USING A MIXED-METHODS CASE STUDY DESIGN TO EXPLORE, EVALUATE, AND ENHANCE A CANCER PATIENT NAVIGATOR PROGRAM

by

LaShawn Marie Curtis

B.A., Johns Hopkins University, 2000

M.P.H., University of Medicine and Dentistry of New Jersey School of Public Health, 2002

Submitted to the Graduate Faculty of

The Graduate School of Public Health in partial fulfillment

of the requirements for the degree of

Doctor of Public Health

University of Pittsburgh

2008

UNIVERSITY OF PITTSBURGH

Graduate School of Public Health

This dissertation was presented

by

LaShawn Marie Curtis

It was defended on

July 23, 2008

and approved by

Dissertation Advisor:
Jeanette Trauth, MPA, MS, PhD
Associate Professor
Department of Behavioral and Community Health Sciences
Graduate School of Public Health
University of Pittsburgh

James Butler, MEd, DrPH
Assistant Professor
Department of Behavioral and Community Health Sciences
Graduate School of Public Health
University of Pittsburgh

Patricia I. Documét, MD, DrPH
Assistant Professor
Department of Behavioral and Community Health Sciences
Graduate School of Public Health
University of Pittsburgh

Robert M. Goodman, MA, MPH, PhD
Dean and Professor
School of Health, Physical Education, and Recreation
Indiana University Bloomington

Lyn B. Robertson, RN, MSN, DrPH
Associate Director of Cancer Control Services
University of Pittsburgh Medical Center Cancer Centers

USING A MIXED-METHODS CASE STUDY DESIGN TO EXPLORE, EVALUATE, AND ENHANCE A CANCER PATIENT NAVIGATOR PROGRAM

LaShawn Marie Curtis, DrPH

University of Pittsburgh, 2008

Background: Successful strategies for addressing inequalities in cancer care are greatly needed as critical racial/ethnic and socioeconomic cancer burden disparities persist in the United States. Patient navigation programs are a promising approach to reducing cancer care disparities.

Methods: A mixed-methods evaluation was conducted to systematically collect, analyze and share information about the context, activities, and early impacts of the University of Pittsburgh Medical Center (UPMC) Cancer Centers' Minority Outreach Pilot Program (MOPP), a newly implemented cancer patient navigator intervention. The dissertation applies and integrates two evaluation frameworks: 1) the Centers for Disease Control and Prevention (CDC) Framework for Program Evaluation, which provides an organizing structure and standards for conducting sound public health program evaluation, and 2) the RE-AIM framework, which helps to focus the evaluation on issues that are both relevant to stakeholders and critical to assessing the public health impact and generalizability of interventions. The evaluation employs a case study design that includes qualitative (e.g., program document review and informal and semi-structured interviews) and quantitative (e.g., descriptive statistical analysis of program database) methods to examine MOPP development and implementation.

Results: The MOPP evaluation provided valuable qualitative and quantitative data related to program implementation achievements and challenges. Additionally, the evaluation produced useful products (e.g., logic model and data reporting templates) and led to immediate small-scale enhancements (e.g., database modifications). Results from the program evaluation suggest that

MOPP is generally being implemented as planned. However, findings also called attention to key issues that should be monitored closely within the MOPP program, and, perhaps, within the larger patient navigation movement. These key issues include: the challenges of effectively navigating patients with substance abuse and the need to address the emotional burden of patient navigator work.

Conclusion: The public health significance of the evaluation lies in its potential to strengthen MOPP's impact on reducing cancer care disparities in the UPMC patient population. In addition, publication of the evaluation research will contribute to the growing evidence base for cancer patient navigator interventions and address the need to develop the literature on patient navigation.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

PREFACE

It is "by the grace of God I am what I am" (I Corinthians 15:10), and so I begin this acknowledgments section giving all honor and glory to God, with whom all things are possible. I thank God for provision, for covering me in peace, and for working *all* things together for my good; for growing me spiritually over these past few years to where I begin the next journey stronger, wiser, better. Hallelujah!

I am tremendously blessed with a family that loves, protects and supports me in and through all of life's ups and downs. To my parents, Jimmie and Barbara Curtis, I thank you for the sacrifices you so willingly and cheerfully make for all of your children. Thank you for nurturing in us a strong faith in God and a rigorous work ethic. You encourage us to dream without limits, and your love supports and keeps us as we do just that. Jimmie II, Jeanette, Aaron, Michael & Chandra, thank you for loving me through the past three years. Family, I share this achievement with you because I certainly couldn't have done it without you. Thank you, I love you.

Throughout my doctoral studies, I have leaned a great deal on a wonderful group of friends who have been cheerleaders, editors, sound boards—basically everything I needed whenever I needed it, and then some. Ericka Harris, Antoine Glasgow, Dolores Beane, Stacy Davis, and Julia Bryan, thank you for keeping me encouraged from across the miles. Keon

Gilbert, Donna Doebler, and Megan Kavanaugh, thank you for sharing this journey with me and for inspiring me through your research and passion for public health.

To Dr. William Houston Curtis, Pastor of Mt. Ararat Baptist Church, thank you for being an awesome shepherd and for delivering messages that build faith. To the children and staff of the Mt. Ararat BRIDGES after school program, thank you for allowing me to shake off the cares of the world a few hours each week with UNO and catch and silly giggles.

To my friends and mentors at the Pennsylvania Department of Health, especially Leslie Best, Serina Gaston, Brian Ebersole, and Calvin Johnson, thank you for supporting me in my doctoral studies from start to finish and for providing awesome opportunities for me to stay connected to real-world public health practice.

Lyn Robertson, Joyce Grater, Beth Simon, Betty Dowdy & Levonia Freelove, I cannot thank you enough for making me feel like a member of the Minority Outreach Pilot Program team. You graciously gave of your time and expertise to help make this evaluation a success, and your support is greatly appreciated. I'm also grateful to the MOPP patients who participated in interviews, providing insight on a very personal experience. I hope that this dissertation research will prove valuable for supporting ongoing program evaluation and improvement and that it will help showcase MOPP's important work.

Lastly, I salute the amazing group of public health researchers and experts that served on my committee. I thank my dissertation Chair, Jeanette Trauth, and committee members, James Butler, Patricia Documét, Bob Goodman, and Lyn Robertson for taking the time to thoughtfully review this dissertation and all the outlines, tables, and not-quite-formulated ideas that came before it. Thank you for guiding and coaching me through this process! It has been an honor and a pleasure working with you.

1.0 INTRODUCTION AND BACKGROUND

A mixed-methods evaluation (i.e., an evaluation that combines qualitative and quantitative methods) was conducted to systematically collect, analyze and interpret, synthesize and share information about the context, activities, and early impacts of the University of Pittsburgh Medical Center (UPMC) Cancer Centers' Minority Outreach Pilot Program (MOPP). MOPP is a patient navigator program that works to ensure access to the latest innovations in cancer treatment, regardless of financial means, for newly diagnosed African American cancer patients seeking care at one of four UPMC medical centers. Patient navigation in cancer care refers to individualized support offered to patients in accessing the cancer care system and overcoming barriers to quality care (United States Department of Health and Human Services, National Institutes of Health, National Cancer Institute [NCI], 2004). MOPP is one of UPMC Cancer Centers' strategies for reducing racial and ethnic disparities in cancer care and cancer clinical trial participation. The evaluation process has led to enhancements in Minority Pilot Outreach Program monitoring. Evaluation findings will be used to support improvements in program implementation and to help plan for program expansion and future evaluation activities. Additionally, planned publication of evaluation findings will help develop the literature on cancer patient navigator programs.

The MOPP evaluation applies the Centers for Disease Control and Prevention (CDC) Framework for Program Evaluation, which provides an organizing structure and standards for

conducting sound public health program evaluation. In addition, the evaluation pays special attention to the underling principles of the RE-AIM evaluation framework—namely that evaluation should focus on issues that are both relevant to stakeholders and critical to assessing the intervention's public health impact and generalizability. Detailed descriptions of these evaluation frameworks are provided in Section 1.5.3. The MOPP evaluation employs a case study design that includes qualitative (e.g., program document review and informal and semi-structured interviews) and quantitative (e.g., descriptive statistical analysis of the program database) methods to examine MOPP development and implementation.

1.1 THE CANCER BURDEN AND DISPARITIES

Patient navigation programs "provide a very promising approach to reducing disparities for cancer and other diseases" (Institute for Alternative Futures, 2007, p. 3). Successful strategies for addressing inequalities in cancer care are needed because critical racial/ethnic and socioeconomic cancer burden disparities persist in the United States: "In terms of disease stage at presentation and 5-year survival rates, a disproportionate burden of disease falls on members of racial and ethnic minority groups, those of lower SES [socioeconomic status], and recent immigrants—groups that, together, may be considered medically underserved or disadvantaged" (Dohan & Schrag, 2005, p. 848). These disparities are examined more closely in the following section, which presents national, state, and county cancer statistics that are of particular relevance to the efforts of UPMC Cancer Centers' Minority Outreach Pilot Program.

1.1.1 Incidence and mortality

In the United States, African Americans are more likely than whites to be diagnosed at a later stage of cancer, possibly due to factors such as less knowledge about cancer symptoms and reduced access to cancer screening services. Detection at a later stage, in turn, contributes to lower cure rates and shorter survival (ACS, 2005). For all cancer sites combined, African Americans are more likely to develop and die from cancer than persons of any other racial or ethnic group. They are also at greater risk of dying of the four most common types of cancer (lung, breast, colon, and prostate cancer) than any other minority group (ACS, 2005). Disparities in the cancer burden among racial/ethnic groups are often compounded by social ills. Poverty, together with related social and cultural factors, influences the entire spectrum of cancer care from prevention, detection and treatment to quality of life and survival. African Americans make up 13% of the US population, but comprise 24% of the nation's poor (American Cancer Society [ACS], 2005). An overlap of poverty and insurance coverage issues also contributes to disparities in cancer care. Low-income men and women who have inadequate or no health insurance coverage are more likely to be diagnosed with cancer at later stages, when survival times are shorter (CDC, 2006/2007).

In Pennsylvania, age-adjusted incidence rates for all cancers among African Americans were consistently higher than the rates for Whites during the eleven-year period 1993-2003 (Pennsylvania Department of Health [PA DOH], 2006). The 2003 cancer incidence rate per 100,000 among African American Pennsylvanians (523.3) was 7.1 percent higher than the rate for White Pennsylvanians (PA DOH, 2006). Additionally, in 2003, the age-adjusted incidence rate for African Americans in Pennsylvania was nearly 5 percent higher than the rate (499.4) recorded for African Americans by the National Cancer Institute's SEER Program (PA DOH,

2006). During the three-year period of 2001-2003, cancers among African American Pennsylvanians were most commonly diagnosed at the local stage (37.2 percent). Compared to Whites, African Americans in Pennsylvania had a lower percentage of cancers diagnosed at early stages (43.5 vs. 50.4) and a higher percentage of cancers diagnosed at late stages (43.8 vs. 39.0).

In Allegheny County, home to the four UPMC sites that participate in the Minority Outreach Pilot Program, the 3-year (2003-2005) age-adjusted cancer incidence rate per 100,000 (498.5) for all residents was significantly higher than the state rate (491.4) (Pennsylvania Department of Health [PA DOH], n.d.). In addition, the 3-year (2003-2005) county cancer incidence rate for African Americans (556.9 per 100,000) was significantly higher than the rate (491.2) for Whites (PA DOH, n.d.).

1.1.2 Clinical trials

Participation in cancer clinical trials (CCT) helps researchers make significant advances in the fight against cancer and provides patients with access to state-of-the-art treatments (C-Change, n.d.). An estimated 1.2 million Americans will receive a diagnosis of cancer this year, but only 3-5% of these new cancer patients will participate in a cancer clinical trial (C-Change), and this participation rate is even lower among minority groups and women (Baquet, Commiskey, Daniel Mullins, & Mishra, 2006; Bolen et al., 2006; Ford et al., 2005; Sheppard et al., 2005). Brawley (2004) asserts that racial/ethnic disparities in cancer clinical trial participation is also an issue of social justice. Among all cancer patients in the United States, those of higher socioeconomic status have led the increases in CCT accrual over the past several years and, thus, are major beneficiaries of clinical trial participation (Sateren et al., 2002). In addition, examination of the 20% increase in admissions to National Cancer Institute trials since the mid-1990s reveals that

the number of Asian, African American, Hispanic and Native American patients entering trials has remained relatively stable while the enrollment of whites has increased (Christian & Trimble, 2003).

The literature identifies several barriers to and facilitators of participation in cancer clinical trials, including patient and provider knowledge, attitudes and beliefs; access; religious and cultural beliefs; and strict inclusion and exclusion eligibility criteria for trials (Bruner, Jones, Buchanan, & Russo, 2006; Christian & Trimble, 2003; Comis, Miller, Aldige, Krebs, & Stoval, 2003; Ford et al., 2005). Racial and ethnic disparities in cancer clinical trial participation are often assumed to be the result of minorities' unwillingness to participate in health research; however, there is little evidence to support this claim (Wendler et al., 2006; Trauth et al., 2005). In fact, some studies suggest that the primary challenge with CCT recruitment and accrual is not the attitudes of patients or their unwillingness to participate, but rather the limited availability of appropriate trials and the disqualification of large numbers of patients due to comorbidities, insurance coverage issues, or even transportation barriers (Comis, Miller, Aldige, Krebs, & Stoval, 2003). Reluctance of some physicians to engage in accrual (Comis et al., 2003), a reluctance that may be heightened by certain assumptions about patients' willingness and financial ability to participate in CCTs (Michaels, n.d.), also partly explains low CCT participation rates. These barriers speak to the importance of culturally appropriate strategies for CCT recruitment (Sheppard et al., 2005).

1.2 CANCER PATIENT NAVIGATION

1.2.1 Origins and description

Underserved populations face a number of barriers that impede timely quality cancer care, including: being uninsured or underinsured; differing cultural orientations that may contribute to lack of trust in medical systems or difficulties in negotiating relationships with health care providers and organizations; and existing logistical barriers, such as lack of transportation or child care, inconvenient clinic schedules, rural residence and distance from health care centers (Dohan & Schrag, 2005; Fowler, Steakley, Garcia, Kwok. & Bennet, 2006). Such barriers can be placed within a larger context of the "complex and overlapping interplay of poverty, culture, and social injustice" in the United States, which Freemen posits "underscore the challenge of reducing cancer disparities (2004, p. 44). In an effort to help patients overcome financial, communication, medical system, and emotional or fear barriers to cancer screening, diagnosis and timely treatment, the nation's first patient navigator program was implemented in 1990 by Freeman and colleagues at Harlem Hospital in New York City (Fowler et al., 2006; Freeman 2006).

The original patient navigator program model was established in response to key findings from the American Cancer Society's 1989 hearings on cancer in poor populations, in which testimony was heard from patients, their medical care providers and other cancer experts (Freeman, Muth, & Kerner, 1995; Vargas, Ryan, Jackson, Rodriguez, & Freeman, 2008); analysis of mortality data for the Harlem community that revealed racial and ethnic disparities in excess mortality from cancer and other treatable diseases (Vargas et al.; 2008); and Dr. Freeman's "personal experience in providing cancer care to poor black patients in Harlem"

(Freeman, 2006, p. 139). The nation's first patient navigation program focused on reducing breast cancer care disparities among a predominantly poor and African American patient population (Freeman, 2006).

Since the implementation of the first patient navigator program, the Harlem community served has experienced a decrease in the percentage of patients presenting with late stage breast cancer and an increase in the percentage of patients presenting with stage 0 or 1 breast cancer (Vargas et al., 2008). While a causal association has not been established, the initial positive findings from the early navigator model, along with the significant need for interventions that are effective in reducing cancer care disparities, have led to widespread adoption, adaptation, and replication of the patient navigation model across the country (Vargas et. al, 2008). Not only is patient navigation being applied across the broad spectrum of cancer care, it is also being used for a variety of diseases across the United States (Vargas et al., 2008; Freeman, 2007).

Despite its popularity and widespread use, limited study of cancer patient navigation appears in the peer-reviewed literature (Vargas et al, 2008). Moreover, variation exists in the model definitions and descriptions developed by prominent cancer care experts and organizations. In a qualitative study designed to define the processes, structure and contextual influences of the first patient navigator programs, Vargas and colleagues (2008, electronic publication ahead of print) maintain that *patient navigation* is a "system as opposed to a person…. The processes of this intervention are largely defined by navigators removing barriers to care, documenting these barriers, and feeding back this information to directors to implement system level change, thus providing the opportunity to address individual and system level contributors to disparities".

Vargas and colleagues describe the patient navigation system, which is broader in scope than both the action of patient navigation (i.e., supporting and guiding patients through the cancer care system) and the person, or navigator, who performs this action. This system description is complemented by definitions from the National Cancer Institute and C-Change, which detail exactly what is included in patient navigation as an action. According to the National Cancer Institute, patient navigation for cancer care "refers to support and guidance offered to persons with abnormal findings in accessing the cancer care system and overcoming barriers to quality, standard care. Navigation spans the period from abnormal finding from cancer detection procedure through necessary cancer diagnostic tests to completion of cancer treatment" (NCI, 2004, p. 2). C-Change, a national organization comprised of the nation's key cancer leaders from government, business, and non-profit sectors, established a similar definition for patient navigation in cancer care:

> Patient navigation in cancer care refers to individualized assistance offered to patients, families, and caregivers to help overcome health care system barriers and facilitate timely access to quality medical and psychosocial care from pre-diagnosis through all phases of the cancer experience. Navigation services and programs should be provided by culturally competent professional or non-professional persons in a variety of medical, organizational, advocacy, or community settings. The type of navigation services will depend upon the particular type, severity, and/or complexity of the identified barriers (C-Change, 2005).

Clearly, the C-Change definition for cancer patient navigation promotes the context-driven nature of the intervention and acknowledges that variability among programs exists

around navigator characteristics, program setting, and services provided. In 2003, NCI's Center to Reduce Cancer Health Disparities (CRCHD) surveyed 89 community-based cancer patient navigator programs (Garcia, 2005). Among the 51 programs that responded, CRCHD found considerable variation in the services patient navigators provided, training of navigators, and the backgrounds and professional experience of navigators (Garcia, 2005). Garcia reports that some programs have lay navigators, including cancer survivors and community members, while in other programs, navigators are nurses or social workers (2005). With regard to navigator characteristics, Freeman (2006) explains that *patient navigators* are charged with identifying, anticipating, and helping to alleviate barriers to cancer care that patients encounter. Thus, navigators should be sensitive, compassionate, and culturally attuned to the patients and community being served; knowledgeable about the healthcare system and environment; and connected with critical decision makers within the healthcare system, particularly with financial decision makers (Freeman, 2004, 2007).

By design, patient navigation is a context-driven intervention—the services navigators provide are specific to the needs of their patients and the barriers they identify. Consequently, navigator programs throughout the nation vary widely in the strategies they adopt and apply in order to reduce or eliminate cancer care barriers, but interventions often include:

- Providing emotional support to cancer patients, as well as information on what to expect during their cancer care;
- Helping patients understand their diagnoses;
- Coordinating appointments with providers to ensure that patients with suspicious findings receive timely diagnosis and treatment;

- Helping to arrange transportation and/or child/elder care for visits to cancer treatments;
- Helping to arrange language translation or interpretation services;
- Helping patients and their families access support systems; and
- Facilitating access to available financial support and assisting with related paperwork. (Dohan & Schrag, 2005; NCI, 2006).

Navigator program activities may also include community outreach and screening services, efforts to improve access to cancer clinical trials, and partnership building with local organizations and groups to link patients to cancer support groups or needed social services (NCI, n.d.). Patient navigators have some characteristics and roles that are commonly associated with those of community health workers and case managers, including working with populations that experience racial and ethnic disparities in care and coordinating care for a complex disease within a complex care system (Vargas et al., 2008). However, Vargas and colleagues explain that community health workers operate primarily outside of a medical center, unlike navigators (2008). Additionally, unlike navigators in the original intervention model, case managers are generally certified trained health care professionals and may not share a common community or cultural connection with patients served by the program (Vargas et al., 2008). Fleisher maintains that "the purpose of navigation is not to replace or overlap existing roles, but to complement them by filling in gaps in services and *proactively* facilitating the delivery of care to all patients" (2008, p. 1).

In addition to the high degree of variability in the services and structure of cancer patient navigator programs, the popular intervention is also noted as frequently informal and undocumented in health care (C-Change, n.d.):

> …few tertiary hospitals including comprehensive cancer centers appear to have discrete cancer patient navigation programs. Instead, these specialty centers host a variety of services provided by social workers, nurses, and others designed specifically for their cancer patients on an as-needed basis. For cancers other than breast cancer, it is rare to find targeted patient navigation efforts, despite the many different approaches in the past 40 years initiated to help patients and families move through the cancer care system. (C-Change, p.15)

Yet, health researchers, cancer experts, and national cancer organizations appropriately recognize patient navigation as a promising approach to improving the quality of patient care and reducing cancer disparities (Bowles, Tuzzio, Weise, Kirlin, Greene, Clauser, & Wagner, 2008; Fleisher, 2008; Institute for Alternative Futures, 2007). A 2003 National Cancer Institute survey found that over 200 cancer care programs nationwide had some form of patient navigation—many navigation activities and programs were funded by small grants from private foundations (Hede, 2006).

1.2.2 Impact and research gaps

The public health literature suggests that patient navigation is associated with improved rates of screening and follow-up, earlier diagnosis of disease, and higher levels of patient satisfaction (Dohan & Schrag, 2005). Program descriptions and process evaluations further suggest that patient navigator services improve clinics' ability to engage, track, and support patients and to develop and enhance communication and trust between clinic staff and patients from disadvantaged groups (Dohan & Schrag, 2005). However, these inferences are merely

"suggestive of opportunities for future research" because "studies to date have not employed sufficiently rigorous research designs to allow any conclusions about the true effects of navigation programs", and "published evidence from randomized trials demonstrating that navigation is effective in reducing health disparities does not exist"(Dohan & Schrag, 2005, p. 853). One of the only reviews of patient navigation effectiveness published by Dohan and Schrag asserts that "we have no definite knowledge of how or whether programs address barriers to care" (Dohan & Schrag, 2005, p. 853; Hede, 2006). The researchers also argue that "systematic evaluations of navigation only recently have begun and have yet to appear in the literature…many navigation programs have been oriented toward local quality-improvement initiatives rather than scientific research, evaluation, and publication (Dohan & Schrag, 2005, p. 849). On patient navigator evidence to date, the National Cancer Institute summarizes:

> Training people within communities to guide and support patients who need assistance obtaining timely, quality standard cancer care, a concept known as patient navigation, has already demonstrated potential. Patient navigation has increased survival rates among African American breast cancer patients in Harlem, and educated the larger community about cancer prevention and treatment (NCI, 2006, p.2).

The lack of definitive knowledge notwithstanding, Freeman (2004) maintains that "patient navigation is one community intervention that has great potential to save lives by eliminating economic and cultural barriers to the early diagnosis and treatment of cancer" and emphasizes that, in order to win the war on cancer, "we must apply what we know at any given time to all people, and we must also recognize and eliminate all barriers to quality cancer care" (p. 46). In addition to noting the potential value of navigator programs for reducing barriers to

quality cancer care, the literature suggests that patient navigators can play an important role in promoting access to cancer clinical trials (Fowler et al., 2006). Despite, the absence of sufficient rigorous research on the effectiveness of patient navigator programs, navigation is in demand by physicians and is "an appealing concept that many in the health care system are clamoring for" (Hede, 2006, p.159).

Patient navigation is also receiving a great deal of attention at the federal government level, and efforts are underway to address the lack of sufficiently rigorous research on the true effects of navigator programs. The Patient Navigator Outreach and Chronic Disease Act of 2005 was enacted into public law in the United States in June 2005. The Act authorized the Health Resources and Services Administration (HRSA) to administer a $25 million demonstration grant program in coordination with the Indian Health Service, the Office of Rural Health Policy, and the National Cancer Institute (Fowler et al., 2006). NCI's Center to Reduce Cancer Health Disparities (CRCHD) is currently conducting a pilot program in Portland, Oregon to evaluate the effectiveness of using patient navigators to help American Indians overcome the unique barriers to cancer care that they experience. CRCHD has also collaborated with the NCI Radiation Research Program in using navigators to promote recruitment for clinical trials among medically underserved, low income, and minority communities (NCI, 2006, p.1).

In 2005, the National Cancer Institute launched a multi-site Patient Navigator Research Program (PNRP), directed by the CRCHD, to test the navigator approach to increasing patient access to health care. NCI recently awarded a total of 19.5 million in 5-year cooperative grants to eight academic research institutions to establish the PNRP; a ninth site was funded by the American Cancer Society (NCI, 2005). PNRP participating institutions are charged with: 1) developing innovative patient navigator interventions to reduce or eliminate cancer health

disparities, and 2) testing the efficacy and cost-effectiveness of the interventions (NCI, 2006, p.1). PNRP's ultimate aim is to decrease the time between a cancer-related abnormal finding, definitive diagnosis, and delivery of quality standard care (NCI, 2006, p. 1), and PNRP projects are designed to address the following research questions:

- How do patient navigation services assist patients in overcoming cancer care barriers (e.g., financial, language, transportation, health system)?
- To what extent does type/degree of service reduce or eliminate patient barriers to accessing timely, quality standard cancer care?
- Do navigated patients receive more timely cancer care diagnosis and treatment?
- Does matching of patient and navigator demographics and primary spoken language affect standard-of-care adherence and perceived cancer care satisfaction?
- Are patient navigation services cost-effective in reducing cancer health disparities? (NCI, n.d.)

The federal funding of national pilot navigation programs reflects a major commitment to exploring the promise patient navigation holds for reducing cancer disparities, but the emphasis on building a base of rigorous evidence for patient navigation calls to mind current and ongoing debates in the public health field regarding valid forms of evidence (McQueen, 2001).

Indeed, the NCI PNRP and its academic institution grantees will address several important research questions regarding the impact of patient navigator programs by applying scientifically sound and rigorous practices and methods, including: "a central data coordination and program evaluation contractor to conduct formal qualitative and quantitative evaluations"; "rigorous evaluation of navigation intervention effectiveness and cost-effectiveness"; and

research designs that include both a continuous comparison group throughout the study period to "address history effects, system biases, community activities that may impact changes in cancer disparities, and other confounding factors" (NCI, 2004, p. 4). However, results of the multi-site study, which are intended to "provide community-based patient navigator interventions that can be implemented in other communities across the nation", will not be available to the public until 2010 or later (NCI, 2004, p.4).

In the meantime in the world of public health practice, hundreds of patient navigator programs have already been established throughout the country as part of local cancer control efforts by cancer centers, community-based clinics and philanthropy (Dohan & Schrag, 2005; Hede, 2006). Cancer care agencies, such as the UPMC Cancer Centers in Pittsburgh, will likely continue launching navigator services and programs to address identified disparities in the cancer burden, health care systems utilization, and quality of care in their local communities. Existing navigator programs represent public health action in the absence of the best possible evidence regarding the effectiveness of patient navigation. Arguably, timely and practical program evaluation is needed to guide, support and enhance practitioners' effort to use the best available evidence to address cancer care needs and disparities in their communities:

> A continued dialogue will help us to further understand patient navigation and the various roles navigators can play to support patients through the cancer care continuum. As the practice of patient navigation expands, there is a great deal to be learned about the process, political climate, and day-to-day challenges in planning and implementing a navigation program (Fleisher, 2008, p.2).

1.3 UPMC CANCER CENTERS' MINORITY OUTREACH PILOT PROGRAM

1.3.1 Origins and description

The Minority Outreach Pilot Program informs the study for the present dissertation. The University of Pittsburgh Medical Center (UPMC) and UPMC Cancer Centers implemented the Minority Outreach Pilot Program in March 2006 with input from the African American Cancer Care Partnership (AACCP)—a task force of representatives from the Pittsburgh community, local health care centers, academic institutions, and community organizations working to facilitate collaboration among, and guide and coordinate the efforts of, various groups whose goals are to improve the health of African Americans. Lyn Robertson, DrPH, RN, MSN led MOPP planning and development. She received $750,000 in gap funds from UPMC and was charged with using the funds to address two issues identified by the medical center: low levels of treatment compliance and cancer clinical trial participation among its African American patients.

The original goal of the Minority Outreach Program (MOPP) was to eliminate barriers to cancer care by ensuring that African American patients who were newly diagnosed with prostate, lung, breast, or colorectal cancer and who sought care at the Hillman Cancer Center, Magee-Womens Hospital of UPMC, UPMC McKeesport, or UPMC Braddock had access to the latest innovations in cancer treatment, regardless of financial means. However, shortly after MOPP initiation, managers realized that the program had the capacity to contact and serve African American patients at the four program sites who were newly diagnosed with any form of cancer. MOPP operates as a patient navigation system and includes culturally sensitive patient navigator

services, gap funds to cover care for patients on a clinical trial, individualized assessments of barriers to care, and identifying solutions to overcome those barriers.

MOPP's program theory (i.e., the intended relationship between program inputs, activities, outputs, and intended outcomes) represents an adoption and tailoring of the original patient navigator model developed by Freeman in 1990 (Freeman, Muth & Kerner, 1995) and is graphically depicted in Appendix A. The logic model presented in Appendix A was developed as part of the evaluation process presented in the dissertation. It has and can continue to be used by the program to describe MOPP to administrators, stakeholders, and potential funders. The logic model also helps to guide the evaluation activities that were completed for the dissertation and can help inform and direct ongoing program monitoring and future evaluations.

As depicted in the program model, the program is based on certain assumptions that are consistent with the Freeman patient navigation model. Specifically, patient navigation operates as a process in which navigators provide social support to remove the barriers to care patients experience. This social support includes emotional support, or expressions of empathy and caring; instrumental support, which is tangible aid and service; and informational support, or the provision of information, advice and suggestions that patients can use to address problems (Heaney & Israel, 2002). The patient navigation process also includes the documentation of barriers, and the feeding back of barrier information to health care system management to support system level change. The program also operates under the assumption that navigators need to be sensitive, compassionate, and culturally attuned to the patients and community being served; knowledgeable about the health care system & environment; and connected with critical decision makers within the health care system.

The program's resources (including community partnerships, program staff and funding) support the delivery of navigation services, which include barrier assessments, financial counseling and assistance, and cancer clinical trial education and recruitment. Over time, navigator services are intended to lead to change in cancer care knowledge, awareness and behavior among program participants and improvements in cancer care delivery systems. Short-term and intermediate outcomes include increasing patients' knowledge of resources for overcoming barriers to care and increasing the health care centers' knowledge of patient barriers to cancer care and cancer clinical trial participation. Ultimately, the achievement of short-term and intermediate outcomes is expected to lead to the elimination of barriers to cancer care and increased survivorship for the program's target patient population, as well as increased African American representation in cancer clinical trials across participating health care centers. MOPP experiences in achievements in working toward these important long-term outcomes will help improve public health researchers and practitioners' knowledge about improving CCT participation and reducing disparities among minority cancer patients.

Since its initiation in March 2006 through April 2008—the planned data collection end date for the dissertation research—a total of 249 patients have been referred to the Minority Outreach Pilot Program. Of the 249 patients contacted and/or served by the program, 75 have accepted and utilized the program's patient navigator services and 27 have enrolled in cancer clinical trials. It is important to note that the 249 patients listed in the program database include 14 patients for whom navigators were not available because the patients were not receiving care at one of the four participating MOPP sites. However, as part of expanded program activities initiated in 2008, these 14 patients were contacted through MOPP to screen for their willingness and eligibility to participate in a cancer clinical trial (CCT). None of these "CCT screen only"

patients enrolled in trials. Excluding CCT screen only patients, about 32% of the target patient group touched by MOPP accepted and utilized patient navigation services. Navigators and program staff communicate with patients both by phone and face-to-face. Methods and frequency of communication, as well as services provided, are individualized according to each patient's needs and preferences and therefore, may change throughout a patient's cancer care experience.

Common barriers to cancer treatment identified and addressed through the Minority Outreach Pilot Program include: lack of transportation and no or limited health insurance. Program participants have also relayed housing-related, co-morbidity, and job-related concerns. These additional issues can pose barriers to care in the sense they may take priority over compliance with cancer detection and treatment appointments. As presented in the following section, evaluation objectives and questions focused on describing program and patient characteristics through qualitative and quantitative research methods. Hence, detailed summaries of program services and patient demographics are provided throughout the chapters of manuscript drafts and in Chapter 5.

