant is that he/she will have a more accurate assessment of his/her risk for diseases that may be inherited in his/her family. The participant will receive a copy of his/her family health history (pedigree) and may share this information with family members, physicians, and other health care providers. Another potential risk to participants is breach of confidentiality. However, every attempt will be made by the Principal Investigator, study coordinator, and interviewers to prevent any breach of confidentiality.

(2) A Data and Safety Monitoring Plan has been developed and implemented for the pilot study by the Principal Investigator to ensure that there are no changes in the risk/benefit ratio during the course of the study and that confidentiality of research data is maintained. Each member of the study team will meet with the PI and review confidentiality issues and complete a confidentiality agreement, prior to having contact with research subjects. Investigators and study personnel will meet bimonthly to discuss the study (e.g., study goals and modifications of those goals; subject recruitment and retention; progress in data coding and analysis; documentation; identification of adverse events or research subject complaints; violations of confidentiality) and address any issues or concerns at that time. Minutes will be kept for these meetings and will be maintained in the study regulatory binder. Any instances of adverse events will be reported immediately to the University of Pittsburgh IRB using the standard forms and/or procedures that have been established by the IRB. The yearly IRB renewal for this study will include a summary report of the Data and Safety Monitoring Plan findings from the prior year. Moreover, if any adverse effect, e.g., complaint, perceived illness occurs, the interviewer will report to the Principal Investigator who will work with the Genetic Counseling Program to handle potential crisis.

(3) N/A

(4) All data will be kept in locked files. Identity of the participant will not be revealed in any description or publication of this research.

(5) The direct benefit to the participant is increased awareness of his/her risk for particular inherited conditions. The direct benefit of this research is that it could lead to benefits regarding improved health care and service needs for future generations, including children and adults.

5.0 Costs and Payments

5.1 Research Study Costs

(1) No cost to the University is involved. No cost to the participant is involved.

(2) N/A

(3) N/A

5.2 Research Study Payments
The research study participant will not receive any monetary payment for participating in this study. The participant will receive a $5 gift certificate from Giant Eagle, Inc. (grocery store) for their participation.

6.0 List of Appendices
Appendix A: Pre-Session Questionnaire
Appendix B: Post-Session Questionnaire
Appendix C: Participant Contact Information Form
Appendix D: Phone Follow-up Questionnaire
Appendix E: Hand-Drawn Family Health History
Appendix F: Family Health History Produced with Progeny Software
Appendix G: Standard Questioning in a Family Health History Session
Appendix H: Family Health History Pamphlet
Appendix I: Advertisement/Flier for Family Health Histories

6.1 Qualifications of Investigators
1) **Stephen B. Thomas, PhD, Principal Investigator**: Dr. Thomas is the Director of the Center for Minority Health at the University of Pittsburgh's Graduate School of Public Health. He is also a Phillip Hallen Professor of Community Health and Social Justice. Dr. Thomas is involved with several projects related to diverse populations and eliminating health disparities.
2) **Angela Ford, MSW, Co-Investigator**: Ms. Ford is the Associate Director of the Center for Minority Health at the University of Pittsburgh's Graduate School of Public Health. Ms. Ford has a Master Degree in Social Work. She is now a candidate for her PhD in Social Work where her dissertation will examine the "help-seeking behavior of elderly African American women." Ms. Ford is involved with several projects related to diverse populations and health related issues.
3) **Robin Grubs, PhD, CGC, Co-Investigator**: Dr. Grubs is the Co-Director of the Genetic Counseling Program at the University of Pittsburgh's Graduate School of Public Health in the Department of Human Genetics.
4) **M. Michael Barmada, PhD, Co-Investigator**: Dr. Barmada is Assistant Professor in the Department of Human Genetics at the University of Pittsburgh's Graduate School of Public Health. Dr. Barmada's research is primarily concerned with identifying genetic susceptibility loci for common complex disorders and applying various methods derived from statistics, genetics, and epidemiology to the analysis of large, typically family-based samples. His expertise includes using Progeny software to produce and store family health histories and will assist in developing the registry.
5) **John Wilson, PhD, Co-Investigator**: Dr. Wilson is Assistant Professor in the Department of Biostatistics at the University of Pittsburgh's Graduate School of Public Health. Dr. Wilson's research is primarily concerned with statistical methods for cancer research, design of experiments, and nonparametric statistics.
6) **Vinaya Murthy, MPH, Co-Investigator**: Ms. Murthy is a Master candidate in the Genetic Counseling Program at the University of Pittsburgh's Graduate School of Public Health. Ms. Murthy has a Master Degree in Public Health with a concentration in Public Health Genetics.
7) **Kristen Vogel, BA, Co-Investigator**: Ms. Vogel is a Master candidate in the Genetic Counseling Program at the University of Pittsburgh's Graduate School of Public Health. Ms. Vogel has a Bachelor Degree in Biology.

