March 2012

Evaluation of the Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities

Final Report to Congress

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RTI Project Number 0207964.027.000.006

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RTI International

CMS Contract No. 500-00-0024 TO#27

March 2012

This project was funded by the Centers for Medicare & Medicaid Services under contract no. 500-00-0024 TO#27. The statements contained in this report are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services. RTI assumes responsibility for the accuracy and completeness of the information contained in this report.

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EXECUTIVE SUMMARY

Racial and ethnic disparities in cancer screening and treatment have been well documented. Minority populations are less likely to receive cancer screening tests than Whites and, as a result, are more likely to be diagnosed with late-stage cancer (Agency for Healthcare Research and Quality [AHRQ], 2004; National Institutes of Health/National Cancer Institute [NIH/NCI], 2001). Racial and ethnic minorities with positive test results are more likely to experience delays in receiving the diagnostic tests needed to confirm cancer diagnoses (Battaglia et al., 2007; Ries et al., 2003). Similarly, differences in primary cancer treatment and appropriate adjuvant therapy have been shown to exist between White and minority populations (AHRQ, 2004). Although the ability to pay is one of the explanatory factors, similar disparities have been found among Medicare beneficiaries. To address this problem, Congress mandated that the U.S. Department of Health and Human Services conduct demonstrations aimed at reducing disparities in screening, diagnosis, and treatment of cancer among racial and ethnic minority Medicare-insured beneficiaries (Section 122 of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000).

Section 122(c)(1) requires a report to Congress not later than 2 years after the date of implementation of the initial demonstration projects. The first Report to Congress was submitted in September 2008. The second Report to Congress was submitted in October 2010, and a final report will be submitted September 2012. The report is required to evaluate the demonstration project's effectiveness at reducing cancer screening disparities (ES 8) as well as the costs of the projects (ES 9) and the beneficiary satisfaction with the services provided through the demonstrations (ES 10). In addition, the report is to include any other information regarding the demonstration as the Secretary of the U.S. Department of Health and Human Services determines to be appropriate. An appropriation of $25 million was designated to support the demonstration and its evaluation, and the legislation stipulated that at least nine sites be awarded.

When reviewing the budgets of the proposals submitted for consideration, the Centers for Medicare & Medicaid Services (CMS) concluded that it could award either six projects for 4 years or nine projects for 3 years. Given the start-up time needed to implement and accrue participants, a 3-year demonstration would not yield data needed to provide sufficient findings to Congress before the projects would have to be terminated. Therefore, CMS determined that a 4-year demonstration would enable a more comprehensive study of cost-effectiveness based on at least 2 full years of intervention data. It was originally thought that this longer period would permit CMS to determine whether the projects should be extended before they are terminated because CMS would no longer have a mandated appropriation for their continued operation.[1]

CMS contracted with the Schneider Institute for Health Policy at Brandeis University, which, together with the Boston University Center of Excellence in Women's Health and other consultants, was directed to "identify concepts and models that have a high probability of reducing risk factors [for cancer], increase use of Medicare-covered services, and improve health

[1] As discussed later in this report, sites experienced far more difficulty than expected in recruiting participants into the demonstration. As a result, the sites did not begin providing patient navigation services until the demonstration had been operational for a year or more.

and related outcomes for elder of color Medicare beneficiaries" (Brandeis University, 2003). The team developed recommendations for the design of the demonstrations, and CMS decided to assess the use of patient navigators (PNs) to help steer Medicare beneficiaries through the health care system (Brandeis University, 2003). PNs act as liaisons between medical services and the community, working to understand various individual and cultural needs, while connecting patients to the medical community. Although these programs have been widely implemented across the country, their design and their impact on patient outcomes are not uniform.

The American Cancer Society (ACS) was the first organization to introduce a PN program to a hospital in 1990; in 2005, it formally launched the ACS Patient Navigator program. The PNs are full-time employees, are nationally trained, and provide a variety of services to underserved patients. As of 2007 there were 60 program sites across the United States (IAF, 2007). Services range from arranging transportation to providing information on financial assistance programs.