1.3.2 Evaluation needs

The Minority Outreach Pilot Program was launched quickly in an effort to respond to real-time concerns about ensuring high quality cancer care for African American patients, particularly those who were new to the UPMC system, and increasing their participation in cancer clinical trials. As MOPP is a fairly new program, evaluation needs primarily centered on the process of program development and initial years of implementation. The Program Director and staff particularly valued the opportunity to:

- Clearly describe program context, activities, and planned impact to facilitate comparison with other cancer patient navigation interventions and MOPP expansion and possible replication;
- Calculate the cost associated with MOPP development and implementation;
- Identify achievements and challenges in carrying out planned program activities and in meeting short-term objectives; and
- Explore opportunities for program improvement and identify key considerations for program maintenance and expansion.

These stakeholder priorities helped to determine the focus of the evaluation, which is outlined in the following section.

1.4 EVALUATION GOALS, OBJECTIVES AND QUESTIONS

The mixed methods evaluation of the UPMC Cancer Centers' Minority Outreach Pilot Program was designed to accomplish two broad goals: 1) to facilitate enhancements in Minority Outreach Pilot Program implementation, MOPP expansion, and ongoing MOPP monitoring and evaluation; and 2) to contribute to the growing national evidence base for cancer patient navigator programs by illuminating real-world contexts and experiences of patient navigator programs. The following specific objective was developed to support the accomplishment of the two broad dissertation goals: to systematically collect, analyze and interpret, synthesize and share information about the context, activities, outputs and early outcomes of the MOPP by May 2008.

MOPP evaluation questions, design and methods were guided by two evaluation frameworks, the Centers for Disease Control and Prevention (CDC) Framework for Program Evaluation in Public Health and RE-AIM framework; aligned with the priorities of key program stakeholders; and informed by key perspectives from public health evidence and translation debates, as well as by important principles for evaluating complex community interventions. The dissertation employed a case study research design, which included triangulation of data collection and analysis methods to answer the following questions about the Minority Outreach Pilot Program:

- How many participants does the program serve, and what are the characteristics of the program participants?
- What is the program's reach into the target population?
- To what extent is the program being implemented as planned?
- Is the program making progress toward the achievement of short-term outcomes?
- Are there unintended or unexpected program outcomes?
- What are the costs associated with implementing the program?

The evaluation appropriately focuses primarily on program implementation, or process, as MOPP is a newly implemented program.

1.5 GUIDING PERSPECTIVES, PRINCIPLES AND FRAMEWORKS

1.5.1 Key perspectives from public health evidence and translation debates

This dissertation research applies and encourages broad thinking with regard to what types of evidence are considered sufficiently sound and valid to support public health decision-making. The issue of how one defines evidence and categorizes it hierarchically—typically with study designs ranked according to the strength of their internal validity, with randomized control trials being the gold standard and descriptive case reports falling to the weaker end of the hierarchy (Petticrew & Roberts, 2003)—has been a topic of intense debate in the public health field since the 1990s (McQueen, 2002; Petticrew & Roberts, 2003). The evidence-based public health movement grew out of the clinical evidence-based medicine model (McGuire, 2005), but over the years, public health researchers and practitioners have questioned the appropriateness and relevance of a clinical model for assessing the effectiveness of public health interventions (Goodman, 2001; Green, 2001; Green & Glasgow, 2006; McQueen, 2001). The public health evidence debate is multifaceted and reflects several related historic and ongoing tensions in the field. An extensive review of these tensions and the history of the evidence debate are discussed in the third dissertation manuscript (Chapter 4). A summary of the widely-debated evidence issues is provided in Table 1.

Table 1. Summary of Debated Evidence Issues in Public Health

Tensions	Arguments
Paradigms	There are historic differences between the ways in which "postivists/empirical realists and interpretivists/constructionists understand reality and causation" (McGuire, 2005, p.558).
Sciences & Methods	There is disagreement regarding the "relative value of evidence based on epidemiologic and probabilistic reasoning vs. that based on sociological methods" (Kemm, 2006, p.320).
Areas of Study with Public Health	There are differences "between concepts of what counts as evidence in biomedical public health versus health promotion practice" (Raphael, 2000, p. 355).
Units of Intervention	"Taking communities rather than individuals as the unit of intervention and the importance of context means that frequently randomized controlled trials are not appropriate for the study of public health interventions" (Kemm, 2006, p.319; Raphael, 2000).
Research vs. Practice	"Differences in approach are sometimes found between practitioners and researchers. Practitioners tend to emphasize the importance of providing services to people and the role of empathy and concern in the intervention process. Researchers, on the other hand, may give more weight to the understanding provided by rigorous scientific analysis and objectivity. (Monette, Sullivan & DeJong, 1997, p. 320). "Significant tension exists between the imperatives of the university-based research enterprise and the obligations of agencies and organizations responsible for addressing the health needs of populations" (Potter & Quill, 2006, p. 14). "Where did the field get the idea that evidence of an intervention's efficacy from carefully controlled trials could be generalized as *the* best practice for widely varied populations and settings?" (Green, 2001, p.167) "Much research fails to translate into practice because the programs and methods used fail to address contextual factors"—they "employ a limited and researcher-centric perspective as to what constitutes 'evidence'" (Glasgow & Emmons, 2007, p. 417).

McQueen provides an insightful summary of the evidence debate as it relates to intervention research and evaluation in communities:

> Within the general area of community research, intervention and evaluation there is currently great debate about what constitutes knowledge in the field and what is evidence, or even whether the notion of evidence is applicable to the evaluation of intervention in communities. In summary, there is non consensus on any 'hierarchy of evidence' between researchers and practitioners in the field" (2001, p. 266).

Amid this evidence debate (highlighted in Table 1), the major, national resources for evidence-based programs, such as The Guide to Community Preventive Services and the National Cancer Institute's Research-Tested Intervention Programs (RTIPs), apply and promote more of a biomedical or epidemiological approach to determining what constitutes sufficient evidence to warrant recommending the widespread adoption and implementation of various public health interventions (McQueen, 2001; Task Force, 2007). Arguably, a broader conceptualization of what constitutes sound, valid evidence in public health is necessary to address the gaps that have resulted from the field's longstanding predilection for positivist-driven conceptualizations of evidence that rely heavily on results from experimental designs:

> many evidence gaps remain and the gaps are not random. There are still cultural, geographical, economic, and methodological biases in determining what is studied and how. The availability of high-quality evidence often seems to favor clinical treatment over prevention, and interventions that are…simple over those that are more complex, those with shorter-term objectives over those that are longer-term…. Much more work is needed to fill these gaps and to shine the light where it is currently dark (Briss, 2005, p. 829).

What counts as evidence in public health is still a contested issue. Nevertheless, there is a general consensus among practitioners that evidence is important in order to: reduce uncertainty in public health decision-making (Raphael, 2000); justify the decisions of public health practitioners regarding public health efforts; and to demonstrate the benefits of adopted interventions to their organizations, funders, policy-makers, and other stakeholders (McQueen, 2002; Raphael, 2000). In addition, it is generally accepted that different evaluation and research questions require different methods of inquiry and that it is "irrational to regard any method as superior for all purposes" (Kemm, 2006, p. 320). So, the ongoing evidence debate need not be viewed as a hindrance to public health research and program evaluation. Quite the opposite—as in the present case, the principles and concepts such as those listed below that have fueled, and grown out of, the evidence debate encourage elevated thinking around the scope, methods, and significance of public health research and evaluation:

- *Types of Evidence*: There are several types of evidence that can be drawn upon in public health program development and evaluation, including theoretical data, feasibility/implementation evidence, contextual information (e.g., constraints, history, resources), intended primary outcome evidence, unintended or unanticipated outcome results, process results, outcome or clinical data, quality improvement data, cost and economic data, qualitative data, local data, internal validity evidence, and external validity evidence (Glasgow & Emmons, 2007).
- *Integrating Evidence*: Methods are needed to integrate and synthesize different types of evidence (Glasgow & Emmons, 2007). Evaluators should use a wide range of qualitative and quantitative methods to move beyond randomized control trials, which

are often not feasible for complex public health programs due to practical and resource constraints (Raphael, 2000; Rychetnik, Frommer, Hawe & Shiell, 2002).

- *Best Quality Evidence*: The term "best quality" evidence should refer to evaluative research that was matched to the stage of development of the intervention; was able to detect important intervention effects; provided adequate process measures and contextual information, which are required for interpreting the findings; and addressed the needs of important stakeholders" (Rychetnik, Frommer, Hawe & Shiell, 2002, p. 125).
- *Best Available Evidence*: For many public health problems, intervention strategies should be recommended based on the best available evidence instead of waiting for the best possible evidence (Glasgow & Emmons, 2007).

This dissertation research will produce process evaluation data, which, as argued above, represents a valid contribution to the cancer patient navigation literature that other practitioners and researchers can draw upon for public health program development and evaluation. As recommended by Glasgow & Emmons (2007), this evaluation also integrates qualitative and quantitative methods to help ensure that the evidence produced regarding the activities and early outcomes of the MOPP program is of high quality. In this dissertation research, the quality of evidence is not established by the use of the most scientifically rigorous design, rather by other key considerations presented by Rychetnik and colleagues above, including the appropriateness of design to program stage and responsiveness to stakeholder needs (2002). Evaluation findings represent a timely contribution to the best available evidence (Glasgow & Emmons, 2007) on cancer patient navigation, which will help practitioners—who cannot afford to wait for the best

possible evidence base to be developed—make informed decisions about adopting and evaluating their navigation interventions.

1.5.2 Important principles for evaluating community interventions

Approaching evaluation through the lens of broader conceptualizations of evidence helps researchers understand that experimental and quasi-experimental designs, although recognized as the most scientifically rigorous designs, are not necessarily the most appropriate or informative designs for evaluating complex community health interventions or real-world efforts to reduce health disparities (Goodman, 2001; Rust & Cooper, 2007). Goodman explains that "in evaluating single and complex community programs, 'how' or 'why' an intervention worked (or did not work) often is *sine qua non*, and qualitative case study designs are considered as optimum in such evaluations" (2001, p. 300). Case studies give an in-depth picture of the implemented program, its organizational context, and the broader environment by integrating qualitative and quantitative information from a variety of sources (Love, 2004).

According to Love (2004), case studies are particularly useful for understanding the implementation of innovative or demonstration programs. If "innovative" is defined according to its use in Rogers's Diffusion of Innovation Model (i.e., a practice that is perceived as new by an organization), the Minority Outreach Pilot Program is appropriately classified as an innovative program and matches well with a case study evaluation design (Oldenburg & Parcel, 2002). Case studies are a common and valuable way to pursue qualitative inquiry, although, it is important to note that case study research is not essentially qualitative (Goodman, 2001; Stake, 2005). In fact, a noted benefit of case studies is their "flexibility and ability to assemble a comprehensive array of quantitative and qualitative data to provide in-depth analysis and

valuable insight" (Love, 2004, p.82). Stake (2005) points out that a "case study optimizes understanding by pursuing scholarly research questions…[and] gains credibility through triangulating the descriptions and interpretations, not just in a single step but continuously throughout the period of study" (p. 443)

Adopting a case study approach to inquiry simply helps to focus the research design. Research design is just one component of a sound, comprehensive program evaluation (CDC, 2005). The evaluation frameworks discussed in the following section helped to organize the overall program evaluation and guide the identification of appropriate data collection and analysis methods.

1.5.3 Guiding evaluation frameworks

The *Centers for Disease Control and Prevention Framework for Program Evaluation in Public Health* serves as the "basic organizational framework" for the overall program evaluation (CDC, 1999, p.2). The MOPP evaluation design also draws on key principles of the RE-AIM evaluation framework (i.e., evaluation should focus on issues that are both relevant to stakeholders and critical to assessing the public health impact and generalizability of public health interventions). For the purposes of this research, RE-AIM fits nicely within the CDC organizational framework. Specifically, the RE-AIM model was used to help focus the evaluation design and methods, which falls under step three of the six-step CDC Framework for Program Evaluation in Public Health.

The CDC Framework for Program Evaluation in Public Health is based on the premise that "good evaluation does not merely gather accurate evidence and draw valid conclusions, but produces results that are *used* to make a difference" (CDC, 2005, p.6). The CDC Framework

defines six steps and four standards for conducting sound evaluations of public health programs. The six Framework steps are:

- *Engage stakeholders*, those persons involved in or affected by the program and primary users of the evaluation.
- *Describe the program* based on need, expected effects, activities, resources, stage, and context. Logic models are valuable tools for graphically depicting program theory.
- *Focus the evaluation design* in terms of purpose, users, uses, questions, methods, and feasibility.
- *Gather credible evidence*. Consider indicators and sources of evidence/methods of data collection, issues of quality and quantity, and logistics.
- *Justify conclusions* according to standards. Conduct data analysis/synthesis, interpret data, and make judgments.
- *Ensure use and share lessons learned*. Provide feedback and draft recommendations. Support stakeholder preparation for receiving and utilizing results. Disseminate findings and follow-up with stakeholders (CDC, 1999).

During each step of the evaluation process, decisions regarding evaluation activities are guided by the four evaluation standards for effective evaluation:

- *Utility*: Serve the information needs of intended users.
- *Feasibility*: Be realistic, prudent, diplomatic, and frugal.
- *Propriety*: Behave legally, ethically, and with regard for the welfare of those involved and those affected.
- *Accuracy*: Reveal and convey technically accurate information.

The RE-AIM framework "offers a comprehensive approach to considering five dimensions important for evaluating the potential public health impact of an intervention": reach, effectiveness, adoption, implementation, and maintenance (Glasgow, Klesges, Dzewaltowski, Estabrooks & Vogt, 2006, p.688). The evaluation model was developed to expand assessment of interventions beyond efficacy to multiple criteria that can help better identify the translatability and public health impact of health promotion interventions (Glasgow, 2002; Glasgow, Vogt, & Boles, 1999). RE-AIM provides a framework for determining if programs are worth continued investment and for identifying programs that work in real-world environments; it's a flexible model that can be used to guide and evaluate a wide range of interventions, from randomized controlled studies to qualitative research (Glasgow, Vogt, & Boles, 1999). RE-AIM is a particularly useful tool for researchers and practitioners whose goal is to translate research into practice (Dzewaltowski, Estabrooks, & Glasgow, 2004; Dzewaltowski, Glasgow, Klesges, Estabrooks, & Brock, 2004; Klesges, Estabrooks, Dzewaltowski, Bull, & Glasgow, 2005; Sussman, Valente, Rohrbach, Skara, & Pentz, 2006).

Descriptions for the five dimensions of RE-AIM are listed below; all dimensions are considered equally important by framework developers for evaluating the translatability and public health impact of interventions (Workgroup to Evaluate and Enhance the Reach and Dissemination of Health Promotion Interventions, 2004).

- *Reach*: Reach refers to the absolute number, proportion, and representativeness of individuals who participate in a given program. *Representativeness* refers to whether participants have characteristics that reflect the target population's characteristics.

- *Efficacy/Effectiveness*: Within the RE-AIM Framework, the efficacy/effectiveness dimension refers to the impact an intervention has on important outcomes. These impacts include potential negative results, quality of life, and costs.
- *Adoption*: Adoption refers to the absolute number, proportion, and representativeness of settings and/or staff who are willing to offer a program.
- *Implementation*: The implementation dimension focuses on how closely staff members at the setting level follow the program that the developers provide. Implementation measures may also assess consistency of delivery as intended by the program, time required for program implementation, and the cost of the program.
- *Maintenance*: Maintenance measures describe the extent to which a program or policy becomes part of routine organizational practices and policies. Within the RE-AIM framework, maintenance also refers to the long-term effects of a program on individual level outcomes six or more months after the most recent intervention contact (Workgroup to Evaluate and Enhance the Reach and Dissemination of Health Promotion Interventions, 2004).

As it is not necessary to investigate all RE-AIM components in every study (Glasgow, Vogt, & Boles, 1999), maintenance was not addressed in the MOPP evaluation because the program is newly implemented. Evaluation questions were developed with attention to reach, effectiveness, adoption, and implementation dimensions, and the RE-AIM formula was used to quantify reach in the MOPP evaluation. The RE-AIM framework also includes a formula for calculating adoption. However, this measure was not appropriate for the MOPP program as UPMC administration selected the four participating pilot project sites by mandate.

2.0 EVALUATION DESIGN AND GENERAL METHODOLOGY

2.1 MIXED-METHODS CASE STUDY DESIGN

A case study research design, which included triangulation of data collection and analysis methods, was applied in the MOPP evaluation. The program evaluation utilized a variety of data sources (data triangulation), as well as quantitative and qualitative methods (methodological triangulation) in an effort to strengthen the study of a single program (Patton, 2002). The purpose of triangulation is to test for consistency in the results yielded by different data sources and inquiry approaches (Patton, 2002). Triangulation allows for a validity cross-check through different modes of inquiry (Patton, 2002; Weiss, 1998). Patton notes that "different types of inquiry are sensitive to different real-world nuances", thus inconsistencies in findings across data sources were not interpreted as a weakness in the credibility of study findings (2002, p.556). Rather, inconsistencies were noted and examined closely in an effort to understand differences in data from divergent sources based on the premise that reasonable explanations for inconsistencies in findings can contribute significantly to the overall credibility of evaluation findings (Patton, 2002). Besculides and colleagues provide a useful explanation of the strength and value of mixed-methods evaluation research:

> A mixed-methods approach strengthens evaluation research, because no single method is without weakness or bias. Quantitative data, for example, may be

> objective, but they often lack the depth needed to elucidate how and why a program works. Qualitative data can enhance understanding of program implementation and operation, but are considered less objective. By combining the two, research can be both objective and rich (2006, p. 2).

Table 2 summarizes the various methods that were used to address each evaluation question. Details about data collection, analysis and triangulation procedures follow.

Table 2. Overview of Multiple Methods Used in the MOPP Evaluation

Evaluation Questions	**Quantitative**	**Qualitative**			
	Descriptive statistical analysis	Observation	Patient Interviews	Staff Interviews	Document Review
1. How many participants does the program serve, and what are the characteristics of the program participants?	✓			✓	
2. What is the program's reach into the target population? *	✓	✓		✓	
3. To what extent is the program being implemented as planned?	✓	✓		✓	✓
4. Is the program making progress toward the achievement of short-term outcomes?	✓		✓	✓	✓
5. Are there unintended or unexpected program outcomes?		✓		✓	
6. What are the costs associated with implementing the program?				✓	✓

*RE-AIM reach calculations

The evaluation primarily focuses on MOPP implementation, or process, which is appropriate for a program that is in its early years of implementation (CDC, 2005). In relating the evaluation questions and focus to the program logic model (Appendix A), data collection activities mainly center on program outputs, or the tangible capacities or products produced by program activities (CDC, 2005). As outputs represent a tangible deliverable produced as a result of activities, or can be interpreted as "activities redefined in tangible or countable terms"; assessing the program's performance on planned outputs helps to determine whether the program is performing as planned (CDC, 2005, p. 22).

2.2 DATA COLLECTION AND ANALYSIS METHODS

The evaluation mixed qualitative and quantitative methods, as outlined in Table 2, to collect, analyze, and cross-analyze data from the following sources: the Minority Outreach Pilot Program database; internal financial records, logs, and forms; field notes from meeting observations; program staff and participant interviews; and public program documents, including presentations and promotional material. Given the multiple evaluation questions, data collection methods, and data sources, the following section is organized by data collection procedures in order to facilitate a clear and detailed presentation of evaluation methods. Analysis procedures are described for each data collection method. In addition, the triangulation protocol for the evaluation is outlined in this section.

2.2.1 Descriptive Statistical Analysis of MOPP Database

MOPP provided access to a de-identified Excel worksheet file that included demographic, diagnosis and referral, treatment, CCT recruitment and participation, barriers to care, and MOPP service provision data for all program participants. A list of the specific database variables included in the evaluation's descriptive statistical analysis is provided in Appendix B. Data collected from the program database covered the period from program implementation (March 2006) through April 2008, which was the planned end date for evaluation data collection. Data was cleaned, which included a process of working with program staff to accurately code or fill-in missing data; recoded as necessary to facilitate analysis; and studied through descriptive statistical analyses in SPSS. As only basic descriptive analyses were performed, recoding mainly consisted of transforming text into nominal variables. For example, the Excel worksheet provided by the program listed comorbidities for all patients in one column. This text data was recoded to create a nominal variable (i.e., 0- no, 1-yes) for each comorbidity recorded in the database. This recoding facilitated frequency calculations for each comorbidity, as well as the calculation of total number of comorbidities for each patient in the database.

Data was analyzed as follows to address evaluation questions #1-4:

- *Evaluation Question #1. How many participants does the program serve, and what are the characteristics of the program participants?*: The Frequencies procedure was used to determine the distribution of the program's participants by selected demographic, cancer diagnosis, and cancer care barriers variables. Frequencies were run for the entire period of March 2006-April 2008 and were also summarized for each program year according to program reporting practices (i.e., March 2006-December 2006; January 2007-Decemember 2007; and January 2008 to present,

which in the case of this evaluation was April 2008). Findings were organized in this manner to facilitate use of evaluation findings by program staff and key stakeholders.

- *Evaluation Question #2. What is the program's reach into the target population*?: The RE-AIM reach calculator was used to quantify dimensions of the program's reach. This online calculator is a simple tool for quickly and easily completing basic calculations related to reach. The calculator prompts researchers and evaluators to calculate and present a little more detail than what is typically presented in intervention studies (i.e., size of the study sample and the proportion of eligible individuals who are willing to participate in the intervention). Using an estimate of the number of individuals in the target population and data on the actual program population (i.e., estimated number exposed to recruitment, number who responded to recruitment, actual number who are eligible, and actual number who participate) the online RE-AIM tool calculates the following measures, which provide useful practice-focused data for researchers, program managers, and policy makers to consider for assessing the appropriateness of various public health interventions for their organization and service population:
    - % of target who respond to recruitment= # responded to recruitment ÷ # in target population x 100
    - % of eligible who participate= # who participate ÷ # eligible x 100
    - % of reach into the target population = # who participate ÷ # in target population x 100
    - % excluded from the study = # ineligible ÷ # responded to recruitment x 100

The number of individuals in the target population, which is limited to newly diagnosed African American patients, was estimated by dividing 235 (i.e., number of the target population touched by the program, excluding CCT screen only participants (see Section 1.3.1), by .85 based on UPMC billing reports and MOPP database entries, which indicate that the program consistently touches about 85% of all African American patients who are newly diagnosed with cancer and seek treatment at one of the four participating program sites.

All other reach formula components listed above were obtained from the de-identified MOPP database file. "Number who responded to recruitment" was defined as the total number of individuals in the program database (n=249). "Actual number who are eligible" (n=235) was calculated by subtracting the 14 individuals contacted for CCT screen only (i.e., ineligible for patient navigator services because they did not receive care at one of the four participating program sites) from total number of individuals in the database (n=249). "Actual number who participate" was defined as the number of individuals in the program database who accepted patient navigator services.

- *Evaluation Question #3. To what extent is the program being implemented as planned?*: To help address this evaluation question, frequencies were run to summarize priority program outputs, including number and types of services provided to program participants. Specifically, descriptive statistical analysis of the program database was conducted to summarize outputs #3, 6, 8, & 10 in the program logic model (see Appendix A).
- Evaluation Question #4. Is the program making progress toward the achievement of short-term outcomes?: The descriptive statistical analysis of the MOPP database

helped to assess the program's progress on short-term outcomes related to addressing barriers to cancer care and increasing CCT participation. Specifically, MOPP's effort to increase knowledge of CCT opportunities and benefits was quantified based on documented outreach for CCT recruitment. Additionally, progress on the planned short-term outcome to increase knowledge of barriers to cancer care and CCT participation among participating centers was partially assessed by quantifying the numbers and types of barriers to cancer care and CCT participation documented in the program database. Lastly the chi-square test procedure was used to quantitatively explore association between acceptance of patient navigators and CCT enrollment. The desired level of significance was set at $p<.05$.

2.2.2 Meeting Observation

MOPP bi-weekly program staff meetings were observed during the period of January-June 2008, and three monthly African American Cancer Care Partnership meetings were attended during the evaluation period in the months of March, April and May. Observation of both staff and AACCP meetings helped the evaluator develop a thorough understanding of both how the program operates and the context in which it operates. Additionally observations provided valuable qualitative data for addressing evaluation questions #3 and 5. During meeting observations, particular attention was paid to issues related to the program implementation experience in an effort to understand whether and how program activities and outputs were being delivered as planned (evaluation question #3). Meeting discussion and oral reports related to program outcomes (evaluation question #5) were also studied closely. Reflective and reflexive

field notes were taken during and after meeting observations. Notes were interpreted through careful reading and focused coding of themes.

2.2.3 Interviews

The evaluation included interviews with three different groups: semi-structured interviews of program staff and participants, as well as informal interviews with the Program Director. All staff members (1 Director, 1 Social Worker, 1 Cancer Control Specialists, and 2 Navigators) were interviewed to help address evaluation questions # 1- 5. Therefore, interviews covered a wide range of topics, including a description of the program and its implementation process from each staff person's perspective. The interview guide is comprised of six questions, including: How would you describe the group of patients you serve through the Minority Outreach Pilot Program?, In what ways are program activities being implemented as planned?, and Based on your experience, has MOPP had any impact, or have the navigation services led to any outcomes that were unplanned? A complete list of staff interview questions and the evaluation questions they were designed to help address is provided in Appendix C.

Staff interviews took place in a private setting (i.e., conference room or office) at the UPMC Cancer Center. The 30-60 minute interviews were tape recorded and transcribed by the evaluator. Transcripts from the semi-structured staff interviews were analyzed using focused coding. The topics of the interview questions (i.e., participant characteristics, reach, implementation achievements, implementation challenges, outcome progress, unintended or unexpected outcomes, and costs) were used to organize and provide a first level of coding for the texts. Then, texts were read closely for emergent and prominent themes within these broader categories. Additionally, the texts were studied closely for themes or issues that seemed to be

outside or beyond the scope and focus of the topics covered in the interview questions. These "new" themes were coded across interviews to identify the concepts most relevant to them and implied relationships between themes.

Phone interviews were conducted with a small sample of program participants to help address evaluation question #4. Therefore, interview questions focused on the impact the program has had on participants and their satisfaction with services received. The interview guide consisted of eight questions, including: How did you first meet [patient navigator]?, What do you like about working with [patient navigator]?, and How would you change what [patient navigator] does? Why? A complete list of participant interview questions is provided in Appendix C. An open-ended interviewing format was used to capture participants' thoughts and insights in their own words (Patton, 2002); however, interview questions were standardized for the following benefits: 1) the exact instrument (interview guide) used in the evaluation can be provided for review and use by evaluator stakeholders and parties interested in evaluation findings; 2) interviewee time is used efficiently because the interview is highly focused; and 3) responses are easy to find and compare, which facilitates analysis (Patton, 2002). During the interviews, patient navigators' names were used in place of the name of the pilot program to avoid confusion that might result from any unfamiliarity with the formal program name. After careful consideration of feasibility and propriety standards (CDC, 2005), phone interviews were chosen for this evaluation, rather than face-to-face or mail interviews, to help minimize patient burden (i.e., MOPP participants face several barriers to cancer care, including transportation and child care issues, and are under the additional emotional and physical strain of the cancer diagnosis and treatment experience).

Program participant interviewees were selected through heterogeneity sampling based on the following characteristics that are especially relevant to the MOPP mission and services: type of cancer; referral source; acceptance, delayed acceptance or decline of patient navigator services; and CCT participation. Heterogeneity sampling is a non-probability, purposive sampling method. This method samples for diversity in an effort to yield both: 1) high quality, detailed description for single patients, which is valuable for documenting the uniqueness of patients served by the program, and 2) important shared themes that cut across patients and establish their significance from having emerged from a heterogeneous sample (Patton, 2002). Based on Patton's philosophy for qualitative inquiry—there are "no rules for sample size in qualitative inquiry", and the size of the sample depends on the purpose of the inquiry, what will be useful and have credibility, and what can be done with available time and resources (Patton, 2002, p. 244)—eleven interviews were planned. The actual number of interviews conducted was reduced to seven for several reasons, including a decline in the health status of selected interviewees, patient refusal, and strict adherence to the planned timeline for data collection activities. However, the seven program participants interviewed satisfied the heterogeneity sampling criteria. Table 3 summarizes participant interviewees by the sampling criteria.

While the heterogeneity sampling criteria was met, saturation was not reached. As presented in the results section, all interviewees described social support services they received through MOPP. However, information shared during one of the final interviews suggests that it may be valuable to further explore patients' level of understanding about the various services MOPP offers.

Table 3. Patient Interviewee Characteristics (n=7)

Characteristic	Count
Age	
20-49	1
50-64	3
65-74	3
total	7
Gender	
female	6
male	1
total	7
Cancer Diagnosis	
breast	3
colon	1
head and neck	1
lung	1
multiple myeloma	1
total	7
Referral Source	
surgeon	2
clinical research coordinator	1
social worker	1
MOPP case finding	3
total	7
Patient Navigator	
accepted	5
delayed acceptance	1
decline	1
total	7
CCT Participation	
yes	3
no	4
total	7

Participant interviewees were selected at random from the de-identified database file according to the heterogeneous sampling criteria previously described. Using program-assigned patient identification numbers, patient navigators and the MOPP social worker identified the patients selected at random by the evaluator and obtained their verbal permission to be contacted by a program evaluator interested in conducting a phone interview with them. Upon patients' approval, the staff screening calls were followed-up by calls from the evaluator during which verbal consent for conducting and tape recording was obtained. Interviewees received $25 Giant Eagle supermarket gift cards for their participation. Interviews were transcribed by the evaluator, studied closely, theme coded by interview question topics, then reviewed again to identify shared and unique themes.

Throughout the evaluation, informal interviews and meetings were held with the Program Director to gather information about the history and context of the Minority Outreach Pilot Program. These interviews were particularly helpful for addressing evaluation question #7 as they provided an opportunity to review internal program reports on spending and to delineate and discuss the program's funding source, in-kind contributions, and start-up and maintenance expenses. Written notes were taken during interviews and meetings with the Program Director, which were later summarized and added to the rich qualitative data collected throughout the study to help address evaluation questions.

2.2.4 Document Review

Document review both directly and indirectly contributed to completion of the evaluation. Program marketing material, presentations to stakeholders and UPMC administration, and internal meeting notes and informal reports documents were studied closely to obtain useful

background and contextual information that facilitated the evaluator's work with the program staff around illustrating the program theory in logic model form. Documents were reviewed to note program data and details that are regularly presented to patients and other stakeholders in an effort to identify and develop a solid understanding of program priorities. Identifying repeated themes of focus across program documents facilitated both the development of appropriate evaluation questions and the accurate interpretation of evaluation findings. In a more direct sense, review of program records related to use of gap funds and transportation assistance provided the actual data on program expenses necessary to calculate the costs associated with implementing MOPP (evaluation question #7).

2.2.5 Triangulation Protocol

The MOPP evaluation employs both data triangulation (i.e., it uses multiple data sources), and methodological triangulation (i.e., a mix of quantitative and qualitative methods) in an effort to strengthen the study of a single program (Patton, 2002). The benefits of triangulation are discussed in detail in Section 1.6.1. As outlined in Table 2, each evaluation question is addressed either through more than one mode of inquiry or two or more data sources within the same mode of inquiry.

Evaluation questions #1 and 2 illustrate the evaluator's method for combining more than one mode of inquiry as both statistical analysis of quantitative program data and analysis of qualitative data from interviews and meeting observations were conducted to investigate participant characteristics and program reach. Information gathered from interviews and meeting observations expanded on, and facilitated accurate interpretation of, quantitative data analysis findings. For example, among the 249 newly diagnosed African American cancer patients

touched by the Minority Outreach Pilot Program, 15, or 15.2%, of the 99 men tracked through MOPP have a prostate cancer diagnosis. Cancer facts and national statistics (i.e., African American men have higher prostate cancer incidence and mortality rates than men of other racial or ethnic groups in the United States (CDC, 2003), and prostate cancer is the most common cancer among African American men (ACS, 2007) call the relatively low numbers of participants with prostate cancer into question. However, qualitative data collected through meeting observations revealed that a specialty group of physicians from urology treat the majority of prostate cancer patients within the UPMC system. This group was described as operating independently, in relation to patient care, from the larger UPMC care centers. Upon reflecting on the quantitative evaluation data on patient characteristics, MOPP Director repeated earlier efforts to initiate a partnership with the urology physician group to provide patient navigator services to any patients who may need them.

As an example of using two or more data sources to address an evaluation question, MOPP staff and participants served as key data sources for helping to assess whether the program was making progress toward the achievement of desired outcomes (evaluation question #4). Findings from staff interviews were compared with findings from participant interviews to identify shared perspectives around program benefits, strengths and weaknesses and to note where perspectives may differ, which is also valuable information for program improvement. It's worth noting that descriptive statistical analysis was also conducted to help answer evaluation #4. This quantitative analysis included a chi-square test for association between patients' acceptance of a patient navigator and their enrollment in a cancer clinical trial. Thus, in addition to multiple data sources, progress toward the achievement of desired outcomes (evaluation question #4) was also addressed through more than one mode of inquiry.