6.2 Bibliography/References

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6.3 N/A
6.4 N/A

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: **THE HEALTHY BLACK FAMILY PROJECT:**
                Assessing the Response of African Americans to Family Health Histories

PRINCIPAL INVESTIGATOR: Stephen B Thomas, PhD
                          Philip Hallen Professor of Community Health & Social Justice
                          Director, Center for Minority Health
                          Department of Behavioral & Community Health Sciences
                          Graduate School of Public Health
                          University of Pittsburgh
                          125 Parran Hall
                          Telephone: 412-624-5665
                          sbthomas@cmh.pitt.edu

CO-INVESTIGATORS:

Vinaya Murthy, MPH Genetic Counseling Student University of Pittsburgh-GSPH 125 Parran Hall Telephone: 412-624-5665	Kristen Vogel, BA Genetic Counseling Student University of Pittsburgh-GSPH 125 Parran Hall Telephone: 412-624-5665
Angela Ford, MSW Associate Director, Center for Minority Health University of Pittsburgh-GSPH 125 Parran Hall Telephone: 412-624-5665	Robin Grubs, PhD Professor of Genetics University of Pittsburgh- GSPH A306 Crabtree Hall Telephone: 412-624-4695
M. Michael Barmada, PhD Professor of Genetics University of Pittsburgh- GSPH A310 Crabtree Hall Telephone: 412-383-7959	John Wilson, PhD Professor of Bio-Statistics University of Pittsburgh-GSPH A431 Crabtree Hall Telephone: 412-624-3053

Why is this research being done?

The Healthy Black Family Project is part of the African American Health Promotion Campaign: Countdown to 2010. This is a multi-year effort to eliminate racial and ethnic health disparities in Pittsburgh. The mission of the Center for Minority Health is to eliminate racial and ethnic health disparities. African Americans are at increased risk for illnesses such as cardiovascular disease, diabetes, and several types of cancer. For many of these conditions, there is a genetic predisposition that can be identified through family health histories, or pedigrees. Personal knowledge of having a family member with one or more of these diseases may influence the accuracy of how you estimate your perception of personal risk.
A family health history can be used as an assessment tool to provide more accurate risk information to families. Once families are identified to be at high risk compared to the general population, they can be encouraged to make lifestyle changes to reduce risk of disease and supported to follow recommendations for early screening and regular visits with a health professional. We also believe that knowing more about family health histories can help African Americans reduce any fear regarding genetic information.

Specific aims of the study include:

1. To determine how knowledge of family health history influences the accuracy of individual risk perception;

2. To determine how knowledge of family health history shapes the willingness of African Americans to participate in clinical research studies; and

3. To determine how knowledge of family health history influences "information seeking" behavior.

Who is being asked to take part in this research study?

Individuals who are at least 18 years of age will be the primary study population. We will recruit a total of 300 individuals from a variety of community settings within the Greater Pittsburgh to participate in the study. We will attempt to over-sample African American participants.

What procedures will be performed for research purposes?

The project dispatches a team of genetic counseling students/counselors to conduct family history interviews of African Americans. Participants will be recruited at community health fairs, barbershops and salons, church settings, and by word-of-mouth through social networks. Once recruited, participants will have their family health histories taken and will be told if they appear to be at risk for any chronic diseases that have genetic risk factors. The family health

history sessions will take place at the location of recruitment or at a location that is mutually agreed upon between the participant and the student/counselor. The family health histories can be entered into a computer database using Progeny software, and a copy of the family health history can be produced for the participant to archive and share with other family members. Interested individuals in the computer database can receive information from The Center for Minority Health regarding clinical and public health research studies.

In step one, you will complete a brief 15 minute pre-session survey. In step two, you will be interviewed for about 30-45 minutes about your family health history. In step three, you will complete the 15 minute post-session survey. The genetic counseling student/genetic counselor will also take a few minutes to talk to you about patterns of disease identified in your family. You will be given a copy of your hand-drawn family health history to take home with you. In approximately one week, a professional graphic display of your family health history will be ready for pick up or can be mailed directly to you. The final step in the study will be a telephone interview at the four week anniversary of joining the study, should you give us your contact information.

Additionally, you will have the OPTION to maintain your name, contact information, and family health history in a database. The Center for Minority Health will send you health information (i.e. health education materials, health fair announcements, etc.) as well as information on clinical research studies related to your family health history. Once you receive the information, you have the option to contact the study investigators if you are interested in participating. Your contact information will be kept within the Center for Minority Health. No outside investigators will have access to any of your health information or contact information.