The National Cancer Institute (NCI) has three research projects to evaluate the cost-effectiveness and efficacy of patient navigation. The main research project (PNRP) is a $25-million, 5-year study of eight sites looking at four types of cancer. Each of the sites individually partners with local organizations to serve underserved populations. This program has a variety of types of navigators—paid professionals and volunteers, social workers and nurses, and laypersons and community health workers. The study is examining whether the type of navigator, the location of the navigator, and language matching affects outcomes, as well as whether the type of navigator impacts cost-effectiveness.

The Health Resources and Services Administration (HRSA) funded six projects for the 2-year demonstration, beginning in September 2008, to support patient navigation programs in communities with significant health disparities and barriers to health services. The PNs are responsible for helping patients learn about chronic disease, such as cancer, diabetes, cardiovascular disease, obesity, and asthma, and helping them access screening and treatment (HRSA, 2012).

The Clinical Directors Network (CDN), a nonprofit network of primary care clinicians in community and migrant health centers, published a study of 1,413 women across 11 health centers. The women participated in a telephone-based PN program designed to improve cancer screening. All of them were overdue for screenings; they were provided with information on screening and given assistance in arranging appointments. Screening rates for three cancers (breast, cervical, and colorectal) increased in the intervention group.

Although these studies began at approximately the same time as the CMS demonstration project, the CMS study included patient navigation interventions aimed at cancer screening and treatment and focused on specific minority populations that had Medicare coverage. Another key difference in terms of the design is that the patient navigation intervention was randomly assigned, so comparing the intervention and control group yields unbiased impacts of patient navigation. In addition, the CMS study included a detailed assessment of the activities and the costs of patient navigation, which allows a more detailed understanding of what patient navigation might include in the different sites. Table ES-1 compares the PN programs.

Table ES-1
Comparison chart:
multi-site patient navigation program overview

Name	Target population	Sites	Focus area	Navigator type
American Cancer Society Patient Navigator Program	Mostly medically underserved	More than 50	Cancer (various types)	Trained PNs
Medicare Cancer Prevention and Treatment	Demonstration for racial and ethnic minorities; minority Medicare fee-for service beneficiaries	6	Breast, cervical, colorectal & prostate cancer	Community health workers, sometimes supervised by nurses or medical social workers
Center to Reduce Cancer Health Disparities Patient Navigator Research Program	Racial/ethnic minorities; low income and underserved	9	Breast, cervical, colorectal & prostate cancer	Various
Clinical Directors Network	Underserved women	11	Screening for breast cancer	Trained care managers

Source: Institute for Alternative Futures, 2007.

Available results from these and other efforts show that patient navigation can improve screening rates and reduce time to treatment in some cases, although there are limitations to the study designs implemented. One retroactive case study found that PN services reduced the time between presentation of breast cancer and initial treatment in an urban setting (Haideri et al., 2011). Patient navigation was also shown to improve mammography adherence among a similar population after a 9-month intervention (Phillips et al., 2010). In several studies with smaller sample sizes (Loreley et al., 2011; Ferrante et al., 2010), the authors concluded that PN services are beneficial to patients with special needs or barriers to treatment, but further research was necessary to generalize more broadly. Similarly, it is well documented that cancer patients value the assistance provided by PNs; many patients cite the emotional support, information, and logistical assistance they receive as evidence of the PNs' effectiveness (Carroll et al., 2010; Hendren et al., 2010). A thorough literature review [Hopkins et al., 2009) of recent research emphasized that 16 of 45 published studies provided data on efficacy of patient navigation services in improving timeliness and receipt of cancer screening, diagnostic follow-up care, and treatment. However, most of these trials had significant methodological limitations, including lack of control group, small sample sizes, and contamination with other interventions, and the authors conclude that further rigorous research is necessary to determine the exact benefits of PN services.