In general, triangulation was operationalized in this evaluation as a cross-checking and elucidation process. For each evaluation question, inconsistencies in findings and differing perspectives, both within and between data collection methods, were noted, and all evaluation data was studied closely to identify possible explanations for inconsistencies. Additionally, qualitative data from interviews and meeting observations added context or depth to results from the statistical analysis of quantitative data from the program database. These triangulation procedures are reflected in the reporting of evaluation findings.

3.0 EVALUATION FINDINGS

3.1 OVERVIEW

This section presents key findings from the MOPP evaluation. Findings are organized by the focus of each of the six evaluation questions. Additionally, the summary of findings under each evaluation question topic reflects key insights obtained through the various methods of inquiry or data sources used (See Table 2). This chapter of detailed evaluation findings is followed by three manuscript drafts (Chapter 4.0, 5.0, 6.0) that include selected evaluation findings from this chapter.

The content of each of the following manuscript chapters is aligned with the focus of targeted journals. Specifically, the first article will be submitted to the Centers for Disease Control and Prevention's *Preventing Chronic Disease* journal and includes evaluation descriptions and findings believed to be most relevant to public health practitioners. The second article focuses on the potential for cancer patient navigator programs to help address racial disparities in cancer clinical trial participation. Thus, it includes key evaluation findings related to cancer clinical trials. The second article will be submitted to the *Journal of Urban Health* as racial/ethnic health disparities are one of the major urban health issues the journal focuses on. It is worth noting that Dr. Freeman (2006) recently published an article about cancer patient navigation in the *Journal of Urban Health*—the planned manuscript could expand nicely on

Freeman's article by exploring CCT education and recruitment efforts within navigator programs. The last article, a critical analysis piece, provides an in-depth study of the translation and evidence arguments that helped to inform the development of this research. It will be submitted to *The Milbank Quarterly*, which is devoted to scholarly analysis of significant issues in health and health care policy. Rather than focusing on specific evaluation findings, the third article applies what was learned about the patient navigation movement throughout this research to higher-level, conceptual thinking about improving public health research translation and, in turn, the public's health.

3.2 CHARACTERISTICS OF PROGRAM PARTICIPANTS

The first evaluation question focuses on describing the characteristic of MOPP program participants. Proper interpretation of descriptive statistical analysis of participant characteristics requires an understanding of the different ways in which MOPP connects and serves African Americans who are newly diagnosed with cancer and receiving care in the UPMC system. Thus, qualitative data collection from both formal and informal interviews with program staff was critical for the effective study of the first evaluation question. The quantitative and qualitative descriptions of program participants presented in this section cover patients referred to, tracked and serviced by MOPP since its implementation in March 2006 through the end date for evaluation data collection, April 2008.

MOPP touches the target population through referrals and case findings. Referrals come from several sources, including:

- UPMC Cancer Centers Cancer Information and Referral Service (CIRS), which is a free cancer information service for the public, staffed by UPMC oncology nurses and social workers. Through CIRS, the general public can obtain information about cancer and cancer-related topics, including general disease sites, prevention, early detection, clinical trials, symptom management, support services, community resources and educational programs (UPMC Cancer Centers, n.d.).
- Clinical research coordinators
- Collaborative practice nurses
- Community agencies
- Self referrals from patients, and referrals from family and friends of the patient
- Oncologists, primary care physicians, surgeons, and other doctors
- UPMC sites (outside of the four MOPP participating sites)
- UPMC Prevention and Early Detection Center (PEDC)
- Social workers within the UPMC system

Case finding is conducted by the MOPP social worker and involves reviewing tailored weekly internal reports on new cancer patients.

All patients from the target population who are identified through referrals and case findings are entered in the MOPP database (n=249). Basic demographic and health care status (e.g., cancer diagnosis, stage, and comorbidities), is recorded in the database using information from patient intake and barrier assessment and from the larger UPMC medical record database. All patients the program connects with, regardless of their UPMC cancer care site, are screened for cancer clinical trial eligibility and, as applicable, are provided information about CCT participation. Beginning in 2008, extended CCT recruitment efforts were documented in the

MOPP database, and so the total program population includes individuals who were targeted for cancer clinical trial screening (n=14) although they were not receiving care at one of the four MOPP participating sites. Many patients identified barriers, even some who decline patient navigator services. So, there are also cases in which patients officially decline the offer to be assigned a patient navigator, but request and receive some kind of service from the program, such as assistance from the social worker in successfully applying for health care insurance. Lastly there are some patients in the MOPP database who were self-referred or referred through the Prevention and Early Detection Program for assistance, usually related to insurance coverage, with follow-up on suspicious cancer screening findings. This follow-up diagnostic care frequently determines that the patients do not have cancer. Of these 14 non-cancer patients, one utilized patient navigator services.

For the purposes of this evaluation, the term program participants refers to all 249 patients that are tracked in the MOPP database as they are each contacted by the program with information about program services, patient navigator services and/or cancer clinical trial participation—any analysis on subsets of the program participants (e.g., CCT screen only patients, non-cancer patients, or navigated patients) are clearly noted throughout the text. Selected participant characteristics are highlighted in Table 4 (see Appendix D for a presentation of Table 4 by program year). About 30% of the 249 program participants are between 20 and 49 years of age, while the majority of program participants fall within the 50-64 age group. Almost 60% of participants are female. Most (26.1%) of the program participants were identified through MOPP case finding. However, a fairly large number of referrals are received from UPMC social workers (18.5%) and through CIRS (15.3%). Seventy-five patients are working with patient navigators. Most patients (37.3%) entered the program with a stage IV cancer

diagnosis. Among program participants, the four most common cancer diagnoses are breast (17.7%); lung, non-small cell (15.3%); colon (7.2%); and head and neck (6.4%). The majority of program participants (73.5%) receive care at the Hillman Cancer Center site. Forty-one (16.5) patients entered the program with a self-pay or uninsured status, while 27.3% were insured through Medicare Managed Care and 22.1% were insured through Medicaid Managed Care.

Table 4. Program Participant Characteristics (n=249)

Characteristic	Count	Percent
Age Group		
<20	1	.4
20-49	74	29.7
50-64	104	41.8
65-74	43	17.3
75+	24	9.6
Unknown	3	1.2
Total	249	100
Gender		
Female	148	59.4
Male	99	39.8
Missing	2	.8
Total	249	100
Referral Source		
Case Finding (MOPP Social Worker)	65	26.1
CIRS	38	15.3
Clinical Research Coordinator	20	8.0
Collaborative Practice Nurse	12	4.8
Community Agency	8	3.2
Oncologist	7	2.8
Other	1	.4
Other Medical Doctor	1	.4
Other UPMC Site	4	1.6
Primary Care Physician	3	1.2
PEDC	11	4.4
Self/Family/Friend	6	2.4
Social Worker	46	18.5
Surgeon	14	5.6
Missing	13	5.2
Total	249	100

Table 4 Continued Characteristic	Count	Percent
Patient Navigator		
Yes	75	30.1
No	174	69.9
Total	249	100
Cancer Stage		
I	15	6.0
II	24	9.6
III	52	20.9
IV	93	37.3
Screening	20	8.0
Unable to Stage	42	16.9
Missing	3	1.2
Total	249	100
Cancer Diagnosis		
no cancer diagnosis	14	5.6
not yet diagnosed	13	5.2
Acute Lymphoblastic Leukemia, Adult	1	.4
Acute Myeloid Leukemia, Adult	3	1.2
Bile Duct Cancer, Extrahepatic	1	.4
Bladder Cancer	1	.4
Brain Tumor, Adult	5	2.0
Brain Tumor, Cerebral Astrocytoma/Malignant Glioma	3	1.2
Brain Tumor, Childhood (Other)	1	.4
Breast Cancer	44	17.7
Cervical Cancer	1	.4
Chronic Myelogenous Leukemia	3	1.2
Colon Cancer	18	7.2
Esophageal Cancer	3	1.2
Head and Neck Cancer	16	6.4
Hodgkin's Lymphoma, Adult	4	1.6
Kaposi's Sarcoma	1	.4
Laryngeal Cancer	2	.8
Lung Cancer, Non-Small Cell	38	15.3
Lung Cancer, Small Cell	4	1.6
Lymphoma, Non-Hodgkin’s Adult	6	2.4
Melanoma	3	1.2
Mesothelioma, Adult	1	.4
Multiple Myeloma/Plasma Cell Neoplasm	6	2.4
Myelodysplastic Syndromes	2	.8
Non-malignant Hematologic Disorder	4	1.6
Osteosarcoma/Malignant Fibrous Histiocytoma	1	.4
Ovarian Epithelial Cancer	1	.4
Pancreatic Cancer	11	4.4
Prostate Cancer	15	6.0

Table 4 Continued Characteristic	Count	Percent
Rectal Cancer	5	2.0
Renal Cell (Kidney)	4	1.6
Renal Pelvis and Ureter, Transitional Cell Cancer	1	.4
Sarcoma, Soft Tissue	3	1.2
Stomach (Gastric) Cancer	2	.8
Thymoma and Thymic Carcinoma	1	.4
Unknown Primary Site	2	.8
Missing	5	2.0
Total	249	100
Cancer Care Site		
Beaver Med Oncology	5	2.0
Hillman	183	73.5
Jefferson Med Oncology	3	1.2
Magee	7	2.8
McKeesport	8	3.2
Mercy	1	0.4
Moon Med Oncology	1	0.4
Murtha Radiology Oncology	1	0.4
Natrona Med Oncology	2	0.8
New Castle	1	0.4
Passavant	1	0.4
Shadyside Hospital or Radiology Oncology	5	2.0
St. Margaret Med Oncology	4	1.6
Missing	27	10.8
Total	249	100
Insurance		
Commercial Indemnity Insurance	1	0.4
Commercial Managed Care (HMO/PPO/POS)	48	19.3
Medicaid Managed Care (HMO/PPO/POS)	55	22.1
Medicaid/Public Assistance	6	2.4
Medicare	7	2.8
Medicare Managed Care (HMO/PPO/POS)	68	27.3
Military (DOD,CHAMPUS,VA)	1	0.4
Other Public Coverage	3	1.2
Self Pay or No Insurance	41	16.5
Missing	19	7.6
Total	249	100

While descriptions of program participants collected in staff interviews included a summary of MOPP's target population (i.e., African American patients newly diagnosed with cancer), diversity was a shared and notable theme. As illustrated by the selected quotes from two

staff members that follow, program staff recognize that, although they serve a group of patients who share a racial classification and disease diagnosis, the program population markedly diverse.

> "Other than being African American, …I think there's a lot of variation…it's a heterogeneous group."
>
> "…all their needs are different. They come from all walks of life….there's no set mold that our patients are coming from."

In addition to acknowledging differences among the patient population, staff recognizes differences in individual patients; that is their needs may change over time, often due to changes in employment status and consequential changes in insurance coverage:

> "I see different patterns of people: at the beginning not needing anything, then needing something later; or patients needing a lot at the beginning and you get it all squared away for them, and they're like, 'I'm fine.' …. Some of our patients have insurance in the beginning because they were working, and then, getting really sick, they haven't been able to work….A lot of these people don't have jobs where they have a lot of money—it's expensive to pick up your insurance. It's expensive even to pay for just your contributions to your insurance even if your company continues to cover you, but you're on their disability and you're now down to 60% of your salary. So, some people just let it go. So, you know, there's a lot of issues that come up after they've been in treatment for a little while and realize they can't go to work."

Other key themes related to participants characteristics that emerged across staff interviews and meeting observations include: a desire to reach participants at earlier diagnosis stages, and the relationship between the UPMC organizational and operating structure and

MOPP recruitment & reach. MOPP staff believes that the low numbers of participants with prostate cancer is largely explained by the organizational and operating structure of UPMC in that the vast majority of prostate cancers are seen through a group of urologist specialists and, therefore, are not readily accessible for MOPP recruitment. Additionally, Magee, one of the four participating sites, was described as conducting a great deal of research, which, due to policies to protect patients from heavy recruitment to various studies and pilot projects, limits the availability of Magee patients available for participation in MOPP. Program staff also explained that McKeesport, another MOPP site, has a patient navigator program through an NCI radiation oncology grant. Although the McKeesport navigator program functions very differently than MOPP—"the patient navigators there are actually like registrars"—that resource at McKeesport may affect their number of referrals to MOPP. However, staff do report a good communication connection and "network" with the McKeesport site.

These findings can facilitate program planning and comparison within the patient navigation movement. Specifically, it encourages program planners to be alert to the diversity of seemingly homogeneous groups, and the detailed quantitative description of the patient population may help other organizations considering patient navigation models determine whether the MOPP approach is a good fit. Additionally, findings suggests that patient navigation programs implemented within large health care systems will need to identify and develop plans for addressing the limitations that varied organizational and operating structures and policies within the larger system may place on participant recruitment and the related issue of program reach, which is discussed in detail in the following section.

3.3 PROGRAM REACH

Reach refers to the absolute number, proportion, and representativeness (i.e., whether participants have characteristics that reflect those of the program's target population) of individuals who participate in a program (Workgroup to Evaluate and Enhance the Reach and Dissemination of Health Promotion Interventions, 2004). Reach is one of five dimensions in the RE-AIM framework, which was developed by Glasgow and colleagues to help better identify the translatability and public health impact of health promotion interventions (Glasgow, 2002).

Using the online RE-AIM reach calculator, which is available for public use at www.re-aim.org, the following reach measures were obtained:

- % of target who respond to recruitment: 90.2
- % of eligible who participate: 31.9
- % of reach into target population 27.2
- % excluded from the intervention: 5.6
- % participation among eligible: 31.9

As outlined in the methodology section, these reach-related measures are calculated based on the number of program participants who accepted a patient navigator. Also, as indicated in quantitative data analysis summaries related to program services presented in the sections that follow, there are some program participants who declined the opportunity to be assigned a patient navigator, but received some form of assistance from the program. It is worth noting that CCT eligibility and barriers assessments are conducted for all program participants (n=249). However, patients who accepted navigator services received ongoing support, individualized support, and follow-up by one of the program's two patient navigators throughout their course of

cancer care. Therefore, the "intervention" is defined as patient navigator acceptance in the reach assessment.

Table 5 describes the characteristics of patients who accepted patient navigators (n=75) and in doing so provides important output data (see output #3 of the logic model in Appendix A) for program description, monitoring, and improvement planning. Almost half of the patients who accept navigators are between 50-64 years of age. Close to 80% of the program participants who accept navigators are female. Among those who accept navigators, most entered MOPP upon case finding by the program social worker (28.0%) and referrals from UPMC social workers (21.3%). Most patients with navigators (42.7%) entered the program with a stage IV cancer diagnosis. Among program participants who accepted navigators, the two most common cancer diagnoses are breast (24.0%) and lung, non-small cell (21.3%). The majority (89.3%) of navigated program participants receive care at the Hillman Cancer Center site. Patients who accept navigators are mostly insured through Medicare Managed Care (33.3%) and Medicaid Managed Care (28.0%).

Table 5. Characteristics for Program Participants Who Accepted Patient Navigators (n=75)

Characteristic	Count	Percent
Age Group		
<20	1	1.3
20-49	14	18.7
50-64	36	48.0
65-74	18	24.0
75+	6	8.0
Total	75	100
Gender		
Female	58	77.3
Male	17	22.7
Total	75	100

Table 5 Continued Characteristic	Count	Percent
Referral Source		
Case Finding (MOPP Social Worker)	21	28.0
CIRS	10	13.3
Clinical Research Coordinator	9	12.0
Collaborative Practice Nurse	3	4.0
Community Agency	2	2.7
Oncologist	5	6.7
Other	1	1.3
Other UPMC Site	1	1.3
PEDC	1	1.3
Self/Family/Friend	1	1.3
Social Worker	16	21.3
Surgeon	5	6.7
Total	75	100
Cancer Stage		
I	4	5.3
II	11	14.7
III	26	34.7
IV	32	42.7
Screening	1	1.3
Unable to Stage	1	1.3
Total	75	100
Cancer Diagnosis		
no cancer diagnosis	1	1.3
Acute Myeloid Leukemia, Adult	1	1.3
Brain Tumor, Adult	1	1.3
Breast Cancer	18	24.0
Chronic Myelogenous Leukemia	1	1.3
Colon Cancer	7	9.3
Esophageal Cancer	2	2.7
Head and Neck Cancer	6	8.0
Hodgkin's Lymphoma, Adult	1	1.3
Lung Cancer, Non-Small Cell	16	21.3
Lung Cancer, Small Cell	3	4.0
Lymphoma, Non-Hodgkin’s Adult	1	1.3
Melanoma	1	1.3
Multiple Myeloma/Plasma Cell Neoplasm	2	2.7
Ovarian Epithelial Cancer	1	1.3
Pancreatic Cancer	5	6.7
Prostate Cancer	2	2.7
Rectal Cancer	3	4.0
Renal Cell (Kidney)	1	1.3
Renal Pelvis and Ureter, Transitional Cell Cancer	1	1.3
Sarcoma, Soft Tissue	1	1.3

Table 5 Continued Characteristic	Count	Percent
Total	75	100
Cancer Care Site		
Hillman	67	89.3
Magee	1	1.3
McKeesport	3	4.0
Shadyside Hospital or Radiology Oncology	1	1.3
Missing	3	4.0
Total	75	100
Insurance		
Commercial Indemnity Insurance	1	1.3
Commercial Managed Care (HMO/PPO/POS)	14	18.7
Medicaid Managed Care (HMO/PPO/POS)	21	28.0
Medicaid/Public Assistance	3	4.0
Medicare	2	2.7
Medicare Managed Care (HMO/PPO/POS)	25	33.3
Self Pay or No Insurance	8	10.7
Missing	1	1.3
Total	75	100

3.4 PROGRAM DELIVERY

The third evaluation question examined the extent to which the MOPP program is being implemented as planned. Document review, which included presentation slides, promotion cards, intake forms, provided valuable background related to program priorities and planned activities and outcomes. Descriptive statistical analysis quantified the program's progress to date on priority outputs. Output data is particularly useful for assessing program implementation because they represent the tangible products of program activities (CDC, 2005). Qualitative data collection (i.e., interviews with staff members and participants and meeting observation) and

analysis provided rich data on implementation achievements, elucidating implementations challenges, and identified key considerations for program improvement.

Assessing patients' barriers to cancer care and providing individualized solutions planning and assistance services, which in the case of some patients includes assigning a navigator, is the program's foremost activity. In working with program staff members to describe the program through logic modeling, staff insisted on graphically highlighting this activity to illustrate its significance (see Appendix A). Similarly, cancer clinical trial education and recruitment is a priority program activity as it is one of the main reasons UPMC and UPMC Cancer Centers' invested in the pilot program—an investment that included significant gap funds intended to cover potential medical expenses for members of the target population receiving cancer care on a clinical trial. The evaluation focused on measuring progress on outputs related to these two priority program activities (i.e., outputs #5-12). The following tables and quantitative descriptions fill in output numbers. Whereas the qualitative data found at the end of this section provides valuable contextual information for the proper interpretation and informed utilization of quantitative data on program outputs.

Outputs #5-7 focus on barriers assessment, identification, and the provision of individualized services to address barriers to care. Program participants, excluding those designated CCT screen only, receive barrier assessments (n=235). Although, data from interviews explains that assessments may be subjectively modified to minimize participant burden. A total of 146 program participants identified at least one barrier to cancer care. Table 6 and Figure 1 present the numbers and types of barriers patients identified for themselves. Comorbidities were documented for 204 of the 235 program participants (excludes CCT screen only). Table 7 and Figure 2 describe the burden of comorbidities among program participants.

Comorbidity data is based on medical record review and is collected by the program because it is a widely recognized barrier for participation in cancer clinical trials (EDICT, n.d.) and because it provides important context related to the other issues participants face in addition to their cancer care.

Table 6. Participant-Identified Barriers to Care (n=235)

Barrier*	Count	Percent
Child Care	6	2.6
Co-morbid Chronic Illness	33	14.0
Elder Care	5	2.1
Financial Problems	38	16.2
Health Beliefs	4	1.7
Housing	7	3.0
Insurance	57	24.3
Job Responsibilities	5	2.1
Other	19	8.1
Poor Support System	5	2.1
Spiritual/Religious Beliefs	1	.4
Transportation	51	21.7
None Identified	89	37.9

* Patients may have identified more than one barrier

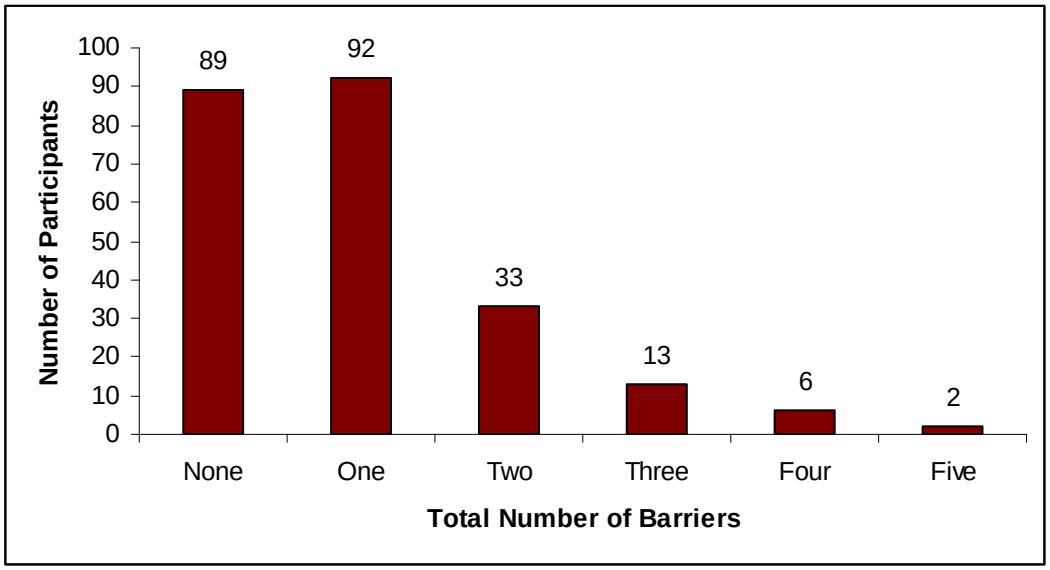


Figure 1. Total Number of Barriers Identified by Program Participants (n=235)

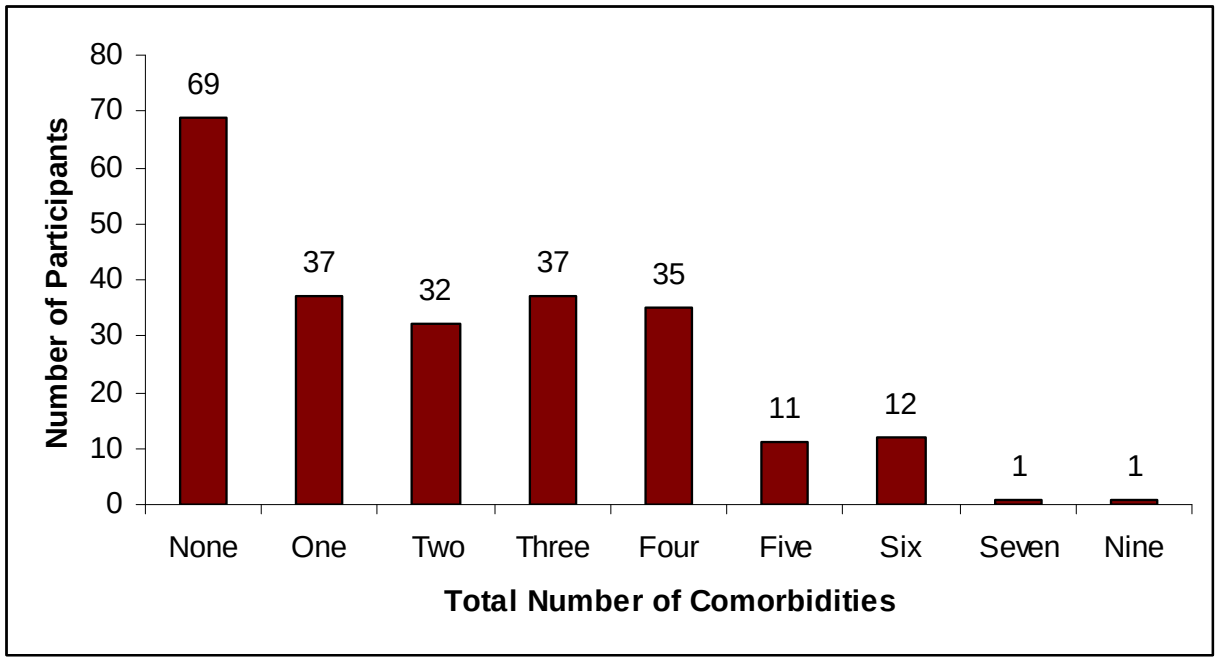


Figure 2. Total Number of Comorbidities Among Program Participants (n=235)

Table 7. Program Participant Comorbidites (n=235)

Comorbidity*	Count	Percent
Addiction	21	8.9
Arthritis	26	11.1
Asthma	15	6.4
Coronary Artery Disease	25	10.6
Other Cancer	13	5.5
Chronic Obstructive Pulmonary Disease	19	8.1
Dementia	6	2.6
Diabetes	37	15.7
Gastroesophageal Reflux Disease	27	11.5
Gastrointestinal Condition	6	2.6
Gout	5	2.1
Hearing	1	.4
Hypercholeserolemia	24	10.2
Hyperlipidemia	15	6.4
Hypertension	99	42.1
Kidney Disease	12	5.1
Liver Disease	10	4.3
Other	62	26.4
Psychiatric	30	12.8
Pulmonary	1	.4
Stroke	7	3.0
Thyroid Disease	9	3.8
Vision	4	1.7

Table 7 Continued Comorbidity*	Count	Percent
None Identified	31	13.2
Unknown	38	16.2

* Patients may have more than one comorbidity

As presented in the Introduction Section, 75 program participants accepted patient navigators. However, at times, per the request of patients or the program social worker, navigators provided services for patients who declined the opportunity to work with a navigator. Since the program's implementation, patient navigators have documented the provision of services for 78 patients, most of whom accepted navigators. Patient navigators use the following codes to classify and record the services they provide:

- Emotional support- providing an outlet for patients to share emotional responses and challenges related to their cancer diagnosis and care; providing encouragement throughout the care process.
- Transportation- obtaining and delivering vouchers for transportation to and from cancer care appointments.
- Check-in- contacting patients via phone or in person to assess satisfaction with, and progression through, cancer care treatment and to determine if patients have any new service needs.
- Appointment reminder.
- Informational or educational call or visit- providing patients with relevant information and literature from the Hillman library, or information about support groups and other services that are available through UPMC sites and community partners.
- Other- may include introductory and follow-up calls to inform patients of MOPP program services.

The number of patients receiving each service is presented in Table 8. It's important to note that one patient may both receive more than one service and receive a particular service on more than one occasion. Additionally, the patient navigator services described in Table 8 do not include services provided by the program social worker; who provides barrier assessments for participants; works with the Cancer Control Specialist to inform participants about, and recruit them for, CCTs; assists patients in obtaining new or additional insurance coverage; and disperses cab vouchers to ensure that patients have transportation to their cancer care site.

It is also important to clarify that the program maintains additional program logs and receipt records to ensure that transportation assistance provided by staff other than the navigators is accurately tracked. Based on this additional transportation data, a total of 23 patients received cab vouchers through the program, and a total of 32 people received assistance accessing various transportation resources, including Older Persons Transportation (OPT), a shared-ride service sponsored by the Allegheny County Area Agency on Aging (ACAAA), and the Medical Assistance Transportation Program (MATP), which is offered by the Allegheny County Department of Human Services. In some cases, patients were eligible for transportation services like MATP, but were too ill at times to use those services.

Table 8. Patient Navigator-Provided Services for Program Participants (n=78)

Service*	# of Participants Receiving Service	Percent
Emotional Support	36	46.2
Transportation	4	5.1
Check-in	58	74.4
Appointment Reminder	3	3.8
Info or Ed Call or Visit	38	48.7
Other	16	20.5

* Patients may receive more than one service and most receive a service more than one time.

Outputs #8 & 9 focus on participant insurance status and services. Type of insurance coverage is identified for all program participants, except those who are CCT screen only. One of the social worker's responsibilities is to assist all patients with no or inadequate insurance in obtaining coverage either through medical assistance or UPMC financial assistance. Because this insurance service is standard practice, as indicated by staff's description of the intake process and program intake forms, the provision of the service is not routinely recorded. The program database documents that at least 10 patients entered the program with a self pay or no insurance status and received assistance from the program to successfully enroll in Medicaid Managed Care or Medicaid/Public Assistance plans. However, given the standard program practice of assisting all uninsured or underinsured patients with obtaining adequate health care coverage, and the fact that 41 patients of the 235 participants (excluding CCT screen only) are identified as falling into this category, the number of participants receiving insurance services through MOPP is likely much higher. Based on staff interviews and meeting observations, it is clear that staff realize the need to tighten participant records and strengthen the program database to better capture key program data, such as number of patients insured or receiving expanded coverage as a result of assistance provided through the MOPP program. This data is particularly useful for estimating some aspects of the program's cost benefits, which is often a major factor in an organization's decision to maintain and expand initiatives.

Outputs #10-12 focus on CCT education and recruitment. As with insurance assistance, it is standard program practice to inform all program participants about cancer clinical trials. However, data related to CCT is more easily and routinely recorded and tracked via fields in the MOPP database. Tables 9 and 10 (see page 116) outline the proportion of total program

participants (n=249, includes CCT screen only) who are enrolled in CCTs and reasons for non-enrollment among participants.

Cancer clinical trial participation rates are one of the program highlights shared at the African American Cancer Care Partnership meetings, as well as through presentations to UPMC Cancer Centers' administration. It was noted through staff and AACCP meeting observation that discussion of the near 11% CCT enrollment rate virtually always included acknowledgement that many patients were ineligible for CCT for medical reasons, including comorbidities and late stage cancer diagnosis. During evaluation planning and implementation, the value of refining the denominator to get a more accurate CCT enrollment rate was discussed with staff. In identifying the number of participants who are actually eligible for CCTs, the program would be able to provide more detailed and informative CCT participation descriptions to community partners, administration and policy makers, and national agencies and organizations that are interested in learning more about MOPP.

The number of participants eligible for CCTs (n=167) was defined as those patients who were not documented as medically ineligible (n=52) or non-cancer (n=30). In calculating the CCTT participation rate as the proportion of program participants enrolled in cancer clinical trials among those who are eligible, MOPP has a 16.2% CCT enrollment rate. Shortly after reviewing the evaluation findings presented in this dissertation from the descriptive statistical analysis of CCT data, program staff worked to further investigate the issue of CCT eligibility among their participants. Based on eligibility criteria for current UPMC trials, staff reviewed program and medical record records to determine whether each patient in the database (n=250 at the time of this additional assessment) was eligible to participate in a CCT. Sixty (24%) of the 250 MOPP participants met eligibility criteria for available trials. Among the 60 participants

who were eligible, 31 were enrolled in a trial. The program's additional assessment of CCT eligibility indicates that, when excluding ineligible patients, there is a 51.6% CCT participation rate among MOPP participants. The second article in this dissertation provides additional descriptive statistics on CCT enrollment within MOPP and reviews challenges related to increasing CCT participation in MOPP and nationally.

As expected and described in the descriptive statistical summaries on program outputs presented throughout this section, qualitative data provided valuable information on the context within which program activities are being carried out. This context aided in the proper interpretation of quantitative analysis. In addition, qualitative data helped to identify implementation achievements and concerns beyond what was possible through descriptive statistical analysis of the program database. Specifically, three broad themes dominated discussion of program implementation (the focus of evaluation question #3) in both staff interviews and meeting observations: time, money, and momentum. These themes are described in more detail below.

Time, more specifically the realization that initiating and successfully conducting many of the program activities would require more time than initially anticipated, was a prominent theme in discussions of program implementation progress. For example, time was presented as a major factor leading to patients' acceptance of patient navigators and other MOPP services:

> "…we can't just jump in there and expect people to welcome us. We have to get to know them, we have to let them know that they can trust us…you tread along in a very careful and cautious way."

Similarly, time, specifically maintaining MOPP promotion and outreach efforts and developing a solid program reputation over time, is identified as a key factor for building a

strong referral base among physicians and clinics within the UPMC system and surrounding service communities:

> "I think they'd hoped to get more referrals from like primary care doctors, and we…really haven't had that…. I would say the process by which we get referrals has been a little bit rocky, and I think we're still working on that, and I think that we, over time, have made it smoother just by [having] us more integrated into all the services that are already at the Hillman—just have [to]continue to have people know who we are and what we do."
>
> "…I think it's [MOPP] impacted a number of different physicians or clinics—I think it could do more. In my opinion, I think it's because it just takes time. We routinely go and visit different PCPs or clinics, etc., and unless, I think, they have a bite initially—like there's really a patient there within the next week or so, they probably forget about it. But once they use it, then it's on their minds."