Your identity on the family health history and questionnaires will be assigned a case number to protect your privacy. If you agree to provide your contact information, we will make sure the information linking the case number with your identity will be kept separate from the surveys.

What are the possible risks of this study?

There may be a risk of discomfort when answering questions about your family health history. Remember, your participation is voluntary and you can refuse to answer any question. Once you complete the family history session, the genetic counseling student/counselor will explain the pattern of diseases in your family tree and identify potential health risks that you should know about. You may be at risk for conditions that you did not previously think were a problem for you. This knowledge may result in emotional stress to you and/or your family. We encourage you to share the information in your family health history with a health professional. If you do not have a medical provider, we will provide you with a referral. In addition, while investigators take precautions to keep the information you disclosed confidential, there is a small risk that there may be a breach of confidentiality.

What are the possible benefits from taking part in this study?

Upon completion of the family health history, you will be given a hand-drawn copy of the pedigree that includes all of the information discussed during the interview. Within one week,

your family health history will be entered into a computer program to produce a professional family health history for you to share with members of your family and health professionals.

The genetic counseling student/counselor will talk to you about the diseases that he or she thinks you are potentially at risk for based on the information that you provide. This risk assessment is designed to increase your awareness of diseases that run in your family. This information may motivate you talk to a health professional about steps you can take to promote health and prevent disease. This information may also be a source of encouragement to other members of your family. We believe knowledge of your family health history is a tool for health promotion and disease prevention.

If I agree to take part in the Healthy Black Family Project, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if, during the conduct of this study, any new information develops which may cause you to change your mind about continuing to participate.

Are there any costs to me if I participate in this research study?

There are no costs to you if you participate in this research study.

Will I be paid if I take part in this research study?

You will not receive payment for participating in this study. However, you will receive a $5 gift card for Giant Eagle, Inc. (grocery store).

Who will know about my participation in this research study?

Any information from your family health history will be kept confidential (private) in accordance with policy outlined by the University of Pittsburgh Institutional Review Board. All records related to your involvement in this study will be stored in a locked file cabinet and/or a password-protected computer database. Your identity on these records will be indicated by a case number rather than by your name, and the information linking the case number with your name will be kept separate from the study records. As another safe guard, your name will NOT appear in any publication resulting from this research. Additionally, you may refuse to share your contact information and still participate in the Healthy Black Family Project. In this way, you are totally anonymous. At the end of this study, any records that personally identify you will remain stored in locked files and will be kept for a minimum of five years.

We will not ask for any identifiable information of family members (i.e. name, address, etc.). No member of the study team will attempt to identify or contact family members based on the relationship information provided. However, you are free to share the information in your family health history with members of your family, friends, and especially your health provider.

In unusual cases, your research records may be released in response to an order from a court of law. It is also possible that authorized representatives from the University of Pittsburgh

Research Conduct and Compliance Office or the sponsors of this research study (National Institutes of Health, National Center for Minority Health and Health Disparity) may review your data for the purpose of monitoring conduct of this study. Also, if the investigators learn that you or someone with whom you involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.

Is my participation in this study voluntary?

Yes! Your participation in this study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time, even after signing this form. You decision will not affect your relationship with the University of Pittsburgh or the Center for Minority Health.

♦♦♦
VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions which I have about my rights as a research participant will be answered by the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh
(1-866-212-2668).

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____   _____
Participant's Signature   Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise.

_____   _____
Printed Name of Person Obtaining Consent   Role in Research Study

_____   _____
Signature of Person Obtaining Consent   Date

◆◆◆

DATABASE VOLUNARY CONSENT

The Center for Minority Health at the University of Pittsburgh maintains a database that stores family health histories and contact information. Interested individuals in the database will be sent health information (i.e., health education materials, health fair announcements, etc.) as well as information on clinical research studies related to family health history.

By signing this form, I give consent to the Center for Minority Health to send me relevant health information. In addition, they can send me information on how I may contact clinical research studies that may be of interest to me.

_____   _____
Participant's Signature   Date

An important aim of genetic counseling is to provide risk information so that individuals and families can make better informed decisions about their health and that of their families. The purpose of this survey is to explore your perceptions of risk for developing certain health conditions. We want to understand whether family health histories (i.e., sharing information about diseases in your family) can help provide you with a more accurate assessment of your risk for developing particular health conditions.

If there is a question that you do not feel comfortable answering, you can skip it and continue on. Please answer the following questions to the best of your ability. DO NOT PROVIDE ANY NAMES OF FAMILY MEMBERS. The survey should take approximately 10 minutes. Thank you for your time.