CMS issued an announcement on December 23, 2004, soliciting cooperative agreement proposals for the Cancer Prevention and Treatment Demonstration (CPTD) for Ethnic and Racial Minorities. In particular, the announcement sought demonstration projects that targeted four legislatively mandated minority populations: American Indians; Asians and Native Hawaiians or

Other Pacific Islanders; African Americans; and Hispanics. By law, CMS was also required to include at least one rural site, one inner-city site, and one site in the Pacific Islands, which CMS limited to the State of Hawaii. Applications were due March 23, 2005. After reviewing all applications and negotiating with individual sites, CMS announced the selection of six CPTD sites on April 3, 2006. Enrollment of beneficiaries began October 1, 2006. The six sites and their target populations are presented in Table ES-2.

Table ES-2
Description of demonstration sites

Site	Location	Lead organizational unit	Priority population
Huntsman Cancer Institute (HCI)	Arizona and Montana	Huntsman Cancer Institute in Utah, Sletten Cancer Institute, Montana (sub to HCI)	American Indians
Johns Hopkins University	Baltimore, Maryland	Bloomberg School of Public Health	African Americans
Josephine Ford Cancer Center (Henry Ford Health System)	Detroit, Michigan (Wayne County)	Josephine Ford Cancer Center–Henry Ford Health System	African Americans
The University of Texas, M.D. Anderson Cancer Center	Houston, Texas (Harris County), later expanded to surrounding countries	Center for Research on Minority Health	Hispanic/Mexican Americans
The University of Medicine and Dentistry of New Jersey	Newark, New Jersey, later expanded to surrounding countries	New Jersey Medical School	Latinos
Moloka'i General Hospital	Moloka'i (island), Hawaii (Maui County)	Moloka'i General Hospital	Asian, Pacific Islanders (primarily Filipinos, Native Hawaiians)

SOURCE: RTI's first round of site visits, 2006–2007.

Four of the six sites were based in academic medical centers that house major cancer treatment centers. The fifth (Josephine Ford Cancer Center [Henry Ford Health System]) is a cancer center based in a large, vertically integrated delivery system, which greatly facilitated the center's access to potential demonstration participants. The sixth (Moloka'i General Hospital) is based in a small general hospital on the island, but is part of the larger Queen's Hospital System.

Two of the sites are located in rural areas. The Moloka'i site is on a small, relatively undeveloped island that is accessible only by small plane because the ocean currents are too strong for ferries to travel from the nearest developed island of Oahu, Hawaii. Huntsman originally targeted American Indian reservations in remote and mountainous sections of Montana and Utah. The final sites included three reservations in Montana (representing four tribes—the

Chippewa Cree, the Assinniboine, the Gros Ventre, and the Blackfeet) and several Navajo communities in the Four Corners area of Arizona, Colorado, New Mexico, and Utah.

The remaining four sites are all located in the inner cities of major metropolitan areas. Because of difficulties recruiting eligible participants, two of the sites (M.D. Anderson and The University of Medicine and Dentistry of New Jersey [UMDNJ]) later expanded their areas to encompass surrounding counties.

ES.1 Demonstration Design

The CPTD was designed to reduce racial/ethnic disparities in cancer prevention and treatment by improving cancer screening rates and completion rates of cancer treatment. Each of the six sites in the CPTD had two study arms: a screening arm and a treatment arm. Each study arm had one intervention group and one control group. The random assignment of participants to intervention and control groups allows unbiased estimates of the impacts of patient navigation, since participant characteristics are not related to assignment to groups. Each participant recruited into the study completed a baseline cancer status assessment survey (CSA) that includes questions on cancer risk factors, utilization of screening tests, and cancer history. This baseline survey served several purposes: (1) the survey was used to assign participants to either the screening or treatment arm, (2) screening history data could be used to help schedule appointments for intervention participants in the screening arm, and (3) sites received a fixed payment from CMS for each survey administered. In addition to CSA payments, sites were paid a capitated amount per enrollee in the intervention group. More detailed information about site payments is presented in Table ES-4.

Participants with a diagnosis of breast, cervical, colorectal, lung, or prostate cancer who had received some form of treatment within the past 5 years were assigned to the treatment arm. Participants who had received treatment in the past 5 years for another type of cancer were excluded from the study. All other participants were assigned to the screening arm.