Lastly, staff generally acknowledged that more time than originally anticipated was required for two major program components: 1) completion of participant barriers and needs assessments, 2) tracking participants and facilitating program monitoring, reporting and improvement through the use of a database. With one respect to time, barriers and needs assessments, which are conducted at intake, were sometimes modified and shortened to minimize patient burden:

> [The program] had planned to do like a longer assessment on each patient, but I think that some times that works out, and sometimes it's really too intrusive."

While a converse issue of time was the significant amount of time it sometimes took to gather the information (e.g., insurance coverage details) necessary to address patients' individual needs and to help patients who had a complex set of needs.

The amount of time required to build a useful and effective program database has far exceeded program projections and has presented challenges for efficient program monitoring and program reporting:

> "…when you try to build a database…it becomes very cumbersome. It seems like you never get to where you want to be until you're almost finished with the project…. I think in the end we will probable have a good database, but it has been so cumbersome…."

It is standard practice to build a database for projects within the UPMC system, partly to ensure compliance with HIPAA requirements related to the protection of patients' health information. Based on information shared during observed meetings between program staff and the database administrator, the database accessed and used by program staff is primarily a Microsoft Access interface, and so staff have no access to the raw program data. Additionally, the interface lacks some features (e.g., error checks for date fields and links between administrator-assigned patient identification numbers and database-assigned identification numbers) that would facilitate accurate data entry and efficient progress reporting. Simple program reports (i.e., frequency reports on various database fields) are generated by the program administrator and provided at the program's request. However, this limits the program's ability to monitor the quality and accuracy of data collection. These challenges and resulting data limitations are reflected throughout the summaries of descriptive statistical analyses of program data provided in this dissertation. Program staff note improvements in the database, but also maintain that a great deal

more work needs to be done to create a database that effectively supports program practice, evaluation and reporting.

Money was another major implementation-related theme identified through interviews and meeting observation. Specifically, that "it was anticipated that the money [$750,000 set aside to cover gaps in coverage for patients receiving cancer care on a clinical trial] would be used overnight", when in fact only about $600 in gap funds have been used since program implementation. More money, about $7,000 worth of cab vouchers, has been spent meeting participants' transportation needs.

Finally, momentum was a major theme that came out at program meetings and staff interviews, in the sense that referrals from outside of the UPMC system and participation from patients at sites other than Hillman have been lower than anticipated. These lower rates of referrals and site participation are reflected in the previously reported descriptive statistical summaries of program data. Certainly, this issue of momentum is related to program staff's notion that it takes time to build effective referral relationships for the program.

3.5 PROGRESS TOWARD SHORT-TERM OUTCOMES

In general, program staff believes the program is making progress toward short-term outcomes, and, in so far as accomplishment of activities are expected to lead to the desired outcomes, quantitative data analysis supports this claim. Short-term outcomes for participants include increased knowledge and resources for overcoming barriers to cancer care; increased knowledge of CCT opportunities and benefits; increased social support; and improved financial means for health care. While there are no standard measures (e.g., social support scale) used to

measure these increases in patients' knowledge or social support status prior to and post MOPP intervention, several data points recorded in the program database serve as reasonable proxy measures for these short-term outcomes. For example, program records show that all participants are contacted by the program and informed of available MOPP services, which include patient navigators. In this sense, MOPP is contributing to patients' knowledge about available resources for overcoming barriers to cancer care. Additionally, the program database tracks the social support services patient navigators provide to their assigned patients, and the social worker works to assist all uninsured or underinsured program participants obtain adequate insurance coverage. Documentation of these services, which was presented in previous sections, arguably reflect progress on short-term outcomes to increase patients' social support and to improve patients' financial means for health care.

Moreover, findings from participant interviews also suggest that the program is making progress on its short-term outcomes for participants. As outlined in Table 3, interviewees represent a heterogeneous sample of program participants (i.e., age, gender, cancer diagnosis and stage, acceptance of navigator services). Even with this diversity, there was a great deal of similarity in interview responses. Each interviewee readily identified ways in which they benefited from working with a patient navigator and/or participation in MOPP, which included receipt of transportation assistance, social support, and financial assistance to cover care and prescriptions:

> "She helped me, you know, with the vouchers to get back and forth, when I needed them, when I had…transportation problems….she helped me get this…patient aid thing where I was getting a gift card every month, and I appreciated that."

"She sits down, and she talks with me, and that helps a lot."

"…getting the prescription, …getting in touch with the people in the study program [CCT], you know she helped me with getting into that."

Short-term outcomes for MOPP participating centers include: increased knowledge of barriers to cancer care and CCT participation and increased awareness of effective strategies for addressing barriers. Quantitative data analysis (see Table 10 on page 116) indicates that the program is achieving these short-term outcomes. A program staff member explains the significance of success on these outcomes:

"…what it [MOPP] is doing for the first time is clearly demonstrating what are the barriers as to why they don't enter trials, which is totally different than what people were sort of guessing because everyone, at least here, was saying it was money, or it's Tuskegee. That's not what we're finding, we're finding the number of comorbidities, the number of other chronic diseases, the late stage diagnoses is what is inhibiting them [large proportion of newly diagnosed African American patients receiving cancer care at participating UPMC sites] from entry on the trial, which allows us to make some decisions internally: Do we write trials that can address patients that have comorbidities of three or better? Do we, you know, really maybe do some further research into does it really make a difference if you have certain comorbidities in regards to trials already here? …it really gives us a clear picture of what the issues are."

3.6 UNINTENDED OR UNEXPECTED OUTCOMES

For the purposes of this evaluation, unintended or unexpected outcomes were defined as those that were not initially planned for or anticipated, as documented in program documents and the logic model; or those outcomes the program staff expresses being insufficiently prepared for, or surprised by. Unintended or unexpected outcomes can include positive and negative consequences. Three significant unintended or unexpected outcomes emerged from the qualitative data from staff interviews and meeting observations. Interestingly, staff identified unintended or unexpected outcomes at various intervention impact, or ecological levels: patient (i.e., individual), patient-navigator relationship (i.e., interpersonal), and the program (i.e., institutional/organizational).

Related to the patients, staff reported seeing more addiction or substance abuse problems than expected, and noting the absence of a drug counselor on staff at Hillman, which is the cancer care site for the majority of the program participants, staff report that it has been challenging, and requires significant time and staff resources, to assist patients with substance abuse problems with their cancer care:

> "There are a little more drug problems than—I mean don't get me wrong, there's not a ton of them, but there is a significant little subset, I think…. So, I was a little bit surprised by that…..we have patients that come from those …backgrounds—if you want to treat them, we do need a lot more intensive contact, or they're just going to get lost."
>
> "One thing I've found, which I was enlightened, but I thought that if somebody was diagnosed with cancer, behaviors changed—like if you smoke, if you drank, all that would change. What I found out was that doesn't

> happen. So, those are other things that people content with because those types of appetites, they take a greater role when you come in here taking treatment…. So, I was just really surprised about that."

Descriptive statistical analysis of program data identified the percentage of medically documented addiction and substance abuse problems among MOPP program participants. The "little subset" described above amounts to 21 patients, or 8.9% of program participants (n=235, excludes CCT screen only patients). However, these numbers may underrepresent the issue because they may not capture non-illicit drug addictions, such as alcohol or nicotine additions, as the substance abuse literature notes inadequate diagnosis and treatment of these conditions by physicians (Klamer & Miller, 1997).

Another unintended or unexpected outcome identified by staff was the impact, both positive and burdensome, that the patient navigator-patient relationship has had on navigators. Staff recognize the potential closeness of navigator-patient relationships: "I've seen some patients get really attached [to the navigators]." However, the closeness of the navigator-patient relationship was also described as the source of some emotional burden as many patients are very sick and may die from cancer while under their navigators' care:

> "You meet the patient, you get to know the patient…okay, so all of that is an emotional impact on the individual. You know, so everybody's different, just they have to be, and I don't know how they can be, prepared for the emotional impact that you might encounter. Patients die…sadly…you may follow somebody a year, or you may follow somebody for six months, or if you meet somebody today—'well, the doctor gave me six months to live'—and in seven or eight months, they're gone."

> "You see these people, and you know they are sick. And, unfortunately, a lot of the patients we get are already stage III or stage IV…when we're introduced to them, we know that there's a good chance they're going to die. That's a definite downside because you get attached to them…and then you start seeing that rapid decline in their health—that's very disturbing, but that's the nature of the beast."

Indeed, the majority of patients navigated (77%), and, for that matter, the majority of MOPP program participants (58%) have a stage III or IV cancer diagnosis, which, given the fact that treatment is often more effective when cancer is detected early (DHHS, Office of Minority Health, 2005), suggests that many of these patients face bleak prognoses, depending, of course, on other relevant factors like cancer type and location. Navigators without a medical background or with limited experience with terminal chronic disease may be particularly affected by the sickness and death they must confront in their work.

Finally, at the program level, the growth of the program, and consequently the expansion of program focus and activities, is generally considered an unexpected outcome among program staff:

> "It's grown into more than what I thought. I really, I didn't anticipate that we'd have this many participants…. Lots of things are happening because we're becoming known because of the program [MOPP], so we're being asked to do this, do we do that, would we help with this."
>
> "We've had every diagnosis come."
>
> "There are some referrals…from the Prevention and Early Detection Clinic and from some of the outside health clinics, and they're not cancer patients

but they're patients that need a work-up. So they're getting referred in to [the program, and we're] getting them in for screening, helping them with their insurance. So I think that what we need to look at is the other piece of what's happening to them."

These descriptions of program growth and expansion (e.g., providing services for patients with all cancers, and even those who are in the process of receiving diagnostic work-ups) are consistent with the descriptive statistical analysis of program participants presented in Table 4. However, the qualitative data provides valuable information regarding the ways in which shifts in program numbers have affected program practices and delivery and monitoring needs.

3.7 PROGRAM COSTS

Cost categories for the Minority Outreach Pilot Program were developed based on the patient navigation literature and MOPP's unique set of program activities, as described in the program logic model. Informal meetings were held with the Program Director to review internal expense logs (e.g., gap funds and cab voucher logs) and to identify program expenses related to the following major budget categories:

- *One-time or up-front costs*: Includes expenses related to research and program development, and the costs for the development of the program database.
- *Recurring Costs*: Which include personnel salary, staff training, program marketing and outreach, information technology support, and the provision of program services (i.e., primarily transportation costs for MOPP).

It is important to note that many common expenses related to program operation, such as office space and utilities, office supplies, landline and mobile telephones, are not directly absorbed by the program—they are covered by virtue of the pilot program's placement within the larger UPMC Cancer Center's system. In this sense, they can be considered in-kind contributions to the pilot program from the Center. Additionally, use of gap funds, which are designated to address gaps in coverage for cancer care on a clinical trial, are monitored as a separate component of the program budget. Almost $600 of gap funds have been used by the program since its initiation.

Start-up costs for the Minority Outreach Pilot Program amounted to $13,500. This one-time expense consisted of $7,500 for research, program development and initial program promotion material and events and $6,000 for the development of the MOPP database. Due to the sensitive and confidential nature of personnel salaries, recurring costs must be presented as the total cost per year for all of the items that fall under this category as listed above. Recurring costs total approximately $95,000 per year. This is a relatively reasonable cost considering the program serves roughly 100 new patients a year and has reached a program population of 249 (as of April 2008).

MOPP's annual program budget can be viewed as fairly low considering the grant funds (a total of $19.5 million over 5 years) NCI recently awarded to 8 research institutions under the Patient Navigation Research Program (PNRP); the American Cancer Society provided additional dollars to fund a ninth site (NCI, 2005). An exact amount of the individual site awards could not be found. But, assuming equitable distribution for the sake of comparison, a single program could be funded at $487,500 a year—this estimate is consistent with the .8 million per year ceiling for applicants listed in the Patient Navigation Research Program RFA (NCI, 2004). As of

June 30, 2007, 806 patients across the PNRP nine sites representing four cancers (breast, cervical, colorectal, and prostate) have received navigators and another 429 received program services that did not include a navigator (Greene et al., 2007). If the PNRP were operational within one year after the program start date (anticipated as 7/2005 in the RFA) as outlined in the funding announcement, these numbers represent about a year's worth of program data. Again, assigning an equal distribution of patients for the purposes of comparison, an NCI PNRP site could potentially be spending up to $487, 500 a year to serve about 137 patients. Although a PNRP site's annual budget undoubtedly includes costs related to conducting rigorous research and evaluation of the intervention.

4.0 ARTICLE #1: ENHANCING A CANCER PATIENT NAVIGATOR PROGRAM THROUGH MIXED-METHODS EVALUATION

Manuscript in Preparation

June 26, 2008

LaShawn M. Curtis, MPH[1], Lyn B. Robertson, RN, MSN, DrPH[2], James Butler, Med, DrPH[1], Patricia I. Documét, MD, DrPH[1], Robert M. Goodman, MA, MPH, PhD[3], Jeanette Trauth, MPA, MS, PhD[1]

[1]University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA, [2] University of Pittsburgh Medical Center Cancer Centers, Pittsburgh, PA, [3] Indiana University Bloomington School of Health, Physical Education, and Recreation, Bloomington, IN

4.1 ABSTRACT

Introduction: An evaluation was conducted to systematically collect, analyze, and share information about the context, activities, and early impacts of the University of Pittsburgh Medical Center Cancer Centers' patient navigation initiative, the Minority Outreach Pilot Program (MOPP).

Methods: The Centers for Disease Control and Prevention Framework for Program Evaluation and the RE-AIM framework informed and guided evaluation activities. The evaluation employed a case study design that mixed qualitative (e.g., program document review and interviews) and quantitative (e.g., descriptive statistical analysis of program database) methods.

Results: From program launch in March 2006 to the end-date for evaluation data collection activities (April 2008), MOPP served a total of 249 patients, among whom 146 experienced at least one barrier to cancer care. Common patient-identified barriers included: no or limited insurance, transportation, and co-morbid chronic illness. During this same period, a total of 75 patients worked with navigators and received services from them, including emotional support (e.g., accompanying patients to treatment appointments) and transportation assistance. Ultimately, 31 program participants enrolled in cancer clinical trials, and reasons for non enrollment were documented for all others. Common reasons for non-enrollment included medical ineligibility and choice of other treatment by medical doctor. A key program implementation challenge identified in the evaluation was the significant amount of time required to develop the program database. Additional issues emerged in the evaluation that have not been found in the literature, such as the difficulty of serving patients with a complex, interrelated set of cancer care barriers and substance abuse problems.

Conclusions: Evaluation findings indicate that MOPP is largely being implemented and is providing services as planned, except for the minimal expenditure of cancer care funds. Evaluation activities and findings facilitated program improvement, including database refinement.

4.2 INTRODUCTION

A mixed-methods evaluation was conducted to systematically collect, analyze, interpret and share information about the context, activities, and early impacts of the University of Pittsburgh Medical Center (UPMC) Cancer Centers' Minority Outreach Pilot Program (MOPP). MOPP is a patient navigator program that works to ensure access to the latest innovations in cancer treatment, regardless of financial means, for newly diagnosed African American cancer patients seeking care at one of four UPMC medical centers. UPMC and UPMC Cancer Centers implemented the Minority Outreach Pilot Program in March 2006 with input from the African American Cancer Care Partnership (AACCP)—a task force of representatives from the Pittsburgh community, local health care centers, academic institutions, and community organizations working to facilitate collaboration among, and guide and coordinate the efforts of, various groups whose goals are to improve the health of African Americans. The navigator program represents one of UPMC Cancer Centers' efforts to address racial and ethnic disparities in cancer care.

C-Change, a national organization comprised of the nation's key cancer leaders from government, business, and non-profit sectors, defines cancer patient navigation as follows:

> Patient navigation in cancer care refers to individualized assistance offered to patients, families, and caregivers to help overcome health care system barriers and facilitate timely access to quality medical and psychosocial care from pre-diagnosis through all phases of the cancer experience. Navigation services and programs should be provided by culturally competent professional or non-professional persons in a variety of medical, organizational, advocacy, or community settings. The type of navigation services will depend upon the particular type, severity, and/or complexity of the identified barriers (C-Change, 2005).

Strategies for addressing inequalities in cancer care, such as patient navigation, are greatly needed as critical racial/ethnic and socioeconomic cancer burden disparities persist in the United States (Dohan & Schrag, 2005). For all cancer sites combined, African Americans are more likely to develop and die from cancer than persons of any other racial or ethnic group, and they are also at greater risk of dying of the four most common types of cancer (lung, breast, colon, and prostate cancer) than any other minority group (American Cancer Society [ACS], 2005).

Underserved populations face a number of barriers that impede timely quality cancer care beyond being uninsured or underinsured, including: cultural orientations and differences that may contribute to lack of trust in medical systems or difficulties in negotiating relationships with health care providers and organizations; and logistical barriers, such as lack of transportation or child care, inconvenient clinic schedules, rural residence and distance from health care centers (Dohan & Schrag, 2005; Fowler, Steakley, Garcia, Kwok. & Bennet, 2006). Such barriers can be placed within a larger context of the "complex and overlapping interplay of poverty, culture,

and social injustice" in the United States, which Freemen posits "underscore the challenge of reducing cancer disparities (2004, p. 44)

In addition to cancer burden disparities, significant disparities exist in cancer clinical trial participation. Participation in cancer clinical trials (CCT) helps researchers make significant advances in the fight against cancer and provides patients with access to state-of-the-art treatments (C-Change, n.d.). An estimated 1.2 million Americans will receive a diagnosis of cancer this year, but only 3-5% of these new cancer patients will participate in a cancer clinical trial (C-Change), and this participation rate is even lower among minority groups and women (Baquet, Commiskey, Daniel Mullins, & Mishra, 2006; Bolen et al., 2006; Ford et al., 2005; Sheppard et al., 2005).

The literature identifies several barriers and facilitators of participation in cancer clinical trials, including patient and provider knowledge, attitudes and beliefs; access; religious and cultural beliefs; and strict inclusion and exclusion eligibility criteria for trials (Bruner, Jones, Buchanan, & Russo, 2006; Christian & Trimble, 2003; Comis, Miller, Aldige, Krebs, & Stoval, 2003; Ford et al., 2005). It is widely assumed that racial and ethnic disparities in cancer clinical trial participation are the result of unwillingness on the part of minorities to participate in health research; however, there is little evidence to support this claim (Wendler et al., 2006; Trauth et al., 2005). In fact, some studies suggest that the primary challenge with CCT recruitment and accrual is not the attitudes of patients or their unwillingness to participate, but rather the limited availability of appropriate trials and the disqualification of large numbers of patients due to comorbidities, insurance coverage issues, or even transportation barriers (Comis et al., 2003).

In an effort to help patients overcome myriad cancer care barriers, the nation's first patient navigator program was implemented in 1990 by Freeman and colleagues at Harlem

Hospital in New York City (Fowler et al., 2006; Freeman 2006). The initial positive findings from the early navigator model, along with the significant need for interventions that are effective in reducing cancer care disparities, have led to widespread implementation of cancer patient navigation across the country (Vargas et. al, 2008). Despite its popularity and widespread use, there is limited study of patient navigation in the peer-reviewed literature (Vargas et al, 2008). However, patient navigation is receiving a great deal of attention at the federal government level, and efforts, such as the National Cancer Institutes' Patient Navigation Research Program (NCI, 2005), are underway to address the lack of sufficiently rigorous research on the true effects of patient navigator programs. Of course, hundreds of patient navigator programs have already been established in the world of public health practice (Dohan & Schrag, 2005; Hede, 2006). Hence, timely and practical program evaluation is needed to help guide and support practitioners' efforts to address cancer care needs and disparities in their communities through navigator programs.

The mixed methods evaluation of the UPMC Cancer Centers' Minority Outreach Pilot Program was designed to accomplish two broad goals: 1) to facilitate enhancements in MOPP implementation, expansion, and ongoing monitoring and evaluation; and 2) to contribute to the growing national evidence base for cancer navigation by illuminating navigator programs' real-world contexts and experiences. The Centers for Disease Control and Prevention Framework for Program Evaluation in Public Health and the RE-AIM framework were integrated and applied to help achieve these evaluation goals.

Cancer patient navigator programs are complex and comprehensive by the nature of both the problems they seek to address and the fragmented system they operate within; thus, evaluations of these interventions, particularly within the context of limited resources can be

challenging. The CDC framework created a process (Engage Stakeholder, Describe the Program, Focus the Evaluation Design, Gather Credible Evidence, Justify Conclusions, and Ensure Use and Share Lessons Learned) and established standards (Utility, Feasibility, Propriety, and Accuracy) that organized the evaluation of a multifaceted, broad intervention; thereby, helping to ensure that a sound, thorough evaluation was conducted (CDC 2005, 1999). Where CDC provided a valuable organizational framework for the complex evaluation task at hand, dimensions of the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, and Maintenance) helped to achieve the second evaluation goal by calling the evaluator's attention to issues that are relevant for public health practice and translation (Glasgow, Klesges, Dzewaltowski, Estabrooks & Vogt, 2006, p.688).

4.3 METHODS

The following section describes both the evaluation process and methods, in an effort to share an approach that was found to be particularly useful and effective for evaluating a complex cancer patient navigator program within the context of real-world program practice and constraints.

Step 1: Engage Stakeholders

Several steps were taken to ensure that key stakeholders were actively engaged throughout the evaluation process. The MOPP evaluation was a dissertation project, so the MOPP Program Director was included on the dissertation committee, which informs and approves all dissertation activities. Additionally, prior to initiating the evaluation, planning meetings were held with program staff to learn about evaluation needs and priorities. Weekly program staff and three monthly AACCP meetings were attended throughout the evaluation

period (January-May 2008) to develop a better understanding of program context and operations, share and receive feedback on evaluation progress reports, and to facilitate utilization of evaluation findings.

Step 2: Describe the Program

A draft description of the program theory, which was depicted graphically in a logic model, was developed based on a review of program documents. Then, working meetings were held with staff to review and revise the model. Any suggested modifications were discussed and refined through group consensus. The MOPP logic model (Appendix A) was a useful and immediate product of the program evaluation—the Program Director expressed plans for using the model in presentations for administrators and other cancer care partners and stakeholders.

Step 3: Focus the Design

A case study design was chosen for the MOPP evaluation. Evaluation design, as well as evaluation questions, were determined based on a number of factors, including: the complexity of the intervention (Goodman, 2001), the early stage of the program, stakeholder evaluation needs, and CDC Framework standards. Case studies give an in-depth picture of the implemented program, its organizational context, and the broader environment by integrating qualitative and quantitative information from a variety of sources (Love, 2004). Table 2 provides an overview of the evaluation design.

Step 4: Gather Credible Evidence

The following methods and data sources were used to address the evaluation questions: descriptive statistical analysis of de-identified, raw data from the MOPP database, which included demographic, diagnostic and service variables; review of program documents, including outreach material and presentations; and qualitative analysis (i.e., close reading, focused-coding,

and theme identification) of transcripts from semi-structured staff and patient interviews and field notes from meeting observations. The data from the program database that was analyzed for this evaluation covered the period from program initiation (March 2006) to April 2008, which was the end date for evaluation data collection.

All five program staff members (1 Director, 1 Social Worker, 1 Cancer Control Specialists, and 2 Navigators) were interviewed to help address evaluation questions #1-5. In addition, phone interviews were conducted with a small sample of program participants to help address evaluation question #4. Participant interviews focused on the impact that the program has had on patients and their satisfaction with services received. Staff and patient interview questions are listed in Appendix C. Seven program participant interviewees were selected through heterogeneity sampling based on the following characteristics that are especially relevant to the MOPP mission and services: type of cancer; referral source; acceptance, delayed acceptance, or decline of patient navigator services; and CCT participation. Heterogeneity sampling was used to yield both: 1) high quality, detailed description for single patients, which is valuable for documenting the uniqueness of patients served by the program, and 2) important shared themes that cut across patients and establish their significance from having emerged from a heterogeneous sample (Patton, 2002). Program participants received gift card incentives for their participation. The evaluation research was approved by the University of Pittsburgh Institutional Review Board.

4.4 RESULTS

Step 5: Justify Conclusions

The MOPP evaluation provided a wealth of data. The following summary of findings focuses on those issues the authors believed to be most relevant to practitioners interested in navigator program development or improvement, as well as key issues that emerged from the data that have not previously been reported in the patient navigation literature.

Participant Characteristics

A total of 249 patients participated in the MOPP program. About 30% of MOPP's 249 program participants are between 20 and 49 years of age, while the majority of program participants fall within the 50-64 age group. Almost 60% of participants are female. Most (26.1%) of the program participants were identified through case finding, which involves the MOPP social worker regularly reviewing tailored system billing reports to identify patients who fall within the program target population. However, a fairly large number of referrals are received from UPMC social workers (18.5%). Seventy-five patients are working with patient navigators. Most patients (37.3%) entered the program with a stage IV cancer diagnosis. Among program participants, the four most common cancer diagnoses are breast (17.7%); lung, non-small cell (15.3%); colon (7.2%); and head and neck (6.4%). The majority of program participants (73.5%) receive care at the Hillman Cancer Center site. Forty-one (16.5%) patients entered the program with a self-pay or uninsured status, while 27.3% were insured through Medicare Managed Care and 22.1% were insured through Medicaid Managed Care.

Descriptions of program participants obtained from staff interviews were aligned with the descriptive statistical data presented above, but also emphasized program participants' diversity:

"…all their needs are different. They come from all walks of life….there's no set mold that our patients are coming from."

Program Reach

The REACH calculator, which is available on the RE-AIM website (www.re-aim.org) was used to calculate the following measures: percent of target population who responded to recruitment (90.2); percent of eligible who participate (31.9); percent of reach into target population (27.2); and percent excluded from the intervention (5.6). While these reach-related measures are calculated based on the number of program participants who accepted patient navigators (75), it is important to note that patients do not have to accept a navigator to receive assistance from the MOPP program. The total number of MOPP participants (249) includes the 75 patients who accepted navigators and 174 who did not.

Implementation Progress

Assessing patients' barriers to cancer care and providing them with individualized solutions and services to help reduce or eliminate those barriers is MOPP's chief program activity. Virtually all participants, excluding a small number (n=14) who receive care at non-participating MOPP sites and are designated as "CCT screen only", receive barrier assessments. A total of 146 program participants identified at least one barrier to cancer care. Barriers most commonly identified by patients included: no or limited insurance (24.3%), transportation (21.7%), financial problems (16.2%), and co-morbid chronic illness (14.0%). Program records indicated that patient navigators provided services to 78 participants, including a few patients who declined the opportunity to work with a navigator, but requested and received some assistance from navigators at some point during their care. Patient navigator services included the provision of emotional support (e.g., accompanying patients to treatment appointment),

transportation assistance, and appointment reminders. In addition to the patient navigator services provided, the program social worker assists all program participants who are classified as self pay or uninsured with obtaining adequate insurance coverage. The social worker also provides transportation assistance to program participants (n=32), and other related social services.

Cancer clinical trial education and recruitment is also a major program activity. During the period covered by this evaluation (March 2006-April 2008), twenty-seven program participants enrolled in cancer clinical trials, and reasons for non enrollment were identified and documented for all program participants who were not enrolled in trials (n=222). Top reasons for non-enrollment included: medical ineligibility (23.4%) and choice of other treatment by medical doctor (23.9%). Excluding non-cancer and medically ineligible patients, MOPP has a 16.2% CCT participation rate, which is a significant achievement considering the 3-5% national rate for CCT participation among new cancer patients (C-Change, n.d.). Only 2.7% of program participant actually refused to participate in a trial. It is worth noting that, shortly after reviewing these evaluation findings, program staff worked to further investigate the issue of CCT eligibility among their participants. Based on eligibility criteria for current UPMC trials, staff reviewed program and medical record records to determine whether each patient in the database (n=250 at the time of this additional assessment) was eligible to participate in a CCT. Among the 60 MOPP participants who met eligibility criteria for available trials, 31 were enrolled in a trial. The program's additional assessment of CCT eligibility indicates that, when excluding ineligible patients, there is a 51.6% CCT participation rate among MOPP participants!

Costs

It is important to note that many expenses commonly related to program operation, such as office space and utilities, are not directly absorbed by the program as they are covered by virtue of the pilot program's placement within the larger UPMC Cancer Center's system. In this sense, they may be considered as in-kind contributions to the program from the Center. Additionally, use of $750,000 in gap funds, which are provided by UPMC to address gaps in coverage for cancer care on a clinical trial, are monitored separately from the program budget. Only about $600 in gap funds have been used by the program since its initiation.

Start-up costs for the Minority Outreach Pilot Program amounted to $13,500. This one-time expense included $7,500 for research, program development and initial program promotion material and events costs, as well as $6,000 for the development of the MOPP database. Due to the sensitive and confidential nature of personnel salaries, recurring costs (i.e., personnel salary, staff training, program marketing and outreach, information technology support, and the provision of program services) are presented in total. These expenses total approximately $95,000 per year.

Noteworthy Themes

Several themes emerged from the qualitative evaluation data that are relevant to navigator program planning and worthy of additional investigation. Time was a dominant theme in the qualitative evaluation data. Staff generally acknowledged that more time than originally anticipated was required for two major program components: 1) completion of participant barriers and needs assessments, and 2) developing a useful and effective program database.

Another key issue that emerged during the evaluation was the difficulty of serving patients with a complex set of interrelated cancer care barriers and substance abuse problems.

Related to the patients, concerns about substance abuse were widely expressed. Staff reported seeing more addiction or substance abuse problems than expected. Noting the absence of a drug counselor on staff at the site, where most participants receive care; staff report that serving patients with substance abuse issues has required significant time and staff resources:

> "There are a little more drug problems than —I mean don't get me wrong, there's not a ton of them, but there is a significant little subset, I think…. So, I was a little bit surprised by that…..we have patients that come from those…backgrounds—if you want to treat them, we do need a lot more intensive contact, or they're just going to get lost."

The descriptive statistical analysis of program data identified the percentage of MOPP participants with documented addiction and substance abuse problems. The "little subset" mentioned above is actually 21 patients, or 8.9% of program participants (n=235, excluding CCT screen only patients).

Also worth noting from evaluation findings is the concern for the emotional burden patient navigators may experience due to their exposure to patient morbidity and death:

> "You meet the patient, you get to know the patient…okay, so all of that is an emotional impact on the individual. You know, so everybody's different, just they have to be, and I don't know how they can be, prepared for the emotional impact that you might encounter. Patients die…sadly…you may follow somebody a year, or you may follow somebody for six months, or if you meet somebody today—'well, the doctor gave me six months to live'—and in seven or eight months, they're gone."

Perhaps this emotional burden is particularly an issue for lay patient navigators who do not have a clinical background or extensive clinical experience that might better prepare and equip them to deal with the illness and death they witness.

4.5 DISCUSSION

Step 6: Ensure Use and Share Lessons Learned

The MOPP evaluation provided valuable qualitative and quantitative data related to program implementation achievements and challenges. Moreover, the evaluation produced useful products (e.g., logic model and data reporting templates) and sparked immediate small-scale enhancements (e.g., database modifications). The evaluation also called attention to key issues that should be monitored closely within the MOPP program, and, perhaps, within the larger public health movement. These key concerns include effectively navigating patients with substance abuse and minimizing the emotional burden work has on patient navigators.

There were several limitations to this study. While the evaluation collected rich data from staff and participant interviews, the absence of input from other stakeholders (e.g., referring physicians and representatives of UPMC administration) is a study limitation. However, evaluation findings will be shared with stakeholders and it is recommended that, as program resources allow, additional stakeholders be involved in future evaluations. Additionally, quantitative data analysis in the evaluation is limited to descriptive statistical analysis, which produces useful information, but cannot provide causal information related to the impact of program activities. More advanced statistical analysis would have required additional data cleaning and collection—likely an extensive medical record review, which could have enhanced

the evaluation by assessing the relationship between program services provided and objective measures of treatment compliance or completion. Although, this would have required a great deal of time and staff resources that were not available for this evaluation, as well as additional precautions for human subjects and health care information protection.

Fleisher rightly insists that "as the practice of patient navigation expands, there is a great deal to be learned about the process, political climate, and day-to-day challenges in planning and implementing a navigation program" (2008, p.2). Ultimately, the MOPP evaluation may prove valuable as a model for conducting program evaluation for cancer patient navigation that enhances local program practice; respects real-world time, funding, and ethical constraints; and systematically collects and disseminates valuable information on program context, implementation, and early outcomes.