Section 1: General Information

1) What is your age?
__ __ age in years

2) What is your gender?
1 Male
2 Female

3) Are you Hispanic or Latino?
1 Yes
2 No
3 Don't know

3a) Which one or more of the following would you say is your race? **(Check all that apply)**
1 White
2 Black or African American
3 Asian
4 Native Hawaiian or Other Pacific Islander
5 American Indian, Alaska Native
6 Other [specify] _____

4) What was the total household income from all sources last year?
1 Less than $10,000
2 Between $10,000 and $20,000
3 Between $20,001 and $35,000
4 Between $35,001 and $50,000
5 Between $50,001 and $75,000
6 Greater than $75,000

5) What is the highest grade or year of school you completed?
1 Grades 8 or less (Elementary)
2 Grades 9 through 11 (Some high school)
3 Grade 12 or GED (High school graduate)
4 College 1 year to 3 years (Some college or technical school)
5 College 4 years or more (College graduate or post-graduate)
6 Graduate level (Masters or PhD)

6) How would you rate your knowledge on genetics?
1 Excellent
2 Very good
3 Good
4 Fair
5 Poor

7) How would you describe your general health?
1 Excellent
2 Very good
3 Good
4 Fair
5 Poor

8) Do you have one person you think of as your personal doctor or health care provider?
1 Yes, only one
2 More than one
3 No
4 Don't know / Not sure

9) Was there a time in the past 12 months when you needed to see a doctor but could not because of the cost?
1 Yes
2 No
3 Don't know / Not sure

10) Do you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs, or government plans such as Medicare?
1 Yes
2 No
3 Don't know / Not sure

Section 2: Risk Perception

11) Have you ever talked to a doctor or nurse about your concerns for developing a disease?
1 Yes   Please describe: _____
2 No
3 Don't know / Not sure

12) In your opinion, how often do you believe each of the following factors increases (or contributes to) an individual's chance or risk for developing a disease such as diabetes, heart disease, and cancer?   (**Please respond for each item listed**)
1=Never   2= Sometimes   3=Always   4=Don't know / Not sure

      Smoking   _____
      Having a poor diet   _____
      Lack of exercise   _____
      Family history (other family members with a disease)   _____

13) What do you think the chances are of a healthy woman the same age as you to develop the following health conditions sometime in her life?   (**Please respond for each condition listed**)
1=Low (<10%)   2=Moderate (10-50%)   3=High (>50%)   4=Don't know / Not sure

      Breast cancer   _____
      Ovarian cancer   _____
      Colon cancer   _____
      Cardiovascular disease   _____
      Lung cancer   _____
      Diabetes   _____
      Alzheimer's disease   _____
      Hypertension   _____

14) What do you think the chances are of a healthy man the same age as you to develop the following health conditions sometime in his life?   (**Please respond for each condition listed**)
1=Low (<10%)   2=Moderate (10-50%)   3=High (>50%)   4=Don't know / Not sure

      Breast cancer   _____
      Colon cancer   _____
      Prostate cancer   _____
      Cardiovascular disease   _____
      Lung cancer   _____
      Diabetes   _____
      Alzheimer's disease   _____
      Hypertension   _____

15) Have you ever been concerned or worried about your chances for developing any of these health conditions?
1 Yes
2 No

15a) If yes, which one(s)? _____
Please describe: _____

16) On a scale from 1 (not worried) – 5 (extremely worried), how would you rate your concern about developing any of the above health condition(s)? _____

17) Do you have a blood relative (mother, father, sister, brother, uncle, aunt, grandmother, grandfather) who had or has a health condition that you are concerned about developing sometime in your life?
1 Yes
2 No
3 Don't know / Not sure

17a) If yes, who and what was the health condition? ***DO NOT INCLUDE NAMES OF FAMILY MEMBERS, ONLY THE RELATIONSHIP TO YOU**

_____

_____

18) Have you ever talked to a health provider about your concern for developing that particular health condition?
1 Yes
2 No
3 Don't know / Not sure

19) At this time, what do you think your chances are of developing any of the following health conditions sometime in your life?   (**Please respond for each condition listed**)
1=Low (<10%)   2=Moderate (10-50%)   3=High (>50%)   4=Don't know / Not sure

Breast cancer	_____
Ovarian cancer	_____
Colon cancer	_____
Prostate cancer	_____
Cardiovascular disease	_____
Lung cancer	_____
Diabetes	_____
Alzheimer's disease	_____
Hypertension	_____

20) At this time, what do you think your chances are of developing any of the following health conditions someday, compared with most individuals your age? (**Please respond for each condition listed**)
1=Much lower   2=Somewhat lower   3=Same   4=Somewhat   higher
5=Much higher   6=Don't know / Not sure

Breast cancer	_____
Ovarian cancer	_____
Colon cancer	_____
Prostate cancer	_____
Cardiovascular disease	_____
Lung cancer	_____
Diabetes	_____
Alzheimer's disease	_____
Hypertension	_____

Thank you very much for your help with our survey. We would appreciate any comments/feedback about your experience.