The study design was based on intent to treat; therefore, participants enrolled in the screening arm remained in that arm, even if they were diagnosed with cancer over the course of the study. Intervention group participants who were diagnosed with cancer received navigation services for their cancer treatment. However, the evaluation continued to treat them as participants in the screening arm.

The main sources of data for this study were surveys administered by the sites to study participants and Medicare claims data from 2002 through 2010. The CSAs were administered by site personnel at baseline, when a study participant enrolled, and at exit, or when a study participant left the study. Sites also administered an annual survey to study participants, though most focused on the intervention group. The baseline CSA was required for someone to be considered a study participant, and the exit CSA was important for measuring program-related change on elements measured in the surveys. Survey data were sent from each site to Thomson Reuters and then on to RTI for analysis. The response rates for the exit CSAs were not ideal and differed by study site and participant status (intervention or control). The CSA data were therefore most useful for answering questions related to satisfaction with the intervention for the intervention group and for providing identifiers that allowed matching to the claims data. Using

the identifying information from the baseline CSA, we matched each study participant to Medicare claims data, which allowed us to address outcomes for all study participants (not just the ones who had responded to the exit CSA). The Medicare claims data were the basis for analysis of changes in screening rates and spending in response to patient navigation interventions. The claims data from 2002 through 2010 allowed us to examine utilization and spending patterns before, during, and even after study enrollment. Because each site implemented its own patient navigation intervention, and because the target populations in each site were so different, all analysis was site specific.

Several other data sources were used for this report. RTI collected data from the sites. Annually, sites submitted to RTI a Cost Assessment Tool (CAT); quarterly, sites submitted PN activity surveys. (More information is provided on these in section ES.12.) CMS provided RTI with enrollment and payment data. In addition, RTI conducted two rounds of site visits with each of the demonstration sites and delivered to CMS a site visit report for each site and each round. The evaluation team did not have access to sites' quarterly progress reports.

ES.2 Demonstration Enrollment

Participation in the demonstration was voluntary, and beneficiaries could drop out at any time. Participants were automatically dropped if they became ineligible. For example, beneficiaries in managed care plans were not eligible for this demonstration, and those who later enrolled in a managed care plan also lost eligibility for the CPTD. Additionally, beneficiaries who were institutionalized or who had elected hospice were ineligible for the demonstration. All participants in the CPTD must be enrolled in Medicare Parts A and B throughout their enrollment in the demonstration.

At the start of the demonstration, sites had projected their expected enrollment into the screening and treatment arms of the study. Table ES-3 displays projected, revised, and actual enrollment for the screening and treatment arms for each site. Enrollment goals varied across sites; the much lower numbers for Moloka'i reflected the small target population on the island. All of the sites expected to enroll more participants into the screening arm of the study than into the treatment arm. Screening enrollment came much closer to meeting site goals, even exceeding it in certain sites. No sites met their goals for treatment arm enrollment.

Table ES-3
Enrollment in the demonstration screening and treatment arms, by demonstration site

	Original total projected enrollment[1]		Revised total enrollment goals[1]		Cumulative enrollment[2]	
Site	Screening	Treatment	Screening	Treatment	Screening	Treatment
Huntsman Cancer Institute	1,800	140	1,635	140	1,743	54
Johns Hopkins University	2,874	200	1,975	200	2,595	172
Josephine Ford Cancer Center (Henry Ford Health System)	1,900	1,150	2,876	274	5,398	440

(continued)

Table ES-3 (continued)
Enrollment in the demonstration screening and treatment arms, by demonstration site

Site	Original total projected enrollment[1]		Revised total enrollment goals[1]		Cumulative enrollment[2]	
	Screening	Treatment	Screening	Treatment	Screening	Treatment
The University of Texas, M.D. Anderson Cancer Center	3,240	360	1,887	900	2,038	299
The University of Medicine and Dentistry of New Jersey	1,284	100	1,259	100	1,190	85
Moloka'i General Hospital	528	50	528	50	488	34
Total	11,626	2,000	10,160	1,664	13,452	1,084

[1] Data provided by the Centers for Medicare & Medicaid Services, 2009.