5.0 ARTICLE #2: ELUCIDATING AND ADDRESSING CANCER CLINICAL TRIAL DISPARITIES THROUGH A PATIENT NAVIGATOR PROGRAM

Manuscript in Preparation

June 26, 2008

LaShawn M. Curtis, MPH[1], Lyn B. Robertson, RN, MSN, DrPH[2],

Beth Simon, RN, MSN, DrPH[2], Joyce Grater, LCSW, PhD[2], Jeanette Trauth, MPA, MS, PhD[1]

[1]University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA,

[2] University of Pittsburgh Medical Center Cancer Centers, Pittsburgh, PA,

5.1 ABSTRACT

Participation in cancer clinical trials (CCT) helps researchers make significant advances in the fight against cancer and provides patients with access to state-of-the-art treatments. An estimated 1.2 million Americans will receive a diagnosis of cancer this year, but only 3-5% of these new cancer patients will participate in a cancer clinical trial, and this participation rate is even lower among minority groups and women. Cancer patient navigation is one potential strategy for improving cancer clinical trial participation among minority and underserved populations. An evaluation was conducted to systematically collect, analyze, and share information about the context, activities, and early impacts of the University of Pittsburgh Medical Center Cancer Centers' patient navigation initiative, the Minority Outreach Pilot Program (MOPP). This article reports detailed evaluation findings related to MOPP's CCT education and recruitment activities in an effort to help address the need to develop and expand the cancer patient navigation literature. Additionally, it is expected that the presentation of MOPP's process for integrating CCT screening and recruitment into their patient navigator program services, which has achieved a 51.6% CCT participation rate among eligible program participants will serve as a national model for other health care centers and organizations that seek to address disparities in CCT participation. Lastly, findings related to reasons for non-enrollment and their relationship to the calculation of CCT participation rates can help influence CCT criteria and policies at both the local level within the UPMC system and, potentially, national level efforts to study and address CCT disparities.

5.2 INTRODUCTION

A mixed-methods evaluation was conducted to systematically collect, analyze, interpret and share information about the context, activities, and early impacts of the University of Pittsburgh Medical Center (UPMC) Cancer Centers' Minority Outreach Pilot Program (MOPP). MOPP is a patient navigator program that works to ensure access to the latest innovations in cancer treatment, regardless of financial means, for newly diagnosed African American cancer patients seeking care at one of four UPMC medical centers. Informing program participants about cancer clinical trials and recruiting them for trial participation is a key program activity. This article shares important evaluation findings related to the achievements and challenges the program has experienced around CCT recruitment efforts. Quantitative (e.g., descriptive statistical analysis of the MOPP database) and qualitative (e.g., observation of staff and partnership meetings) methods were used to evaluate MOPP's success with identifying barriers to CCT participation among program participants and CCT recruitment.

5.3 BACKGROUND

5.3.1 Cancer clinical trial disparities

Participation in cancer clinical trials (CCT) helps researchers make significant advances in the fight against cancer and provides patients with access to state-of-the-art treatments (C-Change, n.d.). An estimated 1.2 million Americans will receive a diagnosis of cancer this year, but only 3-5% of these new cancer patients will participate in a cancer clinical trial (C-Change), and this

participation rate is even lower among minority groups and women (Baquet, Commiskey, Daniel Mullins, & Mishra, 2006; Bolen et al., 2006; Ford et al., 2005; Sheppard et al., 2005).

Brawley (2004) asserts that racial/ethnic disparities in cancer clinical trial participation is also an issue of social justice. Clinical trials provide opportunities for patients to receive state-of-the-art treatments. Among all cancer patients in the United States, those of higher socioeconomic status have led the increases in CCT accrual over the past several years and, thus, are major beneficiaries of clinical trial participation (Sateren et al., 2002). In addition, examination of the 20% increase in CCT admission to National Cancer Institute trials since the mid-1990s shows that the number of Asian, African American, Hispanic and Native American patients entering trials has remained relatively stable while the enrollment of whites has increased (Christian & Trimble, 2003).

The literature identifies several barriers to and facilitators of participation in cancer clinical trials, including patient and provider knowledge, attitudes and beliefs; access; religious and cultural beliefs; and strict inclusion and exclusion eligibility criteria for trials (Bruner, Jones, Buchanan, & Russo, 2006; Christian & Trimble, 2003; Comis, Miller, Aldige, Krebs, & Stoval, 2003; Ford et al., 2005). It is widely assumed that racial and ethnic disparities in cancer clinical trial participation are the result of unwillingness on the part of minorities to participate in health research; however, there is little evidence to support this claim (Wendler et al., 2006; Trauth et al., 2005). In fact, some studies suggest that the primary challenge with CCT recruitment and accrual is not the attitudes of patients or their unwillingness to participate, but rather the limited availability of appropriate trials and the disqualification of large numbers of patients due to comorbidities, insurance coverage issues, or even transportation barriers (Comis, Miller, Aldige, Krebs, & Stoval, 2003). The use of patient navigators is considered a promising strategy for

helping to address the myriad barriers to CCT participation minority and underserved populations face (Fowler et al, 2006).

5.3.2 Patient navigation and cancer clinical trials

The National Cancer Institute explains that *patient navigation* for cancer care "refers to support and guidance offered to persons with abnormal findings in accessing the cancer care system and overcoming barriers to quality, standard care. Navigation spans the period from abnormal finding from cancer detection procedure through necessary cancer diagnostic tests to completion of cancer treatment" (United States Department of Health and Human Services, National Institutes of Health, National Cancer Institute [NCI], 2004, p. 2). Patient navigation is a context-driven intervention as the services navigators provide are specific to the needs of their patients and the barriers they identify. Consequently, navigator programs throughout the nation vary widely in the strategies they adopt and apply in order to reduce or eliminate cancer care barriers, but often include:

- Providing emotional support to cancer patients, as well as information on what to expect during their cancer care;
- Helping patients understand their diagnoses;
- Coordinating appointments with providers to ensure that patients with suspicious findings receive timely diagnosis and treatment;
- Helping to arrange transportation and/or child/elder care for visits to cancer treatments;
- Helping to arrange language translation or interpretation services;
- Helping patients and their families access support systems; and

- Facilitating access to available financial support and assisting with related paperwork. (Dohan & Schrag, 2005; NCI, 2006).

Navigator program activities may also include community outreach and screening services, efforts to improve access to cancer clinical trials, and partnership building with local organizations and groups to link patients to cancer support groups or needed social services (NCI, n.d.).

Freeman (2006) explains that *patient navigators* are charged with identifying, anticipating, and helping to alleviate barriers to cancer care that patients encounter. Thus, they should be sensitive, compassionate, and culturally attuned to the patients and community being served; knowledgeable about the healthcare system and environment; and connected with critical decision makers within the healthcare system, particularly with financial decision makers (Freeman, 2004, 2007). Considering their roles and corresponding essential qualities, patient navigators are uniquely positioned to promote access to cancer clinical trials (Fowler et al., 2006).

5.4 UPMC CANCER CENTERS' MINORITY OUTREACH PILOT PROGRAM

5.4.1 Program description

UPMC and UPMC Cancer Centers implemented the Minority Outreach Pilot Program in March 2006 with input from the African American Cancer Care Partnership (AACCP)—a task force of representatives from the Pittsburgh community, local health care centers, academic institutions, and community organizations working to facilitate collaboration among, and guide the efforts of,

various groups whose goals are to improve the health of African Americans. The navigator program represents one of UPMC Cancer Centers' efforts to address racial and ethnic disparities in cancer care.

According to MOPP's program theory, the intervention is based on certain assumptions that are consistent with the Freeman patient navigation model. Specifically, patient navigation operates as a process by which navigators provide social support to remove the barriers to care that patients experience. This social support includes emotional support—such as expressions of empathy and caring; instrumental support—tangible aid and service; and informational support—such as providing educational information, advice and suggestions that patients can use to address problems (Heaney & Israel, 2002). The patient navigation process also includes the documentation of barriers, and the feeding back of barrier information to health care system management to support system level change. The program also operates under the assumption that navigators need to be sensitive, compassionate, and culturally attuned to the patients and community being served; knowledgeable about the health care system & environment; and connected with critical decision makers within the health care system.

The program's resources (including community partnerships, program staff and funding) support the delivery of navigation services, which include barrier assessments, financial counseling and assistance, and cancer clinical trial education and recruitment. Over time, navigator services are intended to lead to change in cancer care knowledge, awareness and behavior among program participants and improvements in cancer care delivery systems. Short-term and intermediate outcomes include increasing patients' knowledge of resources for overcoming barriers to care and increasing the health care centers' knowledge of patient barriers to cancer care and cancer clinical trial participation. Ultimately, the achievement of short-term

and intermediate outcomes is expected to lead to the elimination of barriers to cancer care and increased survivorship for the program's target patient population, as well as increased African American representation in cancer clinical trials across participating health care centers. MOPP experiences in achievements in working toward these important long-term outcomes will also help improve public health researchers and practitioners' knowledge about improving CCT participation and reducing disparities among minority cancer patients.

5.4.2 Data collection and intervention efforts

Since its initiation in March 2006 through April 2008—the planned data collection end date for the dissertation research—a total of 249 patients have been referred, or recruited through case finding, to the Minority Outreach Pilot Program. Based on program staff's monthly comparisons of MOPP enrollment and UPMC new patient summaries, which are derived from billing data to provide the most accurate data possible; the program reports having contact with about 85% of all newly diagnosed African American patients receiving care at the four participating program sites. Of the 249 patients the program has made contact with and/or served, 75 have accepted and utilized the program's patient navigator services and 27 have enrolled in cancer clinical trials. It is standard program practice to conduct cancer care barrier assessments with all program participants and to inform all program participants about cancer clinical trials. Fidelity to this practice standard is evidenced by the documented CCT enrollment status and reasons for non-enrollment for each participant.

5.5 RESULTS

The following tables present descriptive statistical summaries of data from the MOPP data base for the period of March 2006-April 2006. The proportion of total program participants (n=249) enrolled in CCTs is shown in Table 9, and the reasons for non-enrollment for the 222 MOPP participants who were not enrolled in trials at the time of this analysis are summarized in Table 10.

Table 9. CCT Enrollment Status Among MOPP Participants (n=249)

CCT Status	Count	Percent
Enrolled	27	10.8
Not Enrolled	222	89.2
Total	249	100

Table 10. Reasons for Not Enrolling in CCTs Among MOPP Participants (n=222)

Reason	Count	Percent
Already on Treatment	37	16.7
Lost to Follow-up	15	6.8
MD Chose Other Treatment	53	23.9
Medically Ineligible	52	23.4
No Clinical Research Coverage	2	.9
No HIPPA Consent	2	.9
No Trial Available	3	1.4
Non-Cancer	30	13.5
Pending	2	.9
Poor Performance Status	13	5.9
Prior Cancer	1	.5
Refused	6	2.7
Requires More Surgery	4	1.8
Second Primary (Cancer)	2	.9
Total	222	100

Qualitative data collection activities, particularly meeting observation, revealed the need to quantify reasons for non-enrollment, as well as CCT eligibility among program participants.

Cancer clinical trial participation rates are one of the program highlights shared at the African American Cancer Care Partnership meetings and in presentations to UPMC Cancer Centers' administration and funders. Discussion of the near 11% CCT enrollment rate at program meetings virtually always included an acknowledgement that many patients were ineligible for CCT for medical reasons, including comorbidities and late stage cancer diagnosis. However, the quantifiable effect that ineligibility had on the CCT enrollment rate had not been calculated. This is primarily attributed to the limitations of the program database interface, which did not allow program staff to easily calculate and track the percentage of MOPP participants who were ineligible for CCTs.

The MOPP database is not designed to provide program staff with access to aggregate raw data or create data reports. All program data reports are requested from a database administrator who is otherwise unaffiliated with the program and rather unfamiliar with MOPP activities. Hence, reports generally consist of simple frequencies without adjustment for factors that may affect their value. Considering this context, the evaluator worked with the program staff and database administrator to obtain a de-identified, raw data file for all variables in the database. The data was used to calculate an adjusted enrollment rate and to develop a more detailed description of those program participants who enroll in CCTs.

The number of participants eligible for CCTs (n=167) was defined as those patients who were not documented as medically ineligible (n=52) or non-cancer (n=30). Calculating the CCT participation rate as the proportion of program participants enrolled in cancer clinical trials among those who are eligible, MOPP has a 16.2% CCT enrollment rate. Table 11 presents this adjusted CCT enrollment rate by program year.

Table 11. CCT Enrollment Rate by Program Year, Excluding Medically Ineligible and Non-Cancer Participants

Program Year	Total #of Program Participants*	Number Enrolled in CCT	Percent Enrolled in CCT
2006	75	14	18.7
2007	62	9	14.5
2008	19	4	21.1
unknown	11	0	0
Total	167	27	16.2

***** excluding medically ineligible and non-cancer participants

Table 12 presents selected demographics for the group of program participants MOPP has successfully enrolled in trials during the period covered by this evaluation (March 2006-April 2008). Of MOPP participants enrolled in CCTs (n=27), 48.1% are male and 51.9 % are female. Most (59.3%) program participants enrolled in trials are between 50 and 64 years of age. Breast and colon cancer are the most common cancer diagnoses among CCT enrolled program participants, and about half of the participants have a stage IV diagnosis.

Table 12. Characteristics for Program Participants Enrolled in Cancer Clinical Trials (n=27)

Characteristic	Count	Percent
Age Group		
<20	0	0
20-49	6	22.2
50-64	16	59.3
65-74	4	14.8
75+	1	3.7
Total	27	100
Gender		
Female	13	48.1
Male	14	51.9
Total	27	100

Table 12 Continued Characteristic	Count	Percent
Cancer Stage		
I	1	3.7
II	2	7.4
III	9	33.3
IV	14	51.9
Unable to Stage	1	3.7
Total	27	100
Cancer Diagnosis		
Brain Tumor, Cerebral	1	3.7
Breast Cancer	8	29.6
Colon Cancer	6	22.2
Head and Neck Cancer	5	18.5
Leukemia, Chronic Myelogenous	1	3.7
Lung Cancer, Non-Small Cell	1	3.7
Pancreatic Cancer	3	11.1
Prostate Cancer	1	3.7
Rectal Cancer	1	3.7
Total	27	100

A little over half (51.5%) of the program participants enrolled in trials have between 0-2 co-morbidities. Among CCT participants, 44.4% accepted patient navigators. A chi-square test was conducted to check for any relationship between the acceptance of navigators and CCT enrollment; no indication of a relationship between the two variables was found: χ^2 (1, N=167) = .871, p=.35. However, this result is not unexpected considering the fact that program participants do not have to accept a patient navigator to receive services (e.g., transportation or insurance enrollment assistance) through the program. So, if necessary data were readily available from the larger UPMC patient population, it may be more appropriate to test for association between program participation and CCT enrollment.

It is important to note that shortly after reviewing the evaluation findings presented above from the descriptive statistical analysis of CCT data, program staff worked to further investigate the issue of CCT eligibility among their participants. Based on eligibility criteria for current

UPMC trials, staff reviewed program and patient medical records to determine whether each patient in the database (n=250 at the time of this additional assessment) was eligible to participate in a CCT. Sixty (24%) of the 250 MOPP participants met eligibility criteria for available trials. Among the 60 participants who were eligible, 31 were enrolled in a trial. The program's additional assessment of CCT eligibility indicates that, when excluding ineligible patients, there is a 51.6% CCT participation rate among MOPP participants. As presented in Table 13, reasons for non-enrollment recorded for the remaining 29 patients who were potentially eligible to participate in a CCT, but did not enroll include: patient refusal, patient refusal of cancer treatment in general, patient loss to follow-up, and the absence of documentation regarding the medical doctor's attempt to discuss CCT participation with the patient. Through this additional assessment, the program has also identified the need to improve physician documentation related to efforts to inform patients and recruit them to trials.

Table 13. Additional Program Assessment—Reasons for Non Enrollment Among MOPP Participants Who Are Potentially Eligible for CCTs (n=29)

Reason	Count	Percent
Refused CCT	8	27.6
Refused Treatment	1	3.4
Lost to Follow-up	1	3.4
No Documentation of MD Discussing CCT	19	65.6
Total	29	100

5.6 DISCUSSION

The value of MOPP's CCT education and recruitment efforts is best described by the staff, as they are responsible for utilizing service and evaluation data for program improvement:

> "…what it [MOPP] is doing for the first time is clearly demonstrating what are the barriers as to why they don't enter trials, which is totally different than what people were sort of guessing because everyone, at least here, was saying it was money, or it's Tuskegee. That's not what we're finding, we're finding the number of comorbidities, the number of other chronic diseases, the late stage diagnoses is what is inhibiting them [large proportion of newly diagnosed African American patients receiving cancer care at participating UPMC sites] from entry on the trial, which allows us to make some decisions internally: Do we write trials that can address patients that have comorbidities of three or better? Do we, you know, really maybe do some further research into does it really make a difference if you have certain comorbidities in regard to trials already here? …it really gives us a clear picture of what the issues are."

The MOPP cancer patient navigation system provides myriad services to help address participants' cancer care barriers while collecting data that informs decision-makers about the actual challenges and barriers to CCT participation minority and disadvantaged patients face. In addition, MOPP supports efforts to improve clinical research across the UPMC system. While additional study is required to test association between program participation and CCT

enrollment, data from initial evaluation efforts indicate that the program plays a very valuable role in documenting reasons for disparities in CCT participation among participating UPMC program sites, which is a vital first step to developing appropriate strategies for reducing these inequities.

6.0 ARTICLE #3: AN ALTERNATIVE APPROACH TO IMPROVING PUBLIC HEALTH RESEARCH TRANSLATION: INSIGHTS FROM EVALUATION WORK IN CANCER PATIENT NAVIGATION

Manuscript in Preparation

June 26, 2008

LaShawn M. Curtis, MPH[1] and Robert M. Goodman, MA, MPH, PhD[2]

[1]University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA, [2] Indiana University Bloomington School of Health, Physical Education, and Recreation, Bloomington, IN

6.1 ABSTRACT

Context: The large gap between public health research and public health practice is widely recognized and disconcerting. Research translation, which is defined as the process of moving from research (i.e., tools, information, and strategies developed and ascertained through research) to the actual application of research findings in day-to-day public health practice, is fundamental for improving the public's health. Multiple factors—historical, political, social, economic, scientific (i.e., program development research, evaluation and reporting practices), cultural, and organizational—operate independently and interact to slow and limit translation.

Methods: A review and critical analysis of both scientific factors related to slow and limited research translation and current efforts to address these factors in the public health field was conducted to promote progressive thinking around enhancing translation. The cancer patient navigation movement is described as a case in point for the promise of alternative approaches to the traditional linear and phased processes for moving between public health research and public health practice.

Findings: At least two prominent approaches were identified in the literature for ameliorating scientific factors that impede translation. They were conceptualized as traditional (i.e., approach accepts the general tenets of traditional linear and phased translation models) and alternative (i.e., approach encourages a rethinking and reshaping of the traditional processes and practices for moving between research and practice).

Conclusions: The problem of limited and slow translation in the public health field calls for both more broad and practical conceptualizations of evidence and increased emphasis on contextual realities in program development research. The cancer patient navigation movement

is an exemplar for the development of evidence that is more practice based, a quality that this critical analysis suggests is key for improving and accelerating public health research translation.

6.2 INTRODUCTION

The large gap between public health research and public health practice is widely recognized and disconcerting (Glasgow & Emmons, 2007; Schechter & Brunner, 2005). Research translation—the process of moving from research (i.e., tools, information, and strategies developed and ascertained through research) to the actual application of research findings in day-to-day public health practice—is fundamental for improving the public's health (Dzewaltowski, Glasgow, Klesges, Estabrooks, & Brock, 2004; Schechter & Brunner, 2005; Sussman, Valente, Rohrbach, Skara, & Pentz, 2006). Clearly, in order for the public to benefit from evidence-based health promotion and disease prevention knowledge and strategies that are identified through research, translation must be accelerated and improved so that research findings are applied in real-world public health programs (United States Department of Health and Human Services, Centers for Disease Control and Prevention, Office of Public Health Research [CDC], 2007).

There are multiple factors that slow and limit translation of research findings into practice—historical, political, social, economic, scientific, cultural, and organizational factors can all operate independently or interact to threaten translation (Glasgow & Emmons, 2007). The study of scientific factors that impede translation, which include program development research, evaluation and reporting practices, is of critical importance as these factors are arguably most proximal to, and, therefore, most likely to be influenced by, public health researchers (Glasgow & Emmons). Within the context of scientific factors that impede

translation, a sound and alternative approach to improving research translation is to rethink and enhance traditional linear processes for moving from public health research to public health practice—that is, to support the development of more practice-based evidence (Green & Glasgow, 2006). In essence, the call for more practice-based evidence recognizes the importance of modifying traditional research practices and processes so that studies pay greater attention to real-world practice issues early on in the program development research process (Glasgow & Emmons, 2007; Green & Glasgow, 2006).

6.3 A REVIEW AND CRITICAL ANALYSIS OF KEY TRANSLATION CONCEPTS AND MODELS

In general terms, translation can be defined as a process of changing from one place, state, form or appearance to another; for example, the translation of ideas into action (Merriam-Webster, 2007). *Translation* in the health professions refers to the extended process by which research knowledge that is either directly or indirectly pertinent to health behavior eventually serves the public (Sussman, Valente, Rohrbach, Skara, & Pentz, 2006).

6.3.1 Traditional translation models and concepts

Although translation models have evolved over the last two decades to reflect some bidirectional flow, or feedback loops, between phases; all generally subscribe to a phased depiction of the translation process that was first introduced in the public health literature by Greenwald & Cullen and Flay in the 1980s (Glasgow, Lichtenstein & Marcus, 2003). Many of the models used

to describe translation in current health promotion and disease prevention research draw on the two influential works: 1) Greenwald and Cullen's (1985) five phases of cancer control research, and 2) Flay's (1986) eight-phase model for the development of health promotion programs (Glasgow, Lichtenstein, & Marcus, 2003). Sussman and colleagues (2006, p.11) describe the five-phase translation model (i.e., hypothesis development, or basic research; methods development; controlled intervention trials, or efficacy trials; defined population studies, or effectiveness trials; and demonstration and implementation, or dissemination research) as "inclusive"; the authors maintain that the model reflects major efforts in many research arenas and go on to describe other research translation models against the backdrop of the influential five-phase model (2006, p. 11). Specifically, Sussman and colleagues present additional research translation models and related theories as variations of the widely accepted and used five-phase model

Greenwald & Cullen's Translation Model for Cancer Control

The original five phases of Greenwald and Cullen's translation model are: 1) hypothesis development, which is referred to as the "basic research" phase in current references to the model; 2) methods development; 3) controlled intervention trials, more commonly referred to as efficacy trials; 4) defined population studies, more commonly referred to as effectiveness trials; and 5) demonstration and implementation, or dissemination research (Glasgow, Lichtenstein & Marcus, 2003; Greenwald & Cullen, 1985). The following descriptions of the phases provide useful insight into Greenwald and Cullen's conceptualization of the research translation process:

- In general, *basic research* seeks to investigate new knowledge about phenomena in an effort to establish general principles to explain that phenomena (Potter & Quill, 2006).

- *Methods development* refers to the specification of program development, measurement and analysis designs, or the specification of technology and equipment, required to test the intervention "objectively and accurately" in the larger, comparative studies that take place in subsequent translation phases (Greenwald & Cullen, 1985, p. 545; Sussman, Valente, Rohrbach, Skara, & Pentz, 2006). Methods development studies include pilot tests to investigate feasibility, acceptability, potential participation, validity of data collection instruments, alternative delivery approaches, cost-effectiveness, and possible human subject risk of the proposed intervention within a specific population subgroup (Greenwald & Cullen, 1985).
- *Efficacy trials* test whether an intervention does more good than harm among the target population in an ideal setting, such as a randomized clinical control trial or a community-level trial (United States Department of Health and Human Services, Centers for Disease Control and Prevention [CDC], 2007). In efficacy trials, there is an emphasis on internal validity; the trials are generally associated with highly controlled conditions, such as random selection of participants or units into a trial and random assignment of participants or units to the intervention (Glasgow, Lichtenstein & Marcus, 2003; Sussman et al., 2006).
- *Effectiveness trials* test whether an intervention does more good than harm for the target population in a real world setting (CDC, 2007).
- In the final phase of the standard translation model, *dissemination trials*, there is an emphasis on monitoring and evaluating the conditions that hinder or facilitate widespread use of the intervention (CDC, 2007; Sussman et al., 2006). Greenwald (1985) described Phase 5 trials as large scale demonstration projects in which

intervention fidelity is closely monitored. The Centers for Disease Control and Prevention (2007) have adopted two definitions of *intervention fidelity*: 1) "the adherence of actual treatment delivery to the protocol originally developed"(Mowbray, Holter, Teague, & Bybee, 2003), and a broader definition that considers intervention fidelity as 2) the degree to which program developers implement programs, rather than just the treatment delivery component of the program, as intended by the developers (Sussman et al., 2006).

Flay's Model for the Development of Health Promotion Programs

Greenwald & Cullen's five phase translation model was expanded by Flay in 1986. Flay's model for the development of health promotion programs consists of eight phases: 1) basic research, 2) hypothesis development, 3) pilot applied research, 4) prototype evaluation studies, 5) efficacy trials, 6) treatment effectiveness trials 7) implementation effectiveness trials, and 8) demonstration evaluations. Sussman and colleagues (2006) explain the parallels and variations of the two early translation models:

- In Flay's model, the first two phases, basic research and hypothesis development, expand on Greenwald & Cullen's single hypothesis development phase, although the graphic depiction of the Greenwald & Cullen model indicates that the hypothesis development phase is directly preceded and informed by basic research and epidemiology (see Figure I).
- Flay expands Greenwald and Cullen's second phase, methods development, to include pilot applied research (phase 3) and prototype evaluation studies (phase 4). *Pilot applied research* consists of early tests of new interventions that focus on

immediate outcomes, whereas *prototype evaluation studies* are small studies of a more developed intervention that focuses on longer term outcomes.

- Finally, Flay divides Greenwald and Cullen's fourth phase, effectiveness trials, into two separate effectiveness phases—phase 6, treatment effectiveness trials and phase 7, implementation effectiveness trials. *Treatment effectiveness trials* involve the optimized and controlled delivery of an evidence-based intervention in a real-world setting, compared to *implementation effectiveness trials*, which involve the real-world, or natural, delivery of an evidence-based intervention in a real-world setting.

In the final phases of both models (i.e., dissemination trials in the Greenwald and Cullen model and demonstration evaluations in the Flay model), trials are conducted to optimize widespread public use of the intervention.

Limitations of Early Influential Models

While the Greenwald & Cullen and Flay models imply a linear progression from research to practice through specified stages (Glasgow, Lichtenstein & Marcus, 2003), Sussman and colleagues (2006) logically assert that each of the phases of research can inform phases that come before or after it. However, Glasgow, Lichtenstein and Marcus (2003) note that many researchers and reviewers apply the translation models in a limiting and linear "trickle down" fashion when designing, funding and evaluating research. Murray's description of the translation process fifteen years after it was conceptualized by Flay in 1986 reflects the pervasive linear and restrictive thinking about translation in the public health field:

> Efficacy trials are designed to test whether the intervention causes the observed effect under carefully controlled conditions in which the investigator has control over the assignment of study conditions, the context of the

> intervention, the delivery of the intervention, and the conduct of the evaluation. Treatment and implementation effectiveness trials are used to determine whether the treatment will remain effective when implemented under more realistic conditions. Treatment effectiveness trials relax control over the context of the intervention, whereas implementation effectiveness trials relax control over both context and delivery of the intervention. Finally, demonstration studies include only minimal evaluation activities and are reserved for intervention programs that have already been proven efficacious and effective (2001, p. 307).

Glasgow, Lichtenstein and Marcus (2003) go on to declare that the pervasive linear approach to translation, particularly as it applies to the transition from efficacy to effectiveness trials, is one of the reasons for the "slow and incomplete translation of research findings into practice" (p.1261-2). While the translation models that followed Greenwald & Cullen and Flay's work do reflect some appreciation for a two-way flow of knowledge between translation phases, they still primarily depict the translation process as a distinct set of phases with prescribed and, in some cases, limited two-way flow of knowledge between phases; which supports Glasgow and colleagues' (2004) notion that study design characteristics, especially the linear progression through the research translation process, are likely partly responsible for the gap between research and practice.

Recent Translation Models from the Cancer Control Field

As evaluation experience with innovative cancer interventions fueled this critical analysis of public health translation issues and strategies, it is worth noting some of the additional translation models that have emerged in the field of cancer control research since the Greenwald

& Cullen model was published in 1985, including the National Cancer Institute's (NCI) New Strategy for Cancer Control Research, which is outlined in a 1999 article by Hiatt and Rimer, and The Research Translation Continuum presented in the 2004-2005 *President's Cancer Panel Annual Report*. Readers are referred to these sources for in depth descriptions of these models as space limitations do not allow for a detailed review of these models' components. The NCI and President's Cancer Panel models reflect an evolution from more linear-oriented thinking about the translation process to a conceptualization of translation that incorporates two-way flow, or feedback loops, between research phases.

NCI's new strategy for cancer research adopts a more interdisciplinary conceptualization of the research process, thus expanding on the linear interpretation of the translation process implied in the earlier Greenwald and Cullen and Flay models. However, the component of the earlier phased models that Glasgow, Lichtenstein and Marcus (2003) find most problematic for the successful translation of research findings into public health practice (i.e., the "efficacy-to-effectiveness transition") is not entirely absent in the evolved NCI model. In fact, in their article introducing the new NCI model, Hiatt and Rimer (1999) explicitly support the logical progression of scientific inquiry laid out by Greenwald and Cullen (1985).

It is important to reiterate Glasgow and colleagues' declaration that the Greenwald and Cullen and Flay models operate on the *faulty* assumption that "the best candidates for effectiveness studies—and later dissemination—are interventions that prove successful in certain types of efficacy research", when it is indeed "highly unlikely", according to Glasgow and colleagues, that interventions that prove successful in rigorously controlled efficacy trials will do well in effectiveness trials or in the real-world (2003, p. 1261-2). The faulty efficacy-to-effectiveness assumption is explicitly incorporated into the recent translation continuum

developed by the President's Cancer Panel (PCP) . However, it is important to note that the PCP model, similar to NCI's New Strategy for Cancer Research, represents some re-visioning of the rigorous, linear approach used to describe the translation process in early models as the PCP model promotes a two-way flow of knowledge and influence between phases of the translation process.

Other Variations in the Traditional Translation Model

As mentioned earlier in this section, Sussman and colleagues (2006) sensibly maintain that variations of the five-phase translation model include theories and models that can be envisaged as: 1) concentrating on a subset of the standard five phases, as with diffusion models (see Oldenburg & Parcel, 2002, for a detailed review of Roger's Diffusion of Innovation Model) or as 2) a collapse and merging of the five phases, as reflected in the National Institute's of Health two-step model for the translation of biomedical research (see Westfall, Mold, & Fagnan, 2007 for a thorough review of the NIH Two-Step Model).

6.3.2 Translation challenges

Despite the existence of relatively well-aligned models that describe the process of moving from research to practice, public health research translation is limited and slow. Public health researchers, non-profit organizations and leading government agencies raise the following pressing questions:

- Why is there not more translation of health promotion research to practice? (Glasgow, Lichtenstein & Marcus, 2003)

- How do we shape public health research into a usable form, translating numbers and theories into adaptable, effective models of social change? (Schechter & Brunner, (2005)
- What are effective methods for the broader dissemination, adoption, and implementation of the extensive research that has been conducted on the efficacy and effectiveness of health promotion and disease prevention intervention strategies? (CDC, 2007)

Factors that Impede Translation

While a detailed review of all of the categories of factors that hinder research translation is outside of the focus of this critical analysis, it is worth noting the range of factors that hinder research translation. The literature suggests several explanations for the slow and limited translation of research findings into public health practice: "multiple interacting reasons can be given for the general failure of health research findings to translate into practice, including historical, political, social, economic, scientific, cultural, and organization factors that slow or impede transfer of research into practice" (Glasgow & Emmons, 2007, p. 414). Table 14 provides descriptions by category of factors that impede translation as identified by Sussman and colleagues (2006) and Glasgow & Emmons (2007).