_____
_____
_____
_____

APPENDIX F

Post-Session Survey

We hope that you enjoyed having your family health history done. We would like to ask you a few more questions about risk to see if the family health history session changed your ideas about what conditions you might be at risk for. In addition, this post-session survey is looking at your opinions regarding participating in research.

If there is a question that you do not feel comfortable answering, you can skip it and continue on. Please answer the following questions to the best of your ability. DO NOT PROVIDE ANY NAMES OF FAMILY MEMBERS. The survey should take approximately 10 minutes. We would like to thank you in advance for your willingness to participate in this study.

Section 1: Risk Perception

1) Based on your family health history, what do you think your chances are of developing any of the following health conditions sometime in your life?
(**Please respond for each condition listed**)
1=Low (<10%)   2=Moderate (10-50%)   3=High (>50%)   4=Don't know / Not sure

        Breast cancer   _____
        Ovarian cancer   _____
        Colon cancer   _____
        Prostate cancer   _____
        Cardiovascular disease   _____
        Lung cancer   _____
        Diabetes   _____
        Alzheimer's disease   _____
        Hypertension   _____

2) Based on your family health history, what do you think your chances are of developing any of the following health conditions someday, compared with most individuals your age?
(**Please respond for each condition listed**)
1=Much lower   2=Somewhat lower   3=Same   4=Somewhat   higher
        5=Much higher   6=Don't know / Not sure
        Breast cancer   _____
        Ovarian cancer   _____
        Colon cancer   _____
        Prostate cancer   _____
        Cardiovascular disease   _____
        Lung cancer   _____
        Diabetes   _____
        Alzheimer's disease   _____
        Hypertension   _____

Section 2: Opinions on Research

3) How important do you feel that medical research is?
1 Very important
2 Somewhat important
3 Not very important
4 Not important at all
5 Don't know

4) Have you ever participated as a subject in any medical research studies?
1 Yes
2 No
3 Don't know

5) Have you ever been offered the chance to participate in a medical research study and decided not to participate?
1 Yes
2 No
3 Don't know

6) If you were to describe your general attitude towards medical research involving people, would you say that you feel?
1 Very favorable
2 Somewhat favorable
3 Somewhat unfavorable
4 Very unfavorable
5 Neither favorable nor unfavorable
6 Don't know

7) Would the offer of <u>free medical care</u> make you more likely or less likely to agree to participate in research?
1 More likely
2 Less likely
3 No effect
4 Don't know

8) Would the offer of <u>$500</u> make you more likely or less likely to agree to participate in research?
1 More likely
2 Less likely
3 Have no effect
4 Don't know

9) Would the offer of <u>free medicine</u> make you more likely or less likely to agree to participate in research?
1 More likely
2 Less likely
3 Have no effect
4 Don't know

10) How much do you think scientists benefit from medical research?
1 A great deal
2 A moderate amount
3 Only a little
4 Not at all
5 Depends

11) How much do you think your community benefits from medical research?
1 A great deal
2 A moderate amount
3 Only a little
4 Not at all
5 Depends

12) How much do you think your family and friends benefit from medical research?
1 A great deal
2 A moderate amount
3 Only a little
4 Not at all
5 Depends

13) How much do you think you benefit from medical research?
1 A great deal
2 A moderate amount
3 Only a little
4 Not at all
5 Depends

14) Do you have an interest in having your name in a database that would allow you to receive information about clinical research studies related to your family health history?
NOTE: Answering YES to this question DOES NOT enter you into any database nor does it sign you up to receive any information.
1 Yes
2 No

14a) If you answered yes, what are your expectations? (**Please circle all that apply**)
1 I expect to receive information about *all* of the latest research studies.
2 I expect to receive information about studies that I am eligible for.
3 I expect to be rewarded for participating in research (paid, free health care, etc.)
4 I expect to get the best health care available.
5 Other:_____

14b) If you answered no, what are your primary reasons? (**Please circle all that apply**)
1 I am not interested in participating in research.
2 I am not interested in anything tied to my family/my genetics.
3 I do not want to be part of a database.
4 I do not want to disclose my contact information.
5 Other:_____

15) How would you describe your experience with having your family health history taken? (**Please circle all that apply**)
1 Enjoyable
2 Informative
3 Uncomfortable/Unpleasant
4 Neutral/No opinion

APPENDIX G

One Month Follow-Up Questionnaire

Thank you very much for your help with our survey. We would appreciate any comments/feedback about your experience.

_____
_____
_____
_____

Providing your contact information is completely optional.