Table 14. Categories and Descriptions of Factors that Impede Translation

Categories of Impeding Factors	Descriptions
Historical	• Prevailing practices in intended target settings work against innovation
Political	• Competing demands or competing program alternatives exist • Opposing incentives or regulations hinder translation
Economic	• Financial instability/limited resources exist in organizations that implement public health programs or in programs' intended target settings
Scientific (i.e., research, program development, evaluation & reporting)	• Basic research is conducted without collaboration protocols or attention to application pathways • Research studies are non-relevant or not representative of intervention settings, participants, and/or practitioners • Intervention cost, reach, setting adoption, maintenance, and sustainability are not adequately evaluated • Research findings are not interpreted or reported in ways amenable to dissemination • Interventions are not flexible
Social/Cultural	• Intervention philosophies are not aligned with those of the intervention implementers or target population
Organizational	• Organizational support is limited • Staffing to implement intervention is inadequate

Noting the multiple, interacting factors related to slow and limited research translation, this critical analysis focuses on "scientific" factors that impede translation. Particular attention is paid to understanding how translation can be improved through expanding, enhancing, and/or modifying public health research and program development practices, as these scientific factors are arguably most proximal to public health researchers and practitioners and most likely able to be addressed by public health researchers and practitioners (Glasgow & Emmons, 2006). Notably, because many of the factors that hinder translation interact with, or can possibly

influence, each other; efforts to improve translation through addressing scientific barriers to translation can potentially, albeit indirectly, address translation issues that fall under other categories of impeding factors (e.g., economic barriers which includes the reality limited financial resources in real-world settings).

6.4 APPROACHES FOR ADDRESSING SCIENTIFIC FACTORS THAT IMPEDE TRANSLATION

There has been a great deal of scholarly study on the process of translation. However, while models describing research translation have been developed and amended over the past 20 years, and while several key translation concepts (e.g., intervention fidelity, efficacy and effectiveness) have been defined and studied, public health research translation remains slow and limited. There is general agreement in the public health field that research translation needs to be improved and accelerated. However, within the context of scientific factors that impede translation (i.e., those related to public health research and program development practices), there are at least two prominent approaches proposed in the literature for ameliorating translation-impeding scientific factors. For the purposes of this critical analysis, these two approaches are labeled *traditional* and *alternative* and are conceptualized as follows:

1. The traditional approach accepts the general tenets and translation process depictions of the standard five-phase model (or translation model versions that are, by premise, practically indistinguishable from the standard five-phase model) for moving from research to practice. Consequently, this approach seeks a solution to improving

translation that does not challenge or attempt to significantly change the standard five-phase conceptualization of the translation process.

2. The alternative approach encourages critical examination and rethinking of the standard practices for conducting research and for moving from research to practice. Under this approach, strategies for improving translation include modifying current dominant research practices in the field that are aligned with the linear-oriented, restrictive conceptualization of the translation process depicted in the standard five-phase model.

6.4.1 The traditional approach

It is helpful to explain the concept "traditional approach" to improving translation by briefly reviewing a recently released Request for Applications (RFA) for translation research from the Centers for Disease Control and Prevention (CDC). In an effort to achieve "new scientific knowledge that can accelerate the translation of research findings in to public health practice" the CDC announced the availability of $10 million for "translation research using an evidence-based intervention or policy" (CDC, 2007, p. 3). The recently released Request for Applications (RFA), "Improving Public Health Practice through Translation Research (R18)", seeks to improve translation through conducting research that determines how the spread and use of evidence-based interventions can be increased. In other words, the CDC RFA focuses on improving translation by studying what occurs *after* an intervention has "undergone sufficient scientific evaluation to be proven efficacious or effective (e.g., intervention is considered valid or 'proven' because it is strongly linked to desirable outcome)" (CDC, 2007, p.10). Placing this

strategy within the context of the five-phase translation model, the CDC RFA focuses on improving translation by studying Phase V- dissemination research.

While its phase five context is not explicitly acknowledged in the CDC RFA, the announcement's description of translation research certainly places its traditional approach to improving translation within the final phase of Greenwald and Cullen-aligned translation models: "*Translation research* characterizes the sequence of events (i.e., process) in which a proven scientific discovery (i.e., evidence-based intervention) is successfully institutionalized (i.e., seamlessly integrated into established practice and policy)" (CDC, 2007, p.9). The RFA goes on to specify that "translation research is comprised of dissemination research, implementation research and diffusion research" (CDC, 2007, p. 9). The dissemination, implementation and diffusion fields of study are exactly the focus of what is commonly considered the final phase of the translation process as originally described by Greenwald and Cullen (1985) and as presented in more current literature on translation (Glasgow, Lichtenstein, & Marcus, 2003; Green & Glasgow, 2006; Reuben, 2005; Sussman, Valente, Rohrbach, Skara, & Pentz, 2006). Worth noting are the definitions of these phase five focus areas as presented in the CDC RFA:

- *Dissemination research* is the systematic study of how the targeted distribution of information and intervention materials to a specific public health audience can be successfully executed so that increased spread of knowledge about the evidence-based public health interventions achieves greater use and impact of the intervention.
- *Implementation research* is the systematic study of how a specific set of activities and designed strategies are used to successfully integrate an evidence-based public health

intervention within specific settings (e.g., primary care clinic, community center, school).

- *Diffusion research* is the systematic study of the factors necessary for successful adoption by stakeholders and the targeted population of an evidence-based intervention which results in widespread use (e.g., state or national level) and specifically includes the uptake of new practices or the penetration of broad scale recommendations through dissemination and implementation efforts, marketing, laws and regulations, systems-research and policies (underline added) (p.9).

The underlined passages make it clear that, what are characterized in this paper as traditional approaches to improving translation, focus on evidence-based interventions and, thus, are concerned with parts of the translation process that occur after basic research, methods development, efficacy and intervention trials have been conducted. In fact, the CDC RFA explicitly states that "translation research does not encompass pure biomedical or formative basic science research…. It also does not include the conduct of an initial or replication intervention efficacy or effectiveness trial" (CDC, 2007, p. 9). The RFA's description of translation research and its components is based on the sensible premise that "the greatest health impact on individuals, the community, racial/ethnic and other population experiencing health disparities, and the broader population is achieved when an evidence-based intervention is optimally translated into public health practice and policy" (CDC, 2007, p.7).

Interestingly, this statement regarding the high public health value of evidence-based interventions reflects what Glasgow and colleagues (2003) deem faulty logic in the standard five phase translation model—that is the belief that interventions that do well in efficacy, then effectiveness, studies are positioned to have successful impacts on the health of the public in

real-world settings. In drawing the connection between the CDC-promoted approach to improving translation and criticism of restricted, linear approaches to moving from research to practice (Glasgow, Lichtenstein & Marcus, 2003; Green & Glasgow, 2006), one could argue that the traditional approach to improving translation promotes the view that no change in the development of the "evidence base" (i.e., phases 1- 4 in the standard five phase translation model) need occur to improve translation. At the very least, one could argue that the traditional approach to improving translation downplays the potential to improve translation by modifying or enhancing early translation process stages.

Traditional Approach Trends in Current Translation Research

Traditional thinking around public health research translation is echoed throughout public health literature on dissemination, implementation and diffusion. The literature reflects particular interest in identifying tools and strategies that enhance fidelity in evidence-based intervention dissemination and implementation while allowing for necessary community adaptation (Caburnay, Kreuter, & Donlin, 2001; Elliott & Mihalic, 2004; Harshbarger, Simmons, Coelho, Sloop, & Collins, 2006; Kelly et al., 2000; Owen, Glanz, Sallis, & Kelder, 2006; Paulson, Post, Herinckx, & Risser, 2002). Beyond the fidelity-adaptation theme, there is a growing focus in the literature on the critical importance of implementation research for improving translation (Dusenbury, Brannigan, Hansen, Walsh, & Falco, 2005); and there is, expectedly, also general consensus in the literature that "systematic implementation practices are essential to any national attempt to use the products of science—such as evidence-based programs—to improve the lives of its citizens (Fixsen, Naoom, Blase, Friedman & Wallace, 2005, p.vi).

Key Translation Research Questions

Ultimately, the CDC RFA, which both incorporates and reflects current dissemination, implementation and diffusion literature, calls for proposals to address "the knowledge gap between evidence-based public health interventions and effective delivery" (2007, p. 8). The RFA lists the following key research questions (p. 32-33):

- *Reach*: What were the key factors that determined who in the target audience were successfully or unsuccessfully reached?
- *Adoption*: What factors influenced organizations' or individuals' acceptance of the intervention (e.g., organizational structure, regulation, and cultural norms)?
- *Adoption*: Was cost a factor in the implementers or target population's willingness to adopt the intervention? What opportunity (non-fiscal) costs were incurred?
- *Fidelity*: How was the fidelity of the intervention or system compromised or how did it deviate from the original?
- *Adaptation*: What key components of the intervention or the system were modified to increase adoptability or use? Can the intervention vary, as needed, depending on the audience?
- *Adaptation and Fidelity*: Did the adaptation of the intervention to make it more culturally relevant result in loss of fidelity? Did this result in decreased effectiveness?
- *Feasibility*: What are the realistic cost, time, facility space and human resources (e.g., number of staff and type of training) needed?
- *Outcomes & Impacts*: As a secondary measure, what is the effect of the intervention on health outcomes?

These key translation research questions are worth noting because they are arguably equally valid for each of the two approaches to improving translation (i.e., traditional and alternative) presented in this paper.

Traditional Approach Summary

Conceptually, traditional approaches to improving translation are grounded in phase five-dissemination research (i.e., interventions have undergone sufficient scientific evaluation to be proven efficacious or effective) of the standard five-phase translation model previously reviewed. On one hand, focusing the study of translation on phase five issues is reasonable given the fact that

> despite extensive research on the efficacy and effectiveness of health promotion and disease prevention intervention strategies, little is known regarding effective methods for the broader dissemination, adoption, and implementation of these interventions (CDC, 2007, p.8).

However, a questionable premise drives the traditional approach to improving translation, namely that those interventions that are successful in efficacy trials, then in effectiveness trials, ought to produce significant public health improvements in the real world. And yet, a focus on phase-five issues and a commitment to improving and accelerating the translation of the large number of interventions that have already proven successful in efficacy and effectiveness trials is critical from a resource management vantage point. Slow and limited translation poses a very practical "resource wasting" concern, and distress over the wasting of significant resources that were committed to develop our expansive public health evidence-base is well warranted.

Indeed, the evidence base for health promotion and disease prevention interventions is overwhelmingly comprehensive in some health topic areas. The Guide to Community

Preventive Services, Cancer Control Planet, The National Cancer Institute's Research- Tested Intervention Programs (RTIPs), the National Registry of Evidence-based Programs and Practices (NREPP), and The Diffusion of Effective Behavioral Interventions Project are all national level initiatives that provide and endorse evidence-based recommendations for programs and policies to promote population health. These national repositories of evidence-based interventions cover a wide range of health issues, from health behaviors (e.g., tobacco use and physical activity) to chronic diseases (e.g., cancer) and infectious diseases (e.g., HIV) (Taskforce of Community Preventive Services; United States Department of Health and Human Services [US DHHS], American Cancer Society, and Commission on Cancer; US SHHS, National Cancer Institute; US DHHS, Substance Abuse and Mental Health Services Administration, 2007; Academy for Educational Development, Center on AIDS and Community Health, 2006). Unfortunately, just as the existence of models that describe the translation process does not ensure effective translation from research to practice, a large body of evidence-based interventions does not ensure timely and effective translation of these interventions into practice.

Unfortunately, many of public health's evidence-based resources, such as those described above, go unused or take too long to be adopted and implemented. The CDC RFA notes that, "although most researchers develop evidence-based intervention for public health practice, the rate of adoption and implementation is low due to uncharacterized impediments" (2007, p. 8). And so, the foremost focus in traditional efforts to improve translation is on moving the well-developed evidence base into practice as, according this statement from the CDC RFA, the researchers who developed the extensive public health evidence-base intended. But this intense focus on moving well-developed evidence based into practice begs the question: *To what extent is the development of the public health evidence-base (i.e., phases 1-4 in the standard translation*

model) developed for real-world practice? This is the question and concern that drives what this paper presents in the next section as a alternative approach to improving translation, which proposes that "the 'system' of moving from research to usual service programs, to which we have subscribed, may be broken and may need to be substantially modified" (Glasgow, Lichtenstein, & Marcus, 2003, p. 1263).

6.4.2 The alternative approach

As characterized in this paper, a alternative approach to improving translation involves a critical examination and rethinking of the standard practices for conducting and translating research. The concept of a alternative approach to improving translation, viewed conversely to the traditional approach described in detail in the previous section, was mainly derived from several articles on translation and related issues by Russell E. Glasgow, Lawrence W. Green and colleagues (Glasgow & Emmons, 2007; Green & Glasgow, 2006; Bull, Gillette, Glasgow, & Estabrooks, 2003; Glasgow, 2003; Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004; Green, 2001). The development of this concept was also influenced by evaluation work with a cancer patient navigator program, an innovative, context-driven intervention.

As defined in this paper, the alternative approach to improving translation is grounded in the logic that "much research fails to translate into practice because the programs and methods used fail to address contextual factors," and promotes the view that "if we want more evidence-based practice, we need more practice-based evidence" (Glasgow & Emmons, 2007, p. 417; Green & Glasgow, 2006, p. 126 respectively). In other words, in order to accelerate and improve translation, changes are needed in the way public health research is conducted—greater attention needs to be paid to the context in which programs are delivered (Bull, Gillette, Glasgow, &

Estabrooks, 2003; Glasgow, 2003; Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004; Green, 2001). Glasgow and colleagues (2003) assert that both external validity factors and participatory (with potential beneficiaries, stakeholders and implementers of interventions) research methods "are best addressed [and evaluated in the case of external validity factors] during the planning phases of research…[and]…should not be left for later phases of research but built into efficacy studies" (p. 1264) Moreover, Glasgow and colleagues (2003) promote a science of "larger social units that takes into account and analyzes the social context(s) in which experiments are conducted" (p. 1264). The researchers convincingly regard the current highly controlled nature and linear application of efficacy and effectiveness trials, which is promoted by the standard five-phase translation model and widely subscribed to in health sciences research, as inadequate for developing interventions that are primed for successful implementation in real-world settings.

Clearly, the focus of alternative efforts to improve translation is on the very "'system' of moving from research" to practice (Glasgow et al., 2003, p. 1263)—particularly phases two through five of the standard translation model (i.e., methods development, efficacy trials, and effectiveness trials). Green and Glasgow (2006) explicitly identify the need to improve translation through enhancement of standard research practices and go on to suggest that such enhancements are worth sacrificing some of the control that is the hallmark of efficacy studies:

> If the health professions and their sponsors want more widespread and consistent evidence-based practice, they will need to find ways to generate more practice-based evidence that explicitly addresses external validity and local realities. Practice-based research would produce evidence that more accurately and representatively reflects the program-context interactions and

> circumstances in which the results are expected to be applied. It would do so, of course, with some trade-off of the experimental control exercised in academically based research (p.128).

In keeping with the alternative premise that research translation could be accelerated and improved by enhancing standard research practices—namely by studying external validity and translation during the early stages of research—key translation issues that must be addressed and reported on in order to improve translation in public health include: program reach and representativeness, program or policy implementation and adaptation, outcomes for decision making, and maintenance and institutionalization (Glasgow & Emmons, 2007, p. 420; Glasgow, Lichtenstein, & Marcus, 2003).

In addition to enhancing current research practices to include a focus on these key translation issues, Glasgow and Emmons (2007) advocate for a community-based participatory approach to public health research as a "means of enhancing the relevance and effectiveness of public health interventions" (p. 417). *Community-based participatory research* (CBPR) is a collaborative research process that views the community as an active and equal partner in all phases of the research process (Goodman, 2001; Israel, Schulz, Parker, & Becker, 1998; Scutchfield & Keck, 2003). This community-centered approach is particularly well-aligned with alternative thinking around improving research translation by enhancing research methods to reflect more of the content and complexity of the real world. Glasgow and Emmons (2007) also suggest that CBPR facilitates translation because "effective CBPR partnerships build expertise and capacity in the community for research and prevention, and thus have significant potential to make a lasting impact, even beyond the particular program at hand" (p.417). So, insofar as slow and limited translation is due to a community's limited resources and capacity to implement

evidence based interventions, community participatory approaches to public health research and intervention development can help address both scientific and non-scientific (e.g., social/cultural and organizational) barriers to translation (Goodman et al., 1998; Yoo et al., 2004).

Research Development & Practices

Glasgow and colleagues go beyond describing key translation issues and recommending community-based participatory research principles for the improvement of research translation to present the concept of *practical trials*—a model for developing and evaluating programs with greater attention to context and external validity (Glasgow, 2003; Glasgow & Emmons, 2007; Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004). Glasgow and Emmons (2007) explain that the purpose of *practical trials* is "to provide information that will make health information more relevant and to aid decision makers at multiple levels to evaluate the applicability and generalizability of research", and they present the following scope of study for practical trials:

1. Practical trials answer questions of key stakeholders (e.g., decision makers, policy makers & clinicians).
2. Practical trials assess multiple and relevant outcomes, including cost, generalization, and quality of life.
3. In practical trials, diverse, heterogeneous samples are recruited and robustness across key subgroups is evaluated.
4. Practical trials compare clinically meaningful treatment alternatives using research designs matched to state of knowledge.
5. Practical trials include multiple, representative settings and interventionists.

6. Issues of particular importance in practical behavioral and public health trials include: the level of training & expertise required, and amount of training provided, for implementation; patient or client preferences; and algorithms for intervention tailoring, or intervention manuals (p. 421).

It is important to note that Glasgow and colleagues' writing on practical trials focuses primarily on practical behavioral trials to advance evidence-based behavioral medicine (Glasgow, Davidson, Dobkin, Ockene, & Spring, 2006). However, this paper proposes that the general concept of practical trials, as outlined in the scope of study presented above, could also be applied to, and beneficial for, advancing evidence-based public health—or, rather, practice-based evidence in public health. Because practical trials better reflect the content and complexity of the real world compared to traditional, more controlled efficacy studies (Glasgow & Emmons, 2007; Green & Glasgow, 2006), moving toward more practical trials in health promotion and disease prevention research seems a promising strategy for improving and accelerating public health research translation.

Evaluation and Reporting

In addition to calling for enhancements to standard research practices, Glasgow and Emmons (2007) alternative approach to accelerating and improving translation calls for change in public health evaluation and reporting practices. Accordingly, Glasgow and Emmons (2007) maintain that "a defining feature of the practical trial [an exemplar for developing programs with greater attention to key translation issues] is assessment of multiple and relevant outcomes", and the researchers recommend conducting *broader evaluations* that include multiple outcomes, address generalizability, and report on contextual factors to help enhance integration of research and practice (p. 421). In efforts to conduct broader evaluations, Glasgow and Emmons argue

that program developers should collect more process data. Indeed, process evaluation data are valuable for addressing several key translation questions, including those related to intervention adoption, adaptation, fidelity, and impact. Specifically, data from process evaluations:

- can provide indicators for the impact of an intervention at different levels of program implementation (Glasgow & Emmons, 2007).
- are useful for developing recommendations related to program modifications and adaptation at the community level (Forsetlund, Talseth, Bradley, Nordheim, & Bjorndal, 2003; Glasgow & Emmons, 2007).
- Allow for assessment of community participation, as well as examination of the intermediary role community participation plays in health and related social change outcomes (Butterfoss, 2006).
- aid in understanding relationships between specific program elements and program outcomes (Saunders, Evans, & Joshi, 2005).

RE-AIM

Within the discussion of improving translation through changes to standard public health evaluation and reporting practices, it is important to acknowledge RE-AIM (reach, efficacy/effectiveness, adoption, implementation and maintenance), an evaluation framework recommended throughout the translation literature presented in this paper (i.e., literature relevant to both traditional and alternative approaches to improving translation). Importantly, RE-AIM provides a framework for conducting broader evaluations with significant attention to process data called. RE-AIM (www.re-aim.org) was developed to expand assessment of interventions beyond efficacy to multiple criteria that can help better identify the translatability and public health impact of health promotion interventions (R.E. Glasgow, 2002; R. E. Glasgow, Vogt, &

Boles, 1999). Ultimately, RE-AIM can be used to guide evaluation, as well as planning, conduct, and reporting of studies for researchers and practitioners whose goal is to translate research into practice (Dzewaltowski, Estabrooks, & Glasgow, 2004; Dzewaltowski, Glasgow, Klesges, Estabrooks, & Brock, 2004; Klesges, Estabrooks, Dzewaltowski, Bull, & Glasgow, 2005; Sussman, Valente, Rohrbach, Skara, & Pentz, 2006).

Noticeably, the dimensions of RE-AIM are well aligned with the key translation questions presented in the CDC RFA (see Traditional Approach section of this paper). This alignment is not surprising as the CDC RFA actually encourages funding applicants to use the RE-AIM framework as a guide for evaluating "key variables for translation research…[and] relevant and comprehensive criteria to accurately measure and document the desired outcome" (2007, p. 32). The similarity between RE-AIM dimensions (presented within the context of Glasgow, Green and colleagues alternative approach to improving translation) and key translation questions presented in literature that promotes what this paper has established as a traditional approach to improving translation is also expected because: 1) both approaches (traditional and alternative) draw on the key translation models and concepts presented earlier in this paper (e.g., standard five-phase translation model and diffusion of innovations theory) (Glasgow, 2002; CDC), and 2) as maintained in the Comparison of Approaches section of this paper, key translation questions transcend approaches (traditional versus alternative) for addressing scientific barriers to translation.

Practice-Based Research

The field of practice-based research is generally aligned with the progressive assertions of Glasgow, Green and colleagues (i.e., in order to improve translation, changes in standard research, evaluation and reporting practices must occur) (Bull, Gillette, Glasgow, & Estabrooks,

2003; Glasgow, 2003; Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004; Green, 2001), but arguably broader in concept and application than the practical trials and RE-AIM framework developed and promoted in papers by Glasgow, Green and colleagues. Recall Green and Glasgow's (2006) declaration that "practice-based research would produce evidence that more accurately and representatively reflects the 'program-context interactions' and circumstances in which the results of the research are expected to be applied" (p. 128).

A recent landmark report on practice-based research from the Association of Schools of Public Health (Potter & Quill, 2006) is briefly reviewed to: 1) present the purpose and scope of practice-based research as defined by a leading public health organization, and 2) to highlight progressive thinking in the public health field around improving translation through research systems change beyond the work of Glasgow, Green and colleagues (Glasgow & Emmons, 2007; Green & Glasgow, 2006; Bull, Gillette, Glasgow, & Estabrooks, 2003; Glasgow, 2003; Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004; Green, 2001), although their work certainly seems to represent the most extensive study of the topic in the current literature.

The Association of Schools of Public Health (ASPH), Council of Public Health Practice Coordinators defines practice-based research as "systematic inquiry into the systems, methods, policies, and programmatic application of public health practice [which]… includes science-based inquiry that occurs in practice settings such as field epidemiology, systematic reflection on the practice experience, and laboratory analysis—to the extent that such inquiry produces generalizable knowledge to improve the outcomes of practice or to inform policy making" (Potter & Quill, 2006, p. 3). The stated goal of practice-based research clearly explains how the field relates to research translation: "The goal of practice-based research is to move the knowledge derived from research to creation, through dissemination, and to application to assure

the translation and uptake of relevant science into evidence-based practices" (ibid). According to the ASPH report, in practice-based research, public health research is linked directly to public health practice through a cycle in which: 1) feedback from application, or practice, informs the development of theory, and 2) policies and practices are informed by the re-uptake of knowledge from research.

Practice-based research is described as a flexible process that allows for

> constant adjustments in response to the evolving interests and needs from the community. Thus, approaches, methods, and tools are adapted to the research process by: 1) integrating existing methods with new applications; 2) adapting methods and tools for new applications; 3) translating methods to adapt to emerging and time-sensitive research goals; and 4) developing new and innovative approaches, models, methods, and tools to address current and future research questions (Potter & Quill, 2006, p. 7).

According to the ASPH report, community involvement is key for assuring that research is contextually and socially appropriate and, consequently, translatable. This collaborative and participatory nature of the practice-based research process calls to mind the critical role that community-based participatory principles play in Glasgow, Green and colleagues' alternative approach to improving translation, as well as the researchers' insistence that research be conducted to enhance its relevance to program implementers, key stakeholders and policymakers. Indeed, the ASPH report explains that "practice-based research in public health focuses on important practical issues, engages the experience of practitioners in the advancement of theory, and informs both practice and public policy with scientifically derived evidence to improve community health" (Potter & Quill, 2006, p.17).

While practice-based research is a proponent of scientific rigor, it also promotes innovation and supports, as do Green, Glasgow and colleagues, moving beyond traditional research approaches to develop practical answers to complex public health problems:

> The development, advancement, and dissemination of practice-based research all rely on the rigorous scientific evidence combined with research integrity. Practice-based research goes beyond traditional research approaches and seeks greater innovation in analyzing the socioeconomic and cultural factors that influence population health. Implicit in these innovative approaches is the recognition of new challenges to research integrity (Potter & Quill, 2006, p.18).

In expanding on the recognition of challenges to research integrity, the ASPH report notes that "significant tension exists between the imperatives of the university-based research enterprise and the obligations of agencies and organizations responsible for addressing the health needs of populations" (Potter & Quill, 2006, p. 14). The ASPH report goes on to point out that, in the public health field, there is insufficient funding support for, and a general limited recognition and understanding of, the conduct of practice-based research (Potter & Quill, 2006).

As suggested by Green & Glasgow (2006), practice-base research requires some trade-off with the experimental control traditionally exercised in academically-based research as: 1) the engagement of the community, key partners and stakeholders in practice-based research requires a level of relation-building, information-sharing, and time demands that is not as essential to other, more traditional research-driven, forms of research—thus, practice-based research processes must be flexible; and 2) the effort to solve complex public health programs within the context of real-world settings and academic-practice-community partnerships requires a

comprehensive, multi-method, multi-layered research strategy that goes beyond the types of evidence and methods typically used in tightly controlled efficacy trials (Green & Glasgow, 2006; Potter & Quill, 2006). However, this is not intended to suggest that practice-based research is not subject to standards of rigor and peer-evaluation—the ASPH report clearly states that practice-based research is scholarly and rigorous, in addition to practical—but rather suggests that there are many types of evidence that can inform and support the development and evaluation of public health research and interventions (Green & Glasgow, 2006; Potter & Quill, 2006). Further exploration of this issue of evidence as it relates to the two approaches for addressing scientific barriers that challenge translation follow.

Defining Evidence

As established in previous sections, the alternative approach to improving and accelerating translation calls for changes in standard public health research, program development, evaluation and reporting practices to better address real-world contextual factors. But a critical examination of standard research practices—particularly finding fault in the efficacy-to-effectiveness transition in the early phases of the standard translation model—challenges not only standard intervention development practices, but also calls into question the very notion of what constitutes evidence in the public health field. So Glasgow and Emmons (2007) note that, in addition to a failure to address contextual factors, much research is not translated into practice because it "employs a limited and researcher-centric perspective as to what constitutes evidence" (p. 417). Green (2001) poses a critical question: "Where did the field get the idea that evidence of an intervention's efficacy from carefully controlled trials could be generalized as *the* best practice for widely varied populations and settings?" (p. 167). Related

to Green's question, Peter Briss (2005) of the Centers for Disease Control and Prevention's Community Guide Branch warns that

> many evidence gaps remain and the gaps are not random. There are still cultural, geographical, economic, and methodological biases in determining what is studied and how. The availability of high-quality evidence often seems to favor clinical treatment over prevention, and interventions that are…simple over those that are more complex, those with shorter-term objectives over those that are longer-term…. Much more work is needed to fill these gaps and to shine the light where it is currently dark (p. 829).

While Glasgow and colleagues recognize the value of evidence from tightly controlled efficacy trials, they argue that the field's conceptualization of evidence needs to broaden significantly to include additional evidence types (R. E. Glasgow & Emmons, 2007; R. E. Glasgow, Lichtenstein, & Marcus, 2003; Green & Glasgow, 2006). Glasgow and Emmons (2007) suggest that, for many public health problems, intervention strategies should be recommended based on the best available evidence instead of waiting for the best possible evidence. According to the researchers, there are several types of evidence that can be drawn upon in public health program development and evaluation, including theoretical or mechanism data, feasibility/implementation evidence, contextual information (e.g., constraints, history, resource availability), intended primary outcome evidence, unintended or unanticipated outcome results, process results, outcome or clinical data, quality improvement data, cost and economic data, qualitative data, local data, internal validity evidence, and external validity evidence.

Unfortunately, as noted by Glasgow and Emmons (2007), to date, discussions around different types of methods and the utilization of mixed methods to integrate various types of

evidence have led to unproductive "my evidence is superior to your evidence" debates (p. 418). Furthermore, the authors maintain that there are no set answers to the question of what constitutes evidence, nor are there simple answers to the question of when do researchers have enough evidence to translation research into practice. However, Briss'(2005) warning suggests that, while there are no set answers regarding what constitutes evidence, the public health field clearly favors certain types of evidence. Where Glasgow, Green and colleagues (R. E. Glasgow & Emmons, 2007; R. E. Glasgow, Lichtenstein, & Marcus, 2003; Green & Glasgow, 2006) alternative approach to improving translation suggests the value of various types of evidence in developing and testing interventions, then moving them into practice; the traditional approach to improving translation explored earlier in this paper seems to subscribe to a more narrow view of what constitutes evidence. Conceptualization of evidence is one of the main ways that alternative and traditional approaches to improving translation, as they are characterized in the paper, differ. The following Comparison of Approaches section expands on the differences and similarities between the traditional and alternative approaches for addressing scientific barriers to translation

6.4.3 Comparison of approaches

This paper has used the terms traditional and alternative to describe two dominant approaches presented in the literature for improving and accelerating translation—particularly as this task is related to overcoming scientific barriers to translation. Similarities and differences between the two approaches have been noted throughout this paper and are summarized in Figure 3. Given significant similarities between the two approaches (i.e., agreement on key research questions and promotion of comprehensive, multi-method evaluation frameworks and broad stakeholder

involvement), it is the position of this paper that the traditional and alternative approaches are equally valid for addressing translation issues, and that lessons learned from traditional efforts to improve translation can both inform and benefit from alternative approaches to enhancing translation.

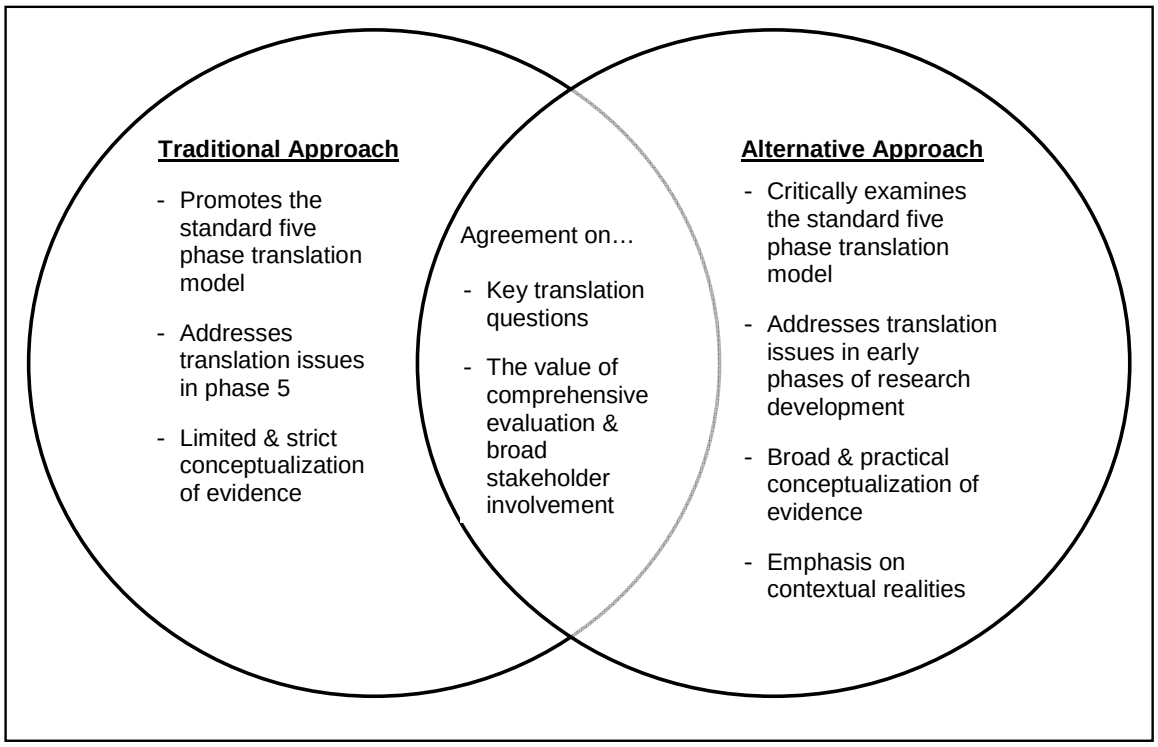


Figure 3. Comparison of Traditional and Alternative Approaches to Improving Translation

Arguably the most critical differences between the two approaches to improving translation is their view of standard research and program development practices, as they are depicted in the five phase translation model, and their conceptualization of evidence. Specifically, the traditional approach focuses on translation issues during phase five of the standard translation model (i.e., after the development of evidence-based programs) (Caburnay, Kreuter, & Donlin, 2001; Elliott & Mihalic, 2004; Harshbarger, Simmons, Coelho, Sloop, & Collins, 2006; Kelly et al., 2000; Owen, Glanz, Sallis, & Kelder, 2006; Paulson, Post, Herinckx,

& Risser, 2002). Thus, the traditional approach does not view standard research and intervention development practices as targets for change in efforts to improve and accelerate translation. Rather the traditional approach implicitly promotes the standard, linearly-applied and highly controlled system of moving from basic research to practice through efficacy then effectiveness trials. So, the question of focus in the traditional approach to improving translation is: *how do we move evidence-based interventions into practice?* (Schechter & Brunner, 2005). Evidence-based within this context means "that the proposed intervention has undergone sufficient scientific evaluation to be proven efficacious or effective", where scientific evaluation primarily refers to peer-reviewed publications of quantitative or qualitative research, evaluation reports, meta-analyses, or descriptive or survey research (CDC, 2006, p.31). There is particular interest in enhancing translation for the large public health evidence base recorded in national guides and clearinghouses, including The Guide to Community Services and the National Guideline Clearinghouse (CDC, 2006). While at first glance the CDC RFA description of sufficient scientific evaluation seems reasonably flexible, it is important to note the preferred requirement of peer-reviewed publication, which Briss (2005) maintains is still very much biased toward more traditional views of what is published as evidence (i.e., tightly controlled trials and simple interventions).

In contrast to traditional approaches, the alternative approach promotes focusing on translation issues in the early phases of research development (Glasgow & Emmons, 2007; Green & Glasgow, 2006). Thus, the alternative approach asserts that standard research and intervention development practices must be modified and enhanced in order to improve and accelerate translation. Moreover, the alternative approach explicitly criticizes the standard linearly applied and highly controlled system of moving from basic research to practice through

efficacy then effectiveness trials (Glasgow, Lichtenstein, & Marcus, 2003). Consequently, the key question of focus in the alternative approach to improving translation is: *how do we change our current system of research, program development and evaluation to develop more practice-based evidence?* While evidence within the context of the alternative approach includes results of highly controlled trials, it is expanded to also include types of evidence that are featured less prominently in the public health literature, including cost and economic data and local historical and contextual data (Glasgow & Emmons, 2007).

As a huge investment has been made in the development of the current public health evidence base; it is certainly worthwhile to explore tools and strategies for moving this evidence base into practice (Schechter & Brunner, 2005; Sussman, Valente, Rohrbach, Skara, & Pentz, 2006), which is established in this paper as a major focus of the traditional approach to improving translation. However, developing evidence with more attention to real-world issues and context is definitely a promising strategy for improving translation, one that this paper argues should be widely supported and adopted in the public health field. Perhaps the alternative approach to improving translation is particularly useful for public health issues, like reducing racial/ethnic disparities in cancer care, for which a limited number of effective health intervention and education strategies exists. In these cases, studies more aligned with the description of practice-based research presented in this paper are arguably the best way to proceed as the flexible, alternative approach will support the development of evidence or interventions that are primed for implementation in real-world settings (Potter & Quill, 2006). Admittedly, the notion of the alternative approach to improving research translation is largely conceptually based. However, the momentum of the cancer patient navigation movement in this

country suggests that this conceptually-derived approach holds some value for enhancing public health translation.

6.5 THE PROMISE OF THE ALTERNATIVE APPROACH—INSIGHTS FROM THE CANCER PATIENT NAVIGATION MOVEMENT

Patient navigation for cancer care "refers to support and guidance offered to persons with abnormal findings in accessing the cancer care system and overcoming barriers to quality, standard care. Navigation spans the period from abnormal finding from cancer detection procedure through necessary cancer diagnostic tests to completion of cancer treatment" (United States Department of Health and Human Services, National Institutes of Health, National Cancer Institute [NCI], 2004, p. 2). There is general consensus throughout the public health field that patient navigation programs "provide a very promising approach to reducing disparities for cancer and other diseases" (Institute for Alternative Futures, 2007, p. 3).

Hundreds of patient navigator programs have already been established throughout the country as part of local cancer control efforts by cancer centers, community-based clinics and philanthropy (Dohan & Schrag, 2005; Hede, 2006). Although, interestingly, "studies to date have not employed sufficiently rigorous research designs to allow any conclusions about the true effects of navigation programs", and "published evidence from randomized trials demonstrating that navigation is effective in reducing health disparities does not exist"(Dohan & Schrag, 2005, p. 853). What then accounts for the intervention model's widespread adoption—an adoption that has gained such widespread momentum, in fact, that it has recently received over $19 million worth of attention from NCI in the form of the Patient Navigator Research Program (PNRP),

which was jointly launched by NCI and the American Cancer Society in 2005. The purpose of the PNRP is the development of innovative patient navigator interventions to reduce cancer health disparities and testing their efficacy and cost-effectiveness (NCI, 2005).

It is the authors' opinion that those characteristics of the original patient navigator model that are consistent with principles and values representative of alternative approaches to translation (Figure 1) contributed to the model's popularity and widespread adoption. In keeping with this reasoning, the development of cancer patient navigation was grounded in contextual realities. In a more global sense, the intervention emerged within the context of both a national cancer care system that experiences significant disparities in disease morbidity and mortality and a public health evidence base void of effective intervention for reducing cancer care disparities. Vargas and colleagues (2008) share that the original patient navigator program model was also established partly in response to analysis of mortality data for the Harlem community that revealed racial and ethnic disparities in excess mortality from cancer and other treatable diseases—that is, it was developed partly in response to local contextual realities. Additionally, at its most basic level, cancer patient navigation can be described as a context-driven intervention as the services navigators provide are specific to the needs of their patients and the barriers they identify (C-Change, 2005).

Applying a broad conceptualization of evidence, another feature this paper attributes to the alternative approach to translation, Dr. Freeman developed the first patient navigation program based on local disease burden data; key findings from the American Cancer Society's 1989 hearings on cancer in poor populations, in which testimony was heard from poor cancer patients, their medical care providers and other cancer experts (Freeman, Muth, & Kerner, 1995; Vargas, Ryan, Jackson, Rodriguez, & Freeman, 2008); and his "personal experience in providing

cancer care to poor black patients in Harlem (Freeman, 2006, p. 139). After publication and promotions of initial positive findings from the early navigator model, findings that included no evidence of causal association, the model was widely adapted and replicated across the country (Vargas et. al, 2008).

It is also worth noting that the seminal article (Freeman, Muth, & Kerner, 1995) on the development of the American Cancer Society-supported Harlem Cancer Education and Demonstration Project (HCEDP), the nation's first patient navigator program, reflected a program development process that, consistent with the alternative approach described in this paper, addressed translation issues early on:

> "The model developed and tested within the HCEDP was designed specifically to rely on individuals with relatively low salaries whose training and experience would be more limited but whose presence within the system could prove affordable….The HCEDP model was based in on the extensive collaborative experience of…promoting and delivering cancer screening services to low-income Harlem residents" (p.21).

In a sense, the cancer patient navigation model represents a complete rearrangement of the standard five phase translation model. The recently launched national rigorous, expensive and relatively controlled efficacy and effectiveness studies have followed more practice based research, that was grounded largely in experiential evidence, and widespread implementation. The cancer patient navigation movement applied an alternative approach to program development and translation with noteworthy success. The public health literature suggests that patient navigation services and programs are associated with improved rates of screening and follow-up, lower clinical stage of presentation, and higher patient satisfaction (Dohan & Schrag,

2005). Program descriptions and process evaluations further suggest that patient navigator services improve clinics' ability to engage, track, and support patients and to develop and enhance communication and trust between clinic staff and patients from disadvantaged groups (Dohan & Schrag, 2005).

6.6 CONCLUSION

The cancer patient navigation movement is described as a case in point for the promise of alternative approaches to the traditional linear and phased processes for moving between public health research and public health practice. The problem of limited and slow translation in the public health field calls for both more broad and practical conceptualizations of evidence and an increased emphasis on contextual realities and public health practice in program development research. The development of the cancer patient navigator model was informed by qualitative data related to the myriad cancer care barriers poor and minority patients face, the real world practice experience of health care professionals, and local health statistics. Thus, the intervention model is characterized as practice based evidence, the development of which is a promising approach for improving public health translation. Cancer patient navigation was developed within the context of real world public health practice rather than through highly controlled research studies, as is the prevailing method of intervention development in public health. Consequently, the original model introduced by Dr. Freeman (1995) was well-suited for implementation in real world practice environments and has been adopted and adapted by hundreds of community and health care settings across the country (Dohan & Schrag 2005). Figure 4 illustrates this non-traditional process of public health program development.

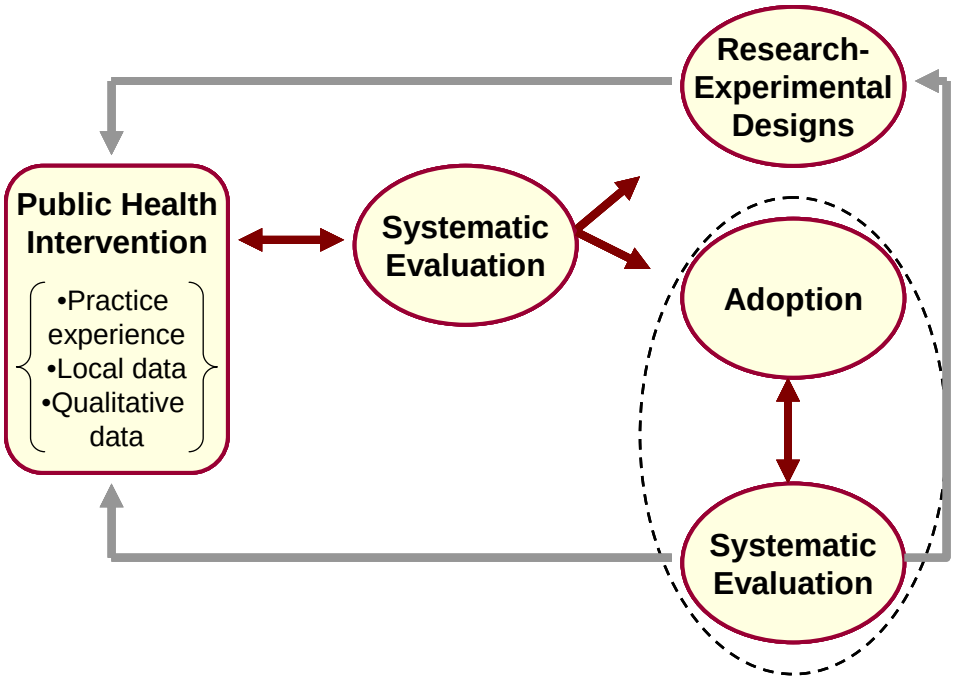


Figure 4. Alternative Approach to Public Health Research Translation

As presented in Figure 4, the alternative approach to moving from public health research to practice is basically a rearrangement of the traditional translation model described in Section 6.3.1. Rather than starting with controlled experimental designs, interventions developed through the alternative approach are more practice-based and are developed within the context of real world public health practice. Findings from systematic evaluation of practice-based interventions can provide valuable quantitative and qualitative data related to program implementation and the desired outcomes the program is *associated* with. Based on these evaluation findings, other practitioners may adopt the intervention model and adapt it to meet fit patients and service communities' unique needs and assets. Evaluation findings may also prompt and inform the development of research studies that assess the intervention's efficacy (i.e., determine whether the intervention *causes* the intended affect). Findings from rigorous

experimental studies are added to the intervention's evidence base and can then inform enhancements to the intervention model. Those who adopt and adapt the original intervention model, whether before or after causal evidence on the intervention's effects is available, can also conduct systematic evaluations. These systematic evaluations will also produce valuable evidence that can be used to inform enhancements to the original model, adopted programs, or experimental studies.

The alternative approach values a broad and practical conceptualization of evidence and places appropriate emphasis on real world contexts. These principles are key for addressing the problem of limited and slow public health research translation. The non-traditional development process of the cancer patient navigation model, and resulting widespread adoption of the model, suggests that the alternative approach to moving between public health research and practice is a valuable method for developing interventions that work in real world settings to effectively address complex public health problems, such as cancer care disparities.

7.0 GENERAL DISCUSSION AND CONCLUSIONS

The MOPP evaluation provided valuable qualitative and quantitative data related to program implementation achievements and challenges. Moreover, the evaluation produced useful products (e.g., logic model and data reporting templates) and sparked immediate small-scale enhancements (e.g., database modifications). The evaluation also called attention to key issues that should be monitored closely within the MOPP program, and, perhaps, within the larger public health movement. These key concerns include effectively navigating patients with substance abuse and minimizing the emotional burden work has on patient navigators. There may be some value in longitudinally studying the issue of the emotional burden patient navigation work places on navigators to determine if and how this staff-reported burden changes over time.

While the evaluation collected rich data from staff and participant interviews, the absence of input from other stakeholders (e.g., referring physicians and representatives of UPMC administration) is a study limitation. However, evaluation findings will be shared with stakeholders and it is recommended that, as resources allow, they be included in future evaluations. Saturation was not reached in the patient interviews, and this is another study limitation. As presented in the results section, all interviewees described social support services they received through MOPP. However, information shared during one of the final interviews suggests that it may be valuable to further explore patients' level of understanding about the

various services MOPP offers. As resources and patients' health conditions allow, future evaluations of the Minority Outreach Pilot Program, and evaluations of cancer patient navigator programs in general, should collect qualitative from larger numbers of patients to help ensure that saturation is reached.

Quantitative data analysis in the evaluation is limited to descriptive statistical analysis, which produces useful information, but cannot provide causal information related to the impact of program activities. The evaluation could have been enhanced through medical chart review to assess relationship between program services provided and objective measures of treatment compliance or completion. Although, this would have required a great deal of time and staff resources, as well as additional precautions for human subjects and health care information protection.

Fleisher rightly insists that "as the practice of patient navigation expands, there is a great deal to be learned about the process, political climate, and day-to-day challenges in planning and implementing a navigation program" (2008, p.2). Ultimately, the MOPP evaluation may prove valuable as a model for conducting program evaluation for cancer patient navigation that enhances local program practice; respects real-world time, funding, and ethical constraints; and systematically collects and disseminates valuable information on program context, implementation, and early outcomes. In turn, the MOPP program can continue to enhance and expand evaluation efforts by incorporating, as appropriate for program resources and stakeholder priorities, data collection and analysis methods found to be practical and informative in other existing cancer patient navigator program.

7.1 RECOMMENDATIONS FOR PROGRAM IMPROVEMENT AND FUTURE EVALUATION & STUDY

The following recommendations were either directly and frequently offered, or informed by ideas shared, in evaluation interviews or observed program meetings. They are summarized and organized in Appendix E according to the levels of the social ecological framework. They are highlighted in this manner to assist program staff, stakeholders and other public health practitioners who have, or are interested in developing cancer patient navigator programs, with targeting program efforts and prioritizing activities for program maintenance and expansion. Additionally, many of these recommendations also represent opportunities for future study within the cancer care and patient navigation field:

- Present detailed participant data, such as those tables and graphs presented in this dissertation, related to ineligibility for CCTs and diagnosis stage to UPMC policymakers and administration to advocate for: 1) an assessment of , and if deemed appropriate, modifications to the types of clinical trials offered and CCT eligibility criteria, 2) continued and enhanced efforts to identify cancer patients early, particularly among minority, disadvantaged, and other populations disproportionately affected by the cancer burden. This may include requests to use program gap funds to cover diagnostic work-ups for patients who are referred through the Prevention and Early Detection Clinic and other UPMC and community screening and early detection efforts. This data should also be shared with national partner cancer organizations to support efforts to reduce disparities in CCT participation and with other stakeholders, including community partners and insurers, to encourage continued and expanded efforts (e.g., patient screening reminders and incentives) for reaching cancer patients earlier.

- Implement regular data quality assurance checks to facilitate improvements to program data collection and the program database. This may include a monthly or quarterly review of the raw data from the program database. As, the current interface presents data under various tabs/screens and only allows users to view data from one patient at a time, it is not conducive to checking for missing or incomplete data, overlap in variables or variable codes, and related issues that can be more easily checked through basic descriptive statistical analysis of the raw program data. If HIPAA or other restrictions prevent the regular review and descriptive statistical analysis of raw program data, it may also be possible to perform data quality checks by requesting more detailed and extensive data tables and reports from the program administrator. Specifically, data reports and tables should account for missing data so the program can easily identify and investigate any errors or challenges in data collection and entry. Additionally, denominators should be noted when reporting percentages to ensure accurate interpretation of program numbers and to facilitate comparisons between subgroups of participants and over time. Lastly, related to CCT enrollment, it is recommended that the program present enrollment among eligible patients to more accurately reflect progress on increasing CCT participation. Perhaps the tables presented in this dissertation could be used by the database administrator as templates for data reporting.
- Present data and concerns around patients with substance abuse and addiction problems to administration and national partner organizations to identify, and potentially advocate for increasing, resources and services to help minimize the negative effects these problems may have on patients' cancer care. This issue does not appear in the patient navigation literature, and may be an important one to explore across the field as these health concerns will likely require significant attention and resources where they exist in patient navigator programs.

- Explore resources and options for assisting staff, particularly those who have regular direct contact with patients, in coping with the emotional impact related to program work. These may include the establishment of employee support groups, or building connections with existing groups. Options could also be explored for adjusting caseload or work responsibilities during periods of high emotional stress. If additional navigators are hired, particularly if lay navigators are hired, training should include a discussion, complete with examples and a quantitative description of participant characteristics, to help, to the extent possible, prepare navigators for coping with sharp health decline and death among their patients.
- Review program theory (i.e., logic model) and summary data related to patients barriers, needs and program services to inform staff discussion and planning around the potential costs, benefits, and options for adding a member with clinical expertise to the staff. While health care professional navigators may be very effective at explaining treatment options and medical findings to patients, it is not necessarily essential or cost-effective to assign health care professionals to patient navigator programs (Freeman, 2007). Based on patient interviews, participants most highly value the program for the assistance they receive in overcoming logistical and access barriers to cancer care. In addition, a great deal of appreciation was expressed for the emotional support provided by patient navigators. The literature does not currently include studies that clearly demonstrate whether trained lay navigators versus health care professional navigators are a better approach within various contexts (Freeman, 2007). However, Dr. Freeman, who is credited with creating and implementing the country's first patient navigator program, maintains: "The decision whether to use lay versus professionally trained navigators (or preferably both) should ultimately be based on the unique needs, structure, and patient population of each organization." (2007, p.2)

- If an expansion is approved, consider phasing in additional program target populations so the expansion can be carefully monitored and necessary adjustments can be made to program resources to ensure all participants continue to receive high quality program services. To the extent possible, improvements to the database should precede program expansion as current database challenges are likely to be exacerbated by rapid increases in the program population. Removal of unused or overlapping fields, and perhaps the addition of new or refined fields should help facilitate efficient, complete and accurate data entry to better support service provision and program monitoring as the intervention continues to grow.
- Review findings from this program evaluation and the program logic model to identify questions for future evaluations and to assess and plan for the availability of data, both quantitative and qualitative, to support ongoing program evaluation, including outcome evaluation as the program matures.

7.2 PUBLIC HEALTH SIGNIFICANCE

Findings from the MOPP evaluation can be used to guide program improvement efforts and to facilitate advocacy for ongoing funding and organizational support, expansion, and, possibly, replication. In supporting MOPP implementation, enhancement, and growth, the proposed evaluation potentially contributes to the reduction of cancer care disparities in Pittsburgh communities served by participating UPMC sites. In addition, this dissertation addresses the need to develop the literature on patient navigation (Dohan & Schrag, 2005). Dohan and Schrag note that "systematic evaluations of navigation only recently have begun and have yet to appear in the literature…many navigation programs have been oriented toward local

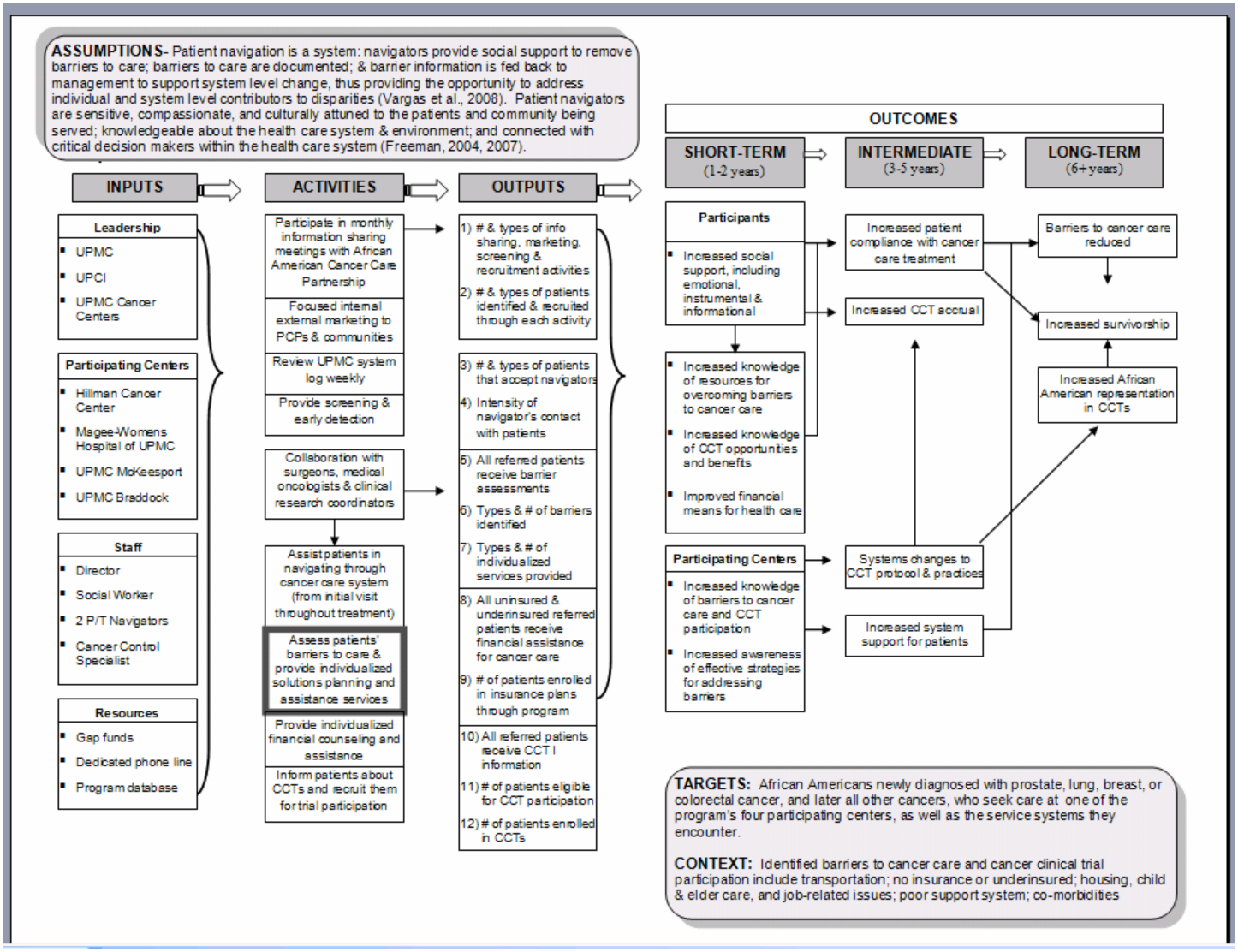
quality-improvement initiatives rather than scientific research, evaluation, and publication (2005, p. 849).

In a recent report on published cancer patient navigator information, C-Change noted that few comprehensive cancer centers appear to have discrete cancer patient navigation programs, and that is rare to find targeted patient navigation efforts for cancers other than breast cancer (date). The unique nature of the Minority Outreach Pilot Program (i.e., it is a discrete and multi-site navigator program housed within a comprehensive cancer center and it serves patients with all cancer diagnoses) suggests that evaluation findings represent a particularly original and valuable contribution to the patient navigation literature.

Fleisher rightly insists that "as the practice of patient navigation expands, there is a great deal to be learned about the process, political climate, and day-to-day challenges in planning and implementing a navigation program" (2008, p.2). It is expected that the MOPP evaluation will serve as a model for conducting navigator program evaluation that enhances local program practice; respects real-world time, funding, and ethical constraints; and systematically collects and analyzes valuable information on program context, implementation, and early outcomes to make meaningful contributions to the patient navigation literature.

APPENDIX A

MINORITY OUTREACH PILOT PROGRAM LOGIC MODEL



APPENDIX B

VARIABLES INCLUDED IN DESCRIPTIVE STATISICAL ANALYSIS OF THE MINORITY OUTREACH PILOT PROGRAM DATABASE

Name	Label	Values	Measurement Level
Patient_ID	program assigned ID #	N/A	nominal
Age	patient age	N/A	interval
Age_Range	patient age range	1 <20 2 20-49 3 50-64 4 65-74 5 75+	nominal
Gender	patient gender	0 Female 1 Male	nominal
Race	patient race	0 African American 1 Other	nominal
Date_Referral	date of patient's referral to program	N/A	interval
Program_Year	year patient entered program	1 2006 2 2007 3 2008	interval
ReferredBy	referral source	1 Case finding- MOPP SW 2 CIRS 3 Clinical Research Coord 4 Collaorative Practice Nurse 5 Community Agency 6 Oncologist	nominal

Name	Label	Values	Measurement Level
		7 Other 8 Other Medical Doctor 9 Other UPMC site 10 Primary Care Physician Prevention Early Detection 11 Center 12 Self-family-friend 13 Social worker 14 Surgeon	
CT_Screen_Only	patient only screened by program for CCT participation	0 No 1 Yes	nominal
NavigatorAccepted	patient accepted navigator	0 No 1 Yes	nominal
Site_Attending	patient's cancer care site	1 Beaver 2 Hillman 3 Jefferson 4 Magee 5 McKessport 6 Mercy 7 Moon Med 8 Murtha 9 Natrona 10 New Castle 11 Passavant 12 Shadyside 13 St. Margaret	nominal
Diagnosis	patient's cancer diagnosis	1 No cancer diagnosis 2 Not yet diagnosed 3 Acute Lymphoblastic Leukemia, Adult 4 Acute Myeloid Leukemia, Adult 5 Bile Duct Cancer, Extrahepatic 6 Bladder Cancer 7 Brain Tumor, Adult 8 Brain Tumor, Cerebral Astrocytoma/Malignant Glioma	nominal

Name	Label	Values	Measurement Level
		9 Brain Tumor, Childhood (Other) 10 Breast Cancer 11 Cervical Cancer 12 Chronic Myelogenous Leukemia 13 Colon Cancer 14 Esophageal Cancer 15 Head and Neck Cancer 16 Hodgkin's Lymphoma, Adult 17 Kaposi's Sarcoma 18 Laryngeal Cancer 19 Lung Cancer, Non-Small Cell 20 Lung Cancer, Small Cell 21 Lymphoma, Non-Hodgkin's Adult 22 Melanoma 23 Mesothelioma, Adult 24 Multiple Myeloma/Plasma Cell Neoplasm 25 Myelodysplastic Syndromes 26 Non-malignant Hematologic Disorder 27 Osteosarcoma/Malignant Fibrous Histiocytoma 28 Ovarian Epithelial Cancer 29 Pancreatic Cancer 30 Prostate Cancer 31 Rectal Cancer 32 Renal Cell (Kidney) 33 Renal Pelvis and Ureter, Transitional Cell Cancer 34 Sarcoma, Soft Tissue 35 Stomach (Gastric) Cancer 36 Thymoma and Thymic Carcinoma 37 Unknown Primary Site	
D_Stage	stage of patient's cancer	0 Screening or unable to stage 1 I 2 II 3 III	ordinal

Name	Label	Values	Measurement Level
		4 IV	
CT_Enrolled	patient's CCT enrollment status	0 No 1 Yes	nominal
ReasonNotEnrolled	reason patient is not enrolled in CCT	0 Enrolled 1 Already on rx 2 Lost to follow-up 3 MD chose other treatment 4 Medically ineligible 5 No crc covereage 6 No hipaa consent 7 No trial available 8 Non-cancer 9 Pending 10 Poor ps 11 Prior cancer 12 Refused 13 Requires more surgery 14 Secondary primary	nominal
Marital_Status	patient's marital status	0 Single 1 Married 2 Divorced 3 Other 4 Unknown 5 Widowed	nominal
LA_Alone	patient's living arrangement (alone)	0 No 1 Yes	nominal
Insurance	patient's insurance provider	1 Commercial Indemnity Insurance 2 Commercial Managed Care (HMO/PPO/POS) 3 Medicaid Managed Care (HMO/PPO/POS) 4 Medicaid/Public Assistance 5 Medicare 6 Medicare Managed Care (HMO/PPO/POS) 7 Military (DOD,CHAMPUS,VA) 8 Other Public Coverage 9 Self Pay or No Insurance	nominal

Name	Label	Values	Measurement Level
Barriers B_CoMorbids B_Elder_Care B_Financial B_Health_Beliefs B_Housing B_Insurance B_Job_Resp B_Other B_Poor_Support B_Spritual_Relig B_Transportation B_None_ID	patient-identified barriers to cancer care: cormobidities, elder care, health beliefs, housing, insurance, job responsibilities, poor support, spiritual/religious, transportation, none identified	0 No 1 Yes	nominal
PN Services Nav1_ES Nav2_Trans Nav3_Check Nav4_AR Nav5_Info_Ed Nav6_Other NavServ_None	services navigators provide patient: emotional support, transportation, check-in with patient via phone or in person, appointment reminder, informational or educational call or visit, other (call backs, efforts to reach by phone, brief intros no PN services recorded)	0 No 1 Yes	nominal
Comorbidities C1_Addiction C2_Arthritis C3_Asthma C4_CAD C5_Cancer_other C6_COPD C7_Dementia C8_Diabetes	patient's medically documented comorbidities	0 No 1 Yes	nominal

Name	Label	Values	Measurement Level
C9_GERD C10_GI_condition C11_Gout C12_Hearing C13_Hypercholeserolemia C14_Hyperlipidemia C15_Hypertension C16_Kidney_Disease C17_Liver_Disease C18_Other C19_Psychiatric C20_Pulmonary_19 C21_Stroke C22_Thyroid_Disease C23_Vision			
Total_CM	patient's total number of comorbidities	N/A	interval

APPENDIX C

STAFF AND PARTICIPANT INTERVIEW SCHEDULES

C.1 STAFF INTERVIEW QUESTIONS BY EVALUATION FOCUS

Evaluation Focus	Staff Interview Questions & Probes
▪ How many participants does the program serve, and what are the characteristics of the program participants?	1. How would you describe the group of patients you serve through the Minority Outreach Pilot Program?
▪ What is the program's reach into the target population?	2. Would you say that the program is serving the intended population? Why or why not?
▪ To what extent is the program being implemented as planned?	3. In what ways are program activities being implemented as planned? In what ways are they not being implemented as planned? Why do you think that is?
▪ Is the program making progress toward the achievement of short-term outcomes?	4. Would you say that the program is making progress toward achieving desired outcomes in patients? Why or why not? In the participating UPMC sites? Why or why not? 5. What kind of changes, if any, do you think should be made to improve the program? For the participants? For the participating UPMC sites? For staff? For the community? 7. How would you summarize the program's current impact on: patients enrolled in the program? On the UPMC sites that participate in the program? On the surrounding community? On you as [staff position]?

Evaluation Focus	Staff Interview Questions & Probes
▪ Are there unintended or unexpected program outcomes?	6. Based on your experience, has MOPP had any impact, or have the navigation services led to any outcomes, that were unplanned? These can be positive or negative unexpected outcomes. Please explain.

C.2 PARTICIPANT INTERVIEW QUESTIONS

1. How did you first meet [name of PN]?
2. How do you two typically meet, over the phone, in person?

   probe: How often do you meet?
3. Has [name of PN] helped you in any way? How?
4. Are there any things you needed help with that [name of PN] didn't help enough with? Please tell me about that.
5. What do you like most about working with [name of PN]? Why?
6. Is there anything that you don't like about working with [name of PN]? Why?
7. How would you change what [name of PN] does? Why?
8. Do you know any of the people [name of PN] works with? [Name of 2nd PN]? [Name of Social Worker]? If yes,

   follow-up: Please tell me a little bit about how you know them and how they've worked with you?

Participants who initially refused, but eventually accepted, patient navigator services were also asked the following questions in addition to those listed above:

9. Why did you decide not to work with [name of PN] at first?

   probe: What made you change your mind?