Name: _____

Address:_____

_____

_____

Phone # _____

Please read the following statements and check all that apply. Your participation is completely optional.

The Center for Minority Health can print off a copy of your family health history using Progeny Software. It will be similar to the hand-drawn copy you received today, however computer-generated. It will be mailed to you in about 1-2 weeks.

_____ Yes, I would like a computer print-out of the family health history that was done today.

A genetic counseling student would like to call you in about a month to see who you told about your family health history. This conversation will take less than five minutes.

_____ Yes, a genetic counseling student can call me in about one month to ask me additional questions on the family health history.

Date: _____

Person Making Phone Call: _____

Hi, my name is _____ and I am a genetic counseling student from The University of Pittsburgh with the Center for Minority Health. About a month ago, you completed a survey and had your family health history completed at _____. As you may recall, you agreed to let us contact you for a follow-up questionnaire. I just have a couple of brief questions to ask you. It should take about five minutes. Is it okay to proceed with the questions?

1) After having your family health history done, how did it make you feel?

2) Did you tell any one about having your family health history drawn out?

3) (**IF THE PERSON SAYS YES**) Who did you tell and when did you tell them?

4) Have you added anything to your family health history since it was drawn up a month ago?

5) Have you seen a health care professional since you had you had your family health history done?

6) (**IF THE PERSON SAYS YES**) Did you share your family health history with the health care professional?

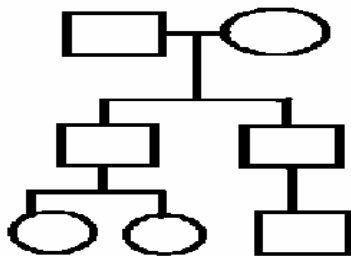7) (**IF THE PERSON SAYS YES**) What did he or she say about it?

8) Do you have any plans to share your family health history with your family in the next six months?

9) Do you plan to share your family health history with a health care professional (i.e., doctor, nurse, pharmacist, physician assistant, or genetic counselor) in the next six months?

HEALTHY BLACK FAMILY PROJECT

MAP OUT YOUR FAMILY HEALTH HISTORY

Brought to you by:
Center for Minority Health
Graduate School of Public Health
University of Pittsburgh

Learn what diseases you may be at risk for so you can take better control of you health

Answer a couple of quick surveys and get a $5 gift card to Giant Eagle

Call Kristen, Beth, or Vinaya at 412-624-5665 for more information or to schedule a session

Must be 18 & over and willing to commit approximately 1 hr of your time

HEALTHY BLACK FAMILY PROJECT

MAP OUT YOUR FAMILY HEALTH HISTORY
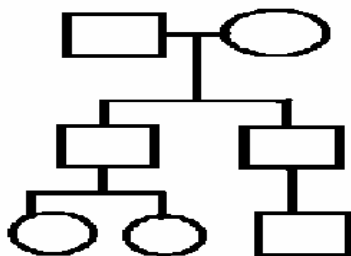
(Location)
(Month, Day, Year)
(Time)

Learn what diseases you may be at risk for so you can take better control of you health

Answer a couple of quick surveys and get a $5 gift card to Giant Eagle

Call Kristen, Beth, or Vinaya at 412-624-5665 for more information or to schedule a session

Must be 18 & over and willing to commit approximately 1 hr of your time

Brochure on Family History

AN EXAMPLE: COLORECTAL CANCER

Colorectal cancer is a common type of cancer that develops in the digestive tract. The digestive tract processes the food that you eat and gets rid of the body's solid waste. Sometimes, the lining of the digestive tract develops precancerous growths called polyps. Polyps can eventually turn into cancer.

Colorectal cancer occurs frequently in people who:

*Are over age 50;

*Are African American, Latino/Hispanic American, Native American, Pacific Islander, or Asian American;

*Have a family history of the disease.

A detailed family history can identify whether colorectal cancer is passed on in families. A pedigree is an important tool used by a doctor to assess whether you may be at an increased risk.

If you know that you are at high risk, you can work to prevent the disease by talking to a medical professional and by maintaining regular screenings. Knowing your family history of colorectal cancer can help you play an active role in your health care and in the prevention of cancer, both for you and your family.

Knowing your family history and maintaining regular screenings can help you live a long, happy, cancer-free life.

RESOURCES

Information on Cancer

*American Cancer Society

www.cancer.org

1-800-227-2345

*National Cancer Institute

www.cancer.gov

1-800-422-6237

*Center for Disease Control

www.cdc.gov/cancer

1-888-842-6355

Information on Genetic Counseling

*National Society of Genetic Counselors

www.nsgc.org

610-872-7608

*University of Pittsburgh

www.pitt.edu/~edugene

1-800-640-GENE/(4363)

*Centers for Disease Control

http://www.cdc.gov/genomics/

Information on the Healthy Black Family Project and the Family Health Histories

*Kristen Vogel: 412-624-4816

*Vinaya Murthy: 412-624-4820

*Beth Dudley: 412-624-4816

Center for Minority Health

Graduate School of Public Health
University of Pittsburgh
125 Parran Hall
Desoto Street
Pittsburgh, PA 15261

Phone: 412-624-5665
Fax: 412-624-8679

CENTER FOR MINORITY HEALTH
www.cmh.pitt.edu

Cancer, heart disease, and diabetes are part of the focus of the University of Pittsburgh's Center for Minority Health African American Health Promotion Campaign 2010 The goal of the national Healthy People Campaign 2010 is to eliminate health inequalities among racial and ethnic communities.

Protect Your Family:
Know Your Family History

"Genes draw your road map, but you still chart your course..."

WHY SHOULD YOU KNOW YOUR FAMILY HISTORY?

Family history is a record that changes as we go through life. By keeping track of births and deaths, marriages, reproductive outcomes, and medical characteristics, the family history becomes an invaluable resource in medical care.

While every disease has some genetic component, shared environment can contribute to disease. Family history may be a good predictor of risk because it takes into account both of these factors.

Each of us should know our family health history and be able to discuss it openly within our families. It is important to be able to accurately identify who may be at increased risk for developing preventable diseases. This information will allow us to improve our health and that of our loved ones.

AM I AT RISK?

Once you have talked to your family, you might notice that a certain condition is common. If this is a worry, there are people that you can talk to. The first person you should see is your doctor. If your doctor agrees that you are at high risk, you should ask to see a genetic counselor.

A genetic counselor is a health professional who works with people who are at risk for diseases that are related to their genes. Genes are stored information in your cells that tell your body how to work. People in the same family have some (but not all) of the same genes. The genetic counselor can take your family history, draw out a pedigree, and answer your questions about being at risk.

WHAT IS A PEDIGREE?

A *pedigree* is a way to put all of your family's health information down on paper and a way to keep it all organized. They are used by health professionals to see if a disease runs in the family. Pedigrees may even be part of your medical record. Below is a sample pedigree.

Oldest Generation

Middle Generation

Youngest Generation

Diabetes   Colorectal Cancer

Colorectal Cancer
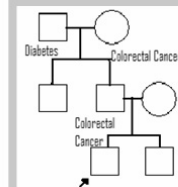
The circles are females and the squares are males. Underneath each one is

APPENDIX I

Analyzed Data

Pre-Family History Risk Perceptions for all conditions

Disease	Number of participants	Average Risk	Moderate Risk	High Risk
Breast cancer	114	62 (54%)	43 (38%)	9 (8%)
Ovarian cancer (women only)	89	42 (47%)	40 (45%)	7 (8%)
Colon cancer	112	57 (51%)	43 (38%)	12 (11%)
Prostate cancer (men only)	21	9 (43%)	8 (38%)	4 (19%)
Cardiovascular disease	117	32 (27%)	58 (50%)	27 (23%)
Lung cancer	105	37 (35%)	44 (42%)	24 (23%)
Diabetes	119	67 (56%)	40 (34%)	12 (10%)
Alzheimer's disease	108	66 (61%)	34 (31%)	8 (7%)
Hypertension	80	24 (30%)	36 (45%)	20 (25%)

Post-Family History Risk Perceptions for all conditions

Disease	Number of participants	Average Risk	Moderate Risk	High Risk
Breast cancer	117	80 (68%)	29 (25%)	8 (7%)
Ovarian cancer (women only)	93	62 (67%)	26 (28%)	5 (5%)
Colon cancer	119	73 (61%)	38 (32%)	8 (7%)
Prostate cancer (men only)	21	5 (24%)	12 (57%)	4 (19%)
Cardiovascular disease	119	38 (32%)	46 (39%)	35 (29%)
Lung cancer	109	41 (38%)	44 (40%)	24 (22%)
Diabetes	120	79 (66%)	30 (25%)	11 (9%)
Alzheimer's disease	108	80 (74%)	22 (20%)	6 (6%)
Hypertension	83	29 (35%)	31 (37%)	23 (28%)

Participants' Perceptions of Women's Health for all conditions, n (% of participants)