Participants who declined patient navigator services outright were asked the following question:

Please tell me why you decided not to accept [name of PN]'s services to help with your care.

APPENDIX D

CHARACTERISTICS OF PROGRAM PARTICIPANTS BY PROGRAM YEAR

The following table presents program participant characteristics by program year. The time periods assigned to each program period (i.e., March 2006-December 2006; January 2007-Decemember 2007; and January 2008 to present, which in the case of this evaluation was April 2008) are aligned with MOPP program monitoring and reporting practices to facilitate use of data for ongoing program planning, evaluation and improvement. Program year data was not recorded for 15 participants, so those participants were not included in this analysis.

Characteristic	**Percent**		
	2006 (n=91)	**2007** (n=106)	**2008** (n=37)
Age Group			
<20	0	.9	0
20-49	30.8	27.4	29.7
50-64	40.7	44.3	40.5
65-74	20.9	14.2	18.9
75+	7.7	11.3	10.8
Unknown	0	1.9	0
Total	100	100	100
Gender			
Female	57.1	66.0	51.4
Male	42.9	34.0	45.9
Missing	0	0	2.7
Total	100	100	100

Characteristic	Percent		
	2006 (n=91)	**2007** (n=106)	**2008** (n=37)
Referral Source			
Case Finding (MOPP Social Worker)	24.2	25.5	37.8
CIRS	16.5	13.2	24.3
Clinical Research Coordinator	12.1	6.6	5.4
Collaborative Practice Nurse	6.6	4.7	2.7
Community Agency	0	6.6	2.7
Oncologist	3.3	3.8	0
Other	1.1	0	0
Other Medical Doctor	0	.9	0
Other UPMC Site	2.2	1.9	0
Primary Care Physician	1.1	.9	2.7
PEDC	3.3	6.6	2.7
Self/Family/Friend	2.2	3.8	0
Social Worker	23.1	17.0	18.9
Surgeon	4.4	8.5	2.7
Missing	0	0	0
Total	100	100	100
Patient Navigator			
No	62.6	63.2	94.6
Yes	37.4	36.8	5.4
Total	100	100	100
Cancer Stage			
I	9.9	3.8	5.4
II	9.9	12.3	2.7
III	26.4	22.6	10.8
IV	40.7	38.7	40.5
Screening	5.5	12.3	5.4
Unable to Stage	7.7	10.4	29.7
Missing	0	0	5.4
Total	100	100	100
Cancer Diagnosis			
no cancer diagnosis	4.4	7.5	5.4
not yet diagnosed	2.2	9.4	2.7
Acute Lymphoblastic Leukemia, Adult	1.1	0	0
Acute Myeloid Leukemia, Adult	0	1.9	2.7
Bile Duct Cancer, Extrahepatic	0	0	0
Bladder Cancer	1.1	0	0
Brain Tumor, Adult	1.1	2.8	2.7
Brain Tumor, Cerebral Astrocytoma/Malignant Glioma	1.1	0	5.4
Brain Tumor, Childhood (Other)	0	.9	0
Breast Cancer	20.9	17.9	13.5

Characteristic	Percent		
	2006 (n=91)	**2007** (n=106)	**2008** (n=37)
Cervical Cancer	0	.9	0
Chronic Myelogenous Leukemia	0	1.9	2.7
Colon Cancer	9.9	4.7	10.8
Esophageal Cancer	2.2	0	2.7
Head and Neck Cancer	4.4	9.4	5.4
Hodgkin's Lymphoma, Adult	2.2	1.9	0
Kaposi's Sarcoma	0	.9	0
Laryngeal Cancer	1.1	0	2.7
Lung Cancer, Non-Small Cell	16.5	11.3	24.3
Lung Cancer, Small Cell	2.2	1.9	0
Lymphoma, Non-Hodgkin's Adult	1.1	2.8	5.4
Melanoma	1.1	1.9	0
Mesothelioma, Adult	1.1	0	0
Multiple Myeloma/Plasma Cell Neoplasm	3.3	2.8	0
Myelodysplastic Syndromes	0	.9	2.7
Non-malignant Hematologic Disorder	0	0	0
Osteosarcoma/Malignant Fibrous Histiocytoma	0	.9	0
Ovarian Epithelial Cancer	1.1	0	0
Pancreatic Cancer	4.4	5.7	2.7
Prostate Cancer	8.8	4.7	2.7
Rectal Cancer	3.3	.9	2.7
Renal Cell (Kidney)	2.2	1.9	0
Renal Pelvis and Ureter, Transitional Cell Cancer	0	.9	0
Sarcoma, Soft Tissue	1.1	1.9	0
Stomach (Gastric) Cancer	0	.9	2.7
Thymoma and Thymic Carcinoma	0	0	0
Unknown Primary Site	2.2	0	0
Missing	0	0	0
Total	100	100	100
Cancer Care Site			
Beaver Med Oncology	0	0	0
Hillman	84.6	76.4	67.6
Jefferson Med Oncology	0	0	0
Magee	2.2	2.8	5.4
McKeesport	2.2	2.8	8.1
Mercy	0	.9	0
Moon Med Oncology	0	0	2.7
Murtha Radiology Oncology	0	0	0
Natrona Med Oncology	0	.9	0
New Castle	0	0	0
Passavant	0	.9	0
Shadyside Hospital or Radiology Oncology	2.2	.9	5.4

Characteristic	Percent		
	2006 (n=91)	**2007** (n=106)	**2008** (n=37)
St. Margaret Med Oncology	0	.9	0
Missing	8.8	12.3	10.8
Total	100	100	100
Insurance			
Commercial Indemnity Insurance	0	.9	0
Commercial Managed Care (HMO/PPO/POS)	25.3	17.9	16.2
Medicaid Managed Care (HMO/PPO/POS)	28.6	21.7	16.2
Medicaid/Public Assistance	1.1	3.8	2.7
Medicare	1.1	4.7	2.7
Medicare Managed Care (HMO/PPO/POS)	27.5	27.4	37.8
Military (DOD,CHAMPUS,VA)	1.1	0	0
Other Public Coverage	0	0	8.1
Self Pay or No Insurance	15.4	20.8	13.5
Missing	0	2.8	2.7
Total	100	100	100

APPENDIX E

KEY THEMES AND ISSUES IDENTIFIED THROUGH MOPP EVALUATION

DR= document review, MO= meeting observations, PI= patient interviews, SI= staff interviews

Social Structure, Policy & Systems

- Exclusionary and rigid *cancer clinical trial (CCT) criteria* present challenges for CCT recruitment (MO, SI).
- *Early detection* is a critical factor for improving CCT participation- we have to *reach* patients earlier & healthier (MO, SI).

Community

- A *strong referral base*, particularly in the community, is important for achieving MOPP goals and outcomes (SI).
- *Community partnerships* are valuable assets for program promotion, recruitment & referrals, and for the reduction of patient-identified barriers to care (MO, SI).
- It takes *time* to build strong community partnerships and to overcome challenges with data reporting and information exchange, such as those currently experienced within the African American Cancer Care Partnership (SI).

Institutional/Organizational

- MOPP is a *patient navigation system* that includes case finding and referral protocols; barriers assessment; individualized solutions planning and services, which may include navigators; and CCT education and recruitment (DR, SI).
- *Sound data collection practices and systems* are vital for program monitoring, quality program delivery, accurate reporting, and effective evaluation (MO, SI).
- Program database development and improvement has required much more *time* than anticipated (MO, SI).
- Strong interest (at program and UPMC-level) in the *cost* of the program (MO, SI).
- The provision of program services has cost much less than anticipated. *Gap funds* have been used minimally (DR, MO, SI).
- Strong interest in *expanding the program* to include: 1) other minority and other populations disproportionately affected by the cancer burden, such as elderly patients, and 2) discretionary use of gap funds for diagnostic services (MO, SI).

Interpersonal

- The *Patient-Navigator relationship*, while valued highly among staff and participants poses an emotional dilemma and burden for navigators over time as many navigated participants die or experience a significant decline in health from cancer (PI, SI).
- Developing and nurturing strong patient-navigator relationships require *time, trust, and compassion* (PI, SI).
- Given the late stage diagnosis of many MOPP patients and program focus on CCT enrollment, it may be necessary to add a staff member with *clinical training* to the program team to expand the level of support offered to patients (MO, SI).

Individual

- Although all are African- American, there is great *diversity among MOPP participants* with regard to backgrounds, degrees of support, and health concerns, and service needs and utilization (MO, SI).
- *Substance abuse and addiction* among participants is a concern as these conditions can hinder compliance with treatment, as well as treatment options and success, and often require significant program resources to address (MO, SI).
- Large number of comorbidities and late stage presentation of cancer among participants represent cancer care shortcomings and major *CCT recruitment challenges* (MO, SI).

BIBLIOGRAPHY

Academy for Educational Development, Center on AIDS and Community Health. (2006). Diffusion of Effective Behavioral Interventions Project Factsheet. Retrieved March 16, 2007, from http://www.effectiveinterventions.org/files/DEBI.pdf

Aiello Bowles, E. J., Tuzzio, L., Wiese, C. J., Kirlin, B., Greene, S. M., Clauser, S. B., et al. (2008). Understanding high-quality cancer care: a summary of expert perspectives. *Cancer, 112*(4), 934-942.

American Cancer Society. Cancer Facts & Figures for African Americans 2005-2006. Atlanta: American Cancer Society, 2005.

American Cancer Society. Cancer Facts and Figures 2007. Atlanta: American Cancer Society; 2007.

American Cancer Society. Cancer Facts and Figures for African Americans 2007-2008. Atlanta: American Cancer Society, 2008.

Anderson, A., & Turner, A. (2007). *Patient navigation: Existing programs, current practices, and guidelines for success*. Seattle: The Cross Cultural Health Care Program.

Baquet, C. R., Commiskey, P., Daniel Mullins, C., & Mishra, S. I. (2006). Recruitment and participation in clinical trials: socio-demographic, rural/urban, and health care access predictors. *Cancer Detect Prev, 30*(1), 24-33.

Battaglia, T. A., Roloff, K., Posner, M. A., & Freund, K. M. (2007). Improving follow-up to abnormal breast cancer screening in an urban population. A patient navigation intervention. *Cancer, 109*(2 Suppl), 359-367.

BC Cancer Agency. (2005). *Patient navigation in cancer care*. Vancouver: Sociobehavioural Research Center.

Besculides, M., Zaveri, H., Farris, R., & Will, J. (2006). Identifying best practices for WISEWOMAN programs using a mixed-methods evaluation. *Prev Chronic Dis, 3*(1), A07.

Bolen, S., Tilburt, J., Baffi, C., Gary, T. L., Powe, N., Howerton, M., et al. (2006). Defining "success" in recruitment of underrepresented populations to cancer clinical trials: moving toward a more consistent approach. *Cancer, 106*(6), 1197-1204.

Brawley, O. W. (2004). The study of accrual to clinical trials: can we learn from studying who enters our studies? *J Clin Oncol, 22*(11), 2039-2040.

Briss, P. A. (2005). Evidence-based: US road and public-health side of the street. *Lancet, 365*(9462), 828-830.

Bruner, D. W., Jones, M., Buchanan, D., & Russo, J. (2006). Reducing cancer disparities for minorities: a multidisciplinary research agenda to improve patient access to health systems, clinical trials, and effective cancer therapy. *J Clin Oncol, 24*(14), 2209-2215.

Bull, S. S., Gillette, C., Glasgow, R. E., & Estabrooks, P. (2003). Work site health promotion research: to what extent can we generalize the results and what is needed to translate research to practice? *Health Educ Behav, 30*(5), 537-549.

Butterfoss, F. D. (2006). Process evaluation for community participation. *Annu Rev Public Health, 27*, 323-340.

Caburnay, C. A., Kreuter, M. W., & Donlin, M. J. (2001). Disseminating effective health promotion programs from prevention research to community organizations. *J Public Health Manag Pract, 7*(2), 81-89.

C-Change. (n.d.). Cancer patient navigation: Published information. Retrieved May 5. 2008, from hyyp://www.c-change.org

C-Change. (n.d.). Clinical Trials. Retrieved March 1, 2007 from http://www.c-changetogether.org/clinical_trials/default.asp

Christian, M. C., & Trimble, E. L. (2003). Increasing participation of physicians and patients from underrepresented racial and ethnic groups in National Cancer Institute-sponsored clinical trials. *Cancer Epidemiol Biomarkers Prev, 12*(3), 277s-283s.

Comis, R. L., Miller, J. D., Aldige, C. R., Krebs, L., & Stoval, E. (2003). Public attitudes toward participation in cancer clinical trials. *J Clin Oncol, 21*(5), 830-835.

Corporate Research Associates. (2004). *Cancer patient navigation evaluation: final report*. Nova Scotia: CRA.

Dohan, D., & Schrag, D. (2005). Using navigators to improve care of underserved patients: current practices and approaches. *Cancer, 104*(4), 848-855.

Dusenbury, L., Brannigan, R., Hansen, W. B., Walsh, J., & Falco, M. (2005). Quality of implementation: developing measures crucial to understanding the diffusion of preventive interventions. *Health Educ Res, 20*(3), 308-313.

Dzewaltowski, D. A., Estabrooks, P. A., & Glasgow, R. E. (2004). The future of physical activity behavior change research: what is needed to improve translation of research into health promotion practice? *Exerc Sport Sci Rev, 32*(2), 57-63.

Dzewaltowski, D. A., Glasgow, R. E., Klesges, L. M., Estabrooks, P. A., & Brock, E. (2004). RE-AIM: evidence-based standards and a Web resource to improve translation of research into practice. *Ann Behav Med, 28*(2), 75-80.

Eliminating Disparities in Clinical Trials Project (EDICT). (2008). Major Deficiencies in the Design and Funding of Clinical Trials: A Report to the Nation Improving on How Human Studies Are Conducted. Retrieved June 6, 2008, from http://www.bcm.edu/edict/home.html

Elliott, D. S., & Mihalic, S. (2004). Issues in disseminating and replicating effective prevention programs. *Prev Sci, 5*(1), 47-53.

Flay, B. R. (1986). Efficacy and effectiveness trials (and other phases of research) in the development of health promotion programs. *Prev Med, 15*(5), 451-474.

Fleisher, L. (2008). One size does not fit all. Retrieved June 3, 2008, from http://patientnavigation.com

Fixsen, D. L., Naoom, S. F., Blase, K. A., Friedman, R. M. & Wallace, F. (2005). Implementation Research: A Synthesis of the Literature. Tampa, FL: University of South Florida, Louis de la Parte Florida Mental Health Institute, The National Implementation Research Network (FMHI Publication #231).

Forsetlund, L., Talseth, K. O., Bradley, P., Nordheim, L., & Bjorndal, A. (2003). Many a slip between cup and lip. Process evaluation of a program to promote and support evidence-based public health practice. *Eval Rev, 27*(2), 179-209.

Fowler, T., Steakley, C., Garcia, A. R., Kwok, J., & Bennett, L. M. (2006). Reducing disparities in the burden of cancer: the role of patient navigators. *PLoS Med, 3*(7), e193.

Ford JG, Howerton MW, Bolen S, Gary TL, Lai GY, Tilburt J, Gibbons MC, Baffi C, Wilson Feuerstein RF, CJ, Tanpitukpongse P, Powe NR, Bass EB. Knowledge and Access to Information on Recruitment of Underrepresented Populations to Cancer Clinical Trials. Evidence Report/Technology Assessment No. 122 (Prepared by the Johns Hopkins University Evidencebased Practice Center under Contract No. 290-02-0018.) AHRQ Publication No. 05-E019-2. Rockville, MD. Agency for Healthcare Research and Quality. June 2005.

Freeman, H. P. (2004). A model patient navigation program. *Oncology Issues*(September/October), 44-46.

Freeman, H. P. (2006). Patient navigation: a community based strategy to reduce cancer disparities. *J Urban Health, 83*(2), 139-141.

Freeman, H.P. (2007). Expert commentary from Dr. Harold Freeman. Retrieved January 3, 2008, from http://www.patientnavigation.com

Freeman, H. P., Muth, B. J., & Kerner, J. F. (1995). Expanding access to cancer screening and clinical follow-up among the medically underserved. *Cancer Pract, 3*(1), 19-30.

Garcia, R. (2005). *Cancer Patient Navigator Program.* Paper presented at The 12th Maryland State Council on Cancer Control Conference.

Glasgow, R. E. (2002). Evaluation of theory-based interventions: The RE-AIM model. In K. Glanz, F. M. Lewis & B. K. Rimer (Eds.), *Health Behavior and Health Education* (3rd ed., pp. 531-544). San Francisco: Jossey-Bass.

Glasgow, R. E. (2003). Translating research to practice: lessons learned, areas for improvement, and future directions. *Diabetes Care, 26*(8), 2451-2456.

Glasgow, R. E., Davidson, K. W., Dobkin, P. L., Ockene, J., & Spring, B. (2006). Practical behavioral trials to advance evidence-based behavioral medicine. *Ann Behav Med, 31*(1), 5-13.

Glasgow, R. E., & Emmons, K. M. (2007). How can we increase translation of research into practice? Types of evidence needed. *Annu Rev Public Health, 28*, 413-433.

Glasgow, R. E., Klesges, L. M., Dzewaltowski, D. A., Bull, S. S., & Estabrooks, P. (2004). The future of health behavior change research: What is needed to improve translation of research into health promotion practice? *Ann Behav Med, 27*(1), 3-12.

Glasgow, R. E., Klesges, L. M., Dzewaltowski, D. A., Estabrooks, P. A., Vogt, T. M.. (2006). Evaluating the impact of health promotion programs: using the RE-AIM framework to form summary measures for decision making involving complex issues. *Health Education Research, 21*, 688-694.

Glasgow, R. E., Lichtenstein, E., & Marcus, A. C. (2003). Why don't we see more translation of health promotion research to practice? Rethinking the efficacy-to-effectiveness transition. *Am J Public Health, 93*(8), 1261-1267.

Glasgow, R. E., Vogt, T. M., & Boles, S. M. (1999). Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health, 89*(9), 1322-1327.

Goodman, R. M. (2001). Community-based participatory research: questions and challenges to an essential approach. *J Public Health Manag Pract, 7*(5), v-vi.

Goodman, R. M. (2001). Evaluation of community-based health programs: An alternate perspective. In N. Schneiderman, M. A. Speers, J. M. Silva, H. Tomes & J. H. Gentry (Eds.), *Integrating behavioral and social sciences with public health*. Washington D.C.: American Psychological Association.

Goodman, R. M., Speers, M. A., McLeroy, K., Fawcett, S., Kegler, M., Parker, E., et al. (1998). Identifying and defining the dimensions of community capacity to provide a basis for measurement. *Health Educ Behav, 25*(3), 258-278.

Green, L. W. (2001). From research to "best practices" in other settings and populations. *Am J Health Behav, 25*(3), 165-178.

Green, L. W., & Glasgow, R. E. (2006). Evaluating the relevance, generalization, and applicability of research: issues in external validation and translation methodology. *Eval Health Prof, 29*(1), 126-153.

Greene, A., Young, P., Taylor, E., Chu, K., & Garcia, R. (2007). *Patient navigation research program evaluation design and implementation.* Paper presented at the American Public Health Association Annual Meeting, Washington, D.C.

Greenwald, P., & Cullen, J. W. (1985). The new emphasis in cancer control. *J Natl Cancer Inst, 74*(3), 543-551.

Guba, E. G., & Lincoln, Y. S. (2005). Paradigmatic controversies, contradiction, and emerging confluences. In N. K. Denzin & Y. S. Lincoln (Eds.), *The handbook of qualitative research* (3rd ed.). Thousand Oaks: Sage Publications.

Harshbarger, C., Simmons, G., Coelho, H., Sloop, K., & Collins, C. (2006). An empirical assessment of implementation, adaptation, and tailoring: the evaluation of CDC's National Diffusion of VOICES/VOCES. *AIDS Educ Prev, 18*(4 Suppl A), 184-197.

Heaney, C.A., & Israel, B.A. (2002). Social Networks and Social Support. In K. Glanz, B. K. Rimer & F. M. Lewis (Eds.), *Health behavior and health education theory, research, and practice* (3rd ed.). San Francisco: Jossey-Bass.

Hede, K. (2006). Agencies look to patient navigators to reduce cancer care disparities. *J Natl Cancer Inst, 98*(3), 157-159.

Hiatt, R. A., & Rimer, B. K. (1999). A new strategy for cancer control research. *Cancer Epidemiol Biomarkers Prev, 8*(11), 957-964.

Institute for Alternative Futures. Patient Navigator Program Overview. Alexandria, VA: Institute for Alternative Futures, 2007.

Israel, B. A., Schulz, A. J., Parker, E. A., & Becker, A. B. (1998). Review of community-based research: assessing partnership approaches to improve public health. *Annu Rev Public Health, 19*, 173-202.

Jack, L., Jr., Liburd, L., Spencer, T., & Airhihenbuwa, C. O. (2004). Understanding the environmental issues in diabetes self-management education research: a reexamination of 8 studies in community-based settings. *Ann Intern Med, 140*(11), 964-971.

Kee, J.E.. (2004). Cost-Effectiveness and Cost-Benefit Analysis. In J. S. Wholey, H. P. Hatry & K. E. Newcomer (Eds.), *Handbook of Practical Program Evaluation* (2 ed.). San Francisco: Josey-Bass.

Kelly, J. A., Heckman, T. G., Stevenson, L. Y., Williams, P. N., Ertl, T., Hays, R. B., et al. (2000). Transfer of research-based HIV prevention interventions to community service providers: fidelity and adaptation. *AIDS Educ Prev, 12*(5 Suppl), 87-98.

Kemm, J. (2006). The limitations of 'evidence-based' public health. *J Eval Clin Pract, 12*(3), 319-324.

Klamen DL & Miller NS. (1997). Integration in education for addiction medicine. *J Psychoactive Drugs, 29*. 263-268.

Klesges, L. M., Estabrooks, P. A., Dzewaltowski, D. A., Bull, S. S., & Glasgow, R. E. (2005). Beginning with the application in mind: designing and planning health behavior change interventions to enhance dissemination. *Ann Behav Med, 29 Suppl*, 66-75.

Kluhsman, B. C., Bencivenga, M., Ward, A. J., Lehman, E., & Lengerich, E. J. (2006). Initiatives of 11 rural Appalachian cancer coalitions in Pennsylvania and New York. *Prev Chronic Dis, 3*(4), A122.

Love, A. (2004). Implementation Evaluation. In J. S. Wholey, H. P. Hatry & K. E. Newcomer (Eds.), *Handbook of Practical Program Evaluation* (2 ed.). San Francisco: Josey-Bass.

Merriam Webster. (n.d.). Merriam Webster Online Dictionary. Retrieved April 3, 2007 from http://www.m-w.com/dictionary/translating

McGuire, W. L. (2005). Beyond EBM: New directions for evidence-based public health. *Perspectives in Biology and Medicine, 48*(4), 557-569.

McQueen, D. V. (2001). Strengthening the evidence base for health promotion. *Health Promotion International, 16*(3), 261-268.

McQueen, D. V. (2002). The evidence debate. *J Epidemiol Community Health, 56*(2), 83-84.

Michaels, M. (n.d.). Current Practices in Clinical Research: A State of Social Injustice. Retrieved April 3, 2007 from http://www.enacct.org

Monette, D. R., Sullivan, T. J., & DeJong, C. R. (1997). *Applied Social Research: Tool for the Human Services* (4 ed.). Orlando: Harcourt.

Mowbray, C. T., Holter, M. C., Teague, G. B., & Bybee, D. (2003). Fidelity criteria: Development, measurement, and validation *American Journal of Evaluation, 24*(3), 315-340

Murray, D. M. (2001). Efficacy and effectiveness trials in health promotion and disease prevention: Design and analysis of group-randomized trials. In N. Schneiderman, M. A. Speers, J. M. Silva, H. Tomes & J. H. Gentry (Eds.), *Integrating behavioral and social sciences with public health*. Washington D.C.: American Psychological Association.

Neuman, L. W. (2002). *Social research methods: Qualitative and quantitative approaches.* (5th ed.). Boston: Allyn and Bacon.

Oldenburg, B., & Parcel, G. S. (2002). Diffusion of Innovations. In K. Glanz, B. K. Rimer & F. M. Lewis (Eds.), *Health behavior and health education theory, research, and practice* (3rd ed.). San Francisco: Jossey-Bass.

Owen, N., Glanz, K., Sallis, J. F., & Kelder, S. H. (2006). Evidence-based approaches to dissemination and diffusion of physical activity interventions. *Am J Prev Med, 31*(4 Suppl), S35-44.

Paulson, R. I., Post, R. L., Herinckx, H. A., & Risser, P. (2002). Beyond components: using fidelity scales to measure and assure choice in program implementation and quality assurance. *Community Ment Health J, 38*(2), 119-128.

Patton, M. Q. (1997). *Utilization-focused Evaluation* (3 ed.). Thousand Oaks: Sage.

Patton, M. Q. (2002). *Qualitative Research & Evaluation Methods* (3 ed.). Thousand Oaks: Sage.

Pennsylvania Department of Health, Bureau of Health Statistics and Research. (November 2006). *Cancer Facts and Figures for African Americans, Pennsylvania, 2002*. Retrieved August 13, 2007, from http://www.dsf.health.state.pa.us/health/lib/health/cff_aa/2006/cff_aa_2006.pdf

Petticrew, M., & Roberts, H. (2003). Evidence, hierarchies, and typologies: Horses for courses. *Journal of Epidemiology in Community Health, 57*, 527-529.

Potter, M., & Quill, B. (2006). *Demonstrating excellence in practice-based research for public health*: Association of Schools of Public Health, Academic Public Health Practice Committee.

Raphael, D. (2000). The question of evidence in health promotion. *Health Promotion International, 15*(4), 355-367.

Reuben, S. H. (2005). *Translating research into cancer care: Delivering on the promise*: The President's Cancer Panel.

Rohrbach, L. A., Grana, R., Sussman, S., & Valente, T. W. (2006). Type II translation: transporting prevention interventions from research to real-world settings. *Eval Health Prof, 29*(3), 302-333.

Rust, G. & Cooper, L.A. (2007). How can practice-based research contribute to the elimination of health disparities? *J Am Board Fam Med, 20*, 105-114.

Rychetnik, L., Frommer, M., Hawe, P., & Shiell, A. (2002). Criteria for evaluating evidence on public health. *Journal of Epidemiology in Community Health, 56*, 119-127.

Sateren, W. B., Trimble, E. L., Abrams, J., Brawley, O., Breen, N., Ford, L., et al. (2002). How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. *J Clin Oncol, 20*(8), 2109-2117.

Saunders, R. P., Evans, M. H., & Joshi, P. (2005). Developing a process-evaluation plan for assessing health promotion program implementation: a how-to guide. *Health Promot Pract, 6*(2), 134-147.

Schechter, C., & Brunner, S. M. (2005). *Bridging the gap between public health research and practice: Lessons from the field*: Academy for Educational Development, Center for Health Communication.

Schwaderer, K. A., & Itano, J. K. (2007). Bridging the healthcare divide with patient navigation: development of a research program to address disparities. *Clin J Oncol Nurs, 11*(5), 633-639.

Scutchfield, F. D., & Keck, C. W. (Eds.). (2003). *Principles of Public Health Practice*: Thomson Delmar Learning.

Sheppard, V. B., Cox, L. S., Kanamori, M. J., Canar, J., Rodriguez, Y., Goodman, M., et al. (2005). Brief report: if you build it, they will come: methods for recruiting Latinos into cancer research. *J Gen Intern Med, 20*(5), 444-447.

Shortell, S. M., & Richardson, W. C. (1978). *Health Program Evaluation*. St. Louis: C.V. Mosby Company.

Stake, R. E. (2005). Qualitative case studies. In N. K. Denzin & Y. S. Lincoln (Eds.), *The sage handbook of qualitative research* (3rd ed.). Thousand Oaks: Sage Publications.

Steinberg, M. L., Fremont, A., Khan, D. C., Huang, D., Knapp, H., Karaman, D., et al. (2006). Lay patient navigator program implementation for equal access to cancer care and clinical trials: essential steps and initial challenges. *Cancer, 107*(11), 2669-2677.

Sussman, S., Valente, T. W., Rohrbach, L. A., Skara, S., & Pentz, M. A. (2006). Translation in the health professions: Converting science into action. *Eval Health Prof, 29*(1), 7-32.

The Task Force on Community Preventive Services, The Guide to Community Preventive Services. (March 2007). Overview. Retrieved August 13, 2007, from http://www.thecommunityguide.org/about/default.htm

Trauth, J.M., Jernigan, J.C., Siminoff, L.A., Musa, D., Neal-Ferguson, D., & Weissfeld, J. (2005). Factors affecting older African American women's decisions to join the PLCO cancer screening trial. *Journal of Clinical Oncology*, 23(34), 8730-8738.

United States Department of Health and Human Services, American Cancer Society, and Commission on Cancer. (n.d.). Cancer Control P.L.A.N.E.T. Factsheet. Retrieved March 16, 2007, from http://cancercontrolplanet.cancer.gov/factsheet.pdf

United States Department of Health and Human Services, Centers for Disease Control and Prevention. Framework for Program Evaluation in Public Health. MMWR 1999;48(No. RR-11)

United States Department of Health and Human Services, Centers for Disease Control and Prevention. (October 2003). Prostate cancer screening: A decision guide for African Americans. Retrieved June 15, 2008, from http://www.cdc.gov/cancer/prostate/prospdf/aaprosguide.pdf

United States Department of Health and Human Services. Centers for Disease Control and Prevention. Office of the Director, Office of Strategy and Innovation. Introduction to program evaluation for public health programs: A self-study guide. Atlanta, GA: Centers for Disease Control and Prevention, 2005.

United States Department of Health and Human Services, Centers for Disease Control and Prevention Office of Public Health Research. (2006/2007). 2006/2007 Cancer Survivorship Fact sheet. Retrieved August 13, 2007, from http://www.cdc.gov/cancer/survivorship/pdf/0607_survivorship_fs.pdf

United States Department of Health and Human Services, Centers for Disease Control and Prevention Office of Public Health Research. (2007). Improving public health practice through translation research (R18). Retrieved February 27, 2007, from http://www.grants.gov

United States Department of Health and Human Services, National Center for Health Statistics (February 2007). Cancer FASTATS. Retrieved April 3, 2007, from http://www.cdc.gov/nchs/fastats/cancer.htm

United States Department of Health and Human Services, National Institutes of Health. (August 2006). NIH Roadmap for medical research fact sheet. Retrieved March 16, 2007, from http://opasi.nih.gov/documents/NIHRoadmap_FactSheet_Aug06.pdf

United States Department of Health and Human Services, National Institutes of Health, National Cancer Institute. (n.d.). What are Patient Navigators and Research Questions. Retrieved August 13, 2007, from http://crchd.cancer.gov/pnp/pnrp-questions.html

United States Department of Health and Human Services, National Institutes of Health, National Cancer Institute. (August 2004). Patient navigator research program (U01). Retrieved August 10, 2007, from http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-05-019.html

United States Department of Health and Human Services, National Institutes of Health, National Cancer Institute. (November 2005). Cancer Health Disparities [factsheet]. Retrieved March 4, 2008, from http://www.cancer.gov/newscenter/benchmarks-vol5-issue6/page2

United States Department of Health and Human Services, National Institutes of Health, National Cancer Institute. (March 2006). The Patient Navigator Research Program [brochure]. Retrieved August 13, 2007, from http://crchd.cancer.gov/attachments/pnrp_brochure.pdf

United States Department of Health and Human Services, Substance Abuse and Mental Health Services Administration. (2007). About NREPP. Retrieved March 16, 2007, from http://nrepp.samhsa.gov/about.htm

United States Department of Health and Human Services, The Office of Minority Health. (2005). Cancer 101. Retrieved August 10, 2007, from http://www.omhrc.gov/templates/content.aspx?ID=2829

Vargas, R. B., Ryan, G. W., Jackson, C. A., Rodriguez, R., & Freeman, H. P. (2008). Characteristics of the original patient navigation programs to reduce disparities in the diagnosis and treatment of breast cancer. *Cancer*.

Weiss, K. B., & Wagner, R. (2000). Performance measurement through audit, feedback, and profiling as tools for improving clinical care. *Chest, 118*(2 Suppl), 53S-58S.

Westfall, J. M., Mold, J., & Fagnan, L. (2007). Practice-based research--"Blue Highways" on the NIH roadmap. *Jama, 297*(4), 403-406.

Workgroup to Evaluate and Enhance the Reach and Dissemination of Health Promotion Interventions. (July 2004). Frequently asked questions about RE-AIM: The basics and Definitions of the Elements. Retrieved August 13, 2007, from http://re-aim.org/2003/FAQs_basic.html