Disease	Average Risk	Moderate Risk	High Risk	Don't Know
Breast cancer	18 (14%)	66 (53%)	30 (24%)	11 (9%)
Ovarian cancer	26 (21%)	62 (50%)	22 (18%)	14 (11%)
Colon cancer	23 (18%)	63 (51%)	23 (18%)	16 (13%)
Cardiovascular disease	16 (13%)	45 (36%)	51 (41%)	13 (10%)
Lung cancer	38 (31%)	51 (41%)	23 (18%)	13 (10%)
Diabetes	20 (16%)	51 (41%)	48 (38%)	6 (5%)
Alzheimer's disease	42 (34%)	42 (34%)	21 (16%)	20 (16%)
Hypertension	12 (10%)	46 (37%)	59 (47%)	8 (6%)

Participants' Perceptions of Men's Health for all conditions, n (% of participants)

Disease	Average Risk	Moderate Risk	High Risk	Don't Know
Breast cancer	82 (66%)	29 (23%)	4 (3%)	9 (7%)
Colon cancer	14 (12%)	60 (48%)	47 (37%)	3 (2%)
Prostate cancer	12 (10%)	36 (29%)	73 (58%)	3 (2%)
Cardiovascular disease	13 (10%)	46 (37%)	62 (50%)	3 (2%)
Lung cancer	34 (27%)	53 (42%)	34 (27%)	3 (2%)
Diabetes	11 (9%)	59 (47%)	51 (41%)	3 (2%)
Alzheimer's disease	41 (33%)	44 (35%)	22 (18%)	17 (14%)
Hypertension	12 (10%)	38 (30%)	69 (55%)	5 (4%)

Participants' Perceptions of Risk Compared to General Population (Pre-Session), n (% of participants)

Disease	Much Lower	Somewhat Lower	Same	Somewhat Higher	Much Higher	Don't Know
Breast cancer	46 (39%)	21 (17%)	32 (26%)	12 (10%)	3 (2%)	7 (6%)
Ovarian cancer	26 (21%)	23 (18%)	32 (26%)	7 (6%)	3 (2%)	6 (5%)
Colon cancer	31 (25%)	37 (30%)	34 (27%)	10 (8%)	2 (2%)	9 (7%)
Prostate cancer	8 (6%)	6 (5%)	7 (6%)	2 (2%)	0	0
Cardiovascular disease	15 (12%)	31 (25%)	41 (33%)	19 (15%)	8 (6%)	7 (6%)
Lung cancer	47 (38%)	33 (26%)	26 (21%)	10 (8%)	3 (2%)	6 (5%)
Diabetes	26 (21%)	23 (18%)	36 (29%)	15 (12%)	4 (3%)	7 (6%)
Alzheimer's disease	42 (34%)	28 (22%)	26 (21%)	10 (8%)	4 (3%)	13 (10%)
Hypertension	20 (16%)	17 (14%)	25 (20%)	12 (10%)	5 (4%)	6 (5%)

Participants' Perceptions of Risk Compared to General Population (Post-Session), n (% of participants)

Disease	Much Lower	Somewhat Lower	Same	Somewhat Higher	Much Higher	Don't Know
Breast cancer	58 (47%)	34 (27%)	16 (13%)	9 (7%)	1 (1%)	1 (1%)
Ovarian cancer	46 (37%)	28 (22%)	17 (14%)	5 (4%)	0	1 (1%)
Colon cancer	54 (43%)	35 (28%)	20 (16%)	11 (9%)	0	4 (3%)
Prostate cancer	5 (4%)	7 (6%)	7 (6%)	2 (2%)	0	1 (1%)
Cardiovascular disease	28 (22%)	30 (24%)	37 (30%)	16 (13%)	8 (6%)	3 (2%)
Lung cancer	58 (46%)	29 (23%)	31 (25%)	5 (4%)	0	2 (2%)
Diabetes	34 (27%)	27 (22%)	29 (23%)	14 (11%)	3 (2%)	4 (3%)
Alzheimer's disease	62 (50%)	19 (15%)	20 (16%)	11 (9%)	0	11 (9%)
Hypertension	21 (17%)	26 (21%)	19 (15%)	12 (10%)	5 (4%)	1 (1%)

Correct Risk Perception

Disease	Accurate (Pre & Post)	Inaccurate (Pre & Post)	Number of Participants Whose Perceptions Changed[a]	Inaccurate To Accurate	Proportion of Participants Whose Perceptions Became More Accurate	95% Confidence Interval
Breast cancer	57	26	29	19	0.655	0.457, 0.820
Ovarian cancer	40	26	22	19***	0.864	0.651, 0.971
Colon cancer	53	30	26	19*	0.731	0.522, 0.884
Prostate cancer	3	9	8	2	0.153	0.032, 0.651
Heart disease	28	49	38	28**	0.737	0.569, 0.866
Diabetes	32	43	29	20	0.689	0.491, 0.847
Alzheimer's disease	58	22	21	16*	0.761	0.528, 0.918

Note: *$p<0.05$, ** $p\leq0.005$, ***$p<0.001$

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