[2] RTI analysis of Cancer Status Assessments (Program csa_n_v2).

ES.3 Randomization Method

Participants within each arm were randomized by a third party to either the intervention (i.e., Patient Navigation) or the control group. Four of the sites randomized at the individual level so that patients were randomly assigned to either group. The remaining sites, Huntsman and Moloka'i, implemented variations on the randomized design. Huntsman focused on American Indians who were spread across numerous remote reservations in Montana and the Four Corners area of Arizona, Colorado, New Mexico, and Utah. Because these communities are closely knit, Huntsman was concerned with assigning individuals living in the same community to different groups. Therefore, Huntsman designed a randomization scheme by clusters of individuals, so that equal numbers of individuals living within a defined geographic area on a reservation were assigned to the intervention group, and the same proportion of people living in a different cluster or area of the same reservation were assigned to the control group. Moloka'i had also been granted permission to implement a variation on the randomization design, because of the close-knit nature of the community on the small island. CMS had granted permission to assign all island residents in the screening and treatment arms to the intervention group, and then assign people living in similar communities on the nearby island of Oahu to the control group. During implementation, the site decided not to recruit screening participants from Oahu and used a Moloka'i-based nutrition education program for the control group. The treatment arm control group on Oahu also faced difficulties, and recruitment in Oahu stopped halfway through the project. Moloka'i did end up closer to a randomized design than they had originally anticipated for the screening arm.

The fact that each site focused on Medicare beneficiaries from a single racial or ethnic minority group greatly strengthened the experimental design because intervention and control participants shared the same racial or ethnic background and were drawn from the same communities. However, in each site, this limited our ability to examine changes in screening rate

disparities between groups. We were able to document changes in screening rates for the target group in each site.

ES.4 Demonstration Funding

This demonstration was designed to have three sources of funding for each project site: (1) start-up payments, (2) payment for administration of CMS-mandated participant surveys, and (3) capitated payments for navigation services. An additional source of emergency funding was also made available during the course of the project.

First, the initial source of demonstration funding was a one-time $50,000 payment at the beginning of each project to help cover start-up costs.

Second, the sites received a fixed payment for each baseline Cancer Status Assessment (CSA) survey they completed on participants in both the intervention and control groups. They also received payments for administering an annual survey to all intervention group participants. CMS required these annual surveys as a means of validating that intervention group members remained enrolled in the demonstration. Sites received payment for similar exit surveys administered at the end of the demonstration period for all participants, both intervention and control. Payments for all surveys were negotiated individually with sites and vary considerably.

Third, sites received a capitated monthly payment for each intervention group participant per month of enrollment. This payment covered the cost of navigation services and varied across sites. The sites proposed payment rates on the basis of their expected costs and then negotiated these amounts with CMS. The same rate was used for intervention participants in both the site's screening arm and its treatment arm, despite the potentially higher navigation intensity for treatment participants. Since treatment participants were not in the initial active phases of treatment, as most had been diagnosed 3-5 years before the demonstration baseline, this was not a concern.

Capitation payments and the CSA payments were negotiated in advance between each site and CMS. Capitation and CSA payments therefore varied by site. Sites billed CMS for the CSA surveys using special demonstration billing codes. Monthly capitation payments were made to the sites automatically, once participants were enrolled in the intervention group, and continued as long as they remained eligible. There was no beneficiary liability (i.e., no coinsurance or deductible) for these demonstration navigation services. All clinical screening, diagnosis, and treatment services were billed and paid through the normal Medicare claims process.

Five of the six sites (all but Moloka'i) incurred substantial debt in the first year (above and beyond the $50,000 in start-up funding), generally because slower-than-expected enrollments meant that staffing and other costs were not quickly offset by capitation payments. In response to these mounting financial obligations, CMS renegotiated with individual sites, increasing capitation payments, CSA payments, lump sum payments, or some combination of these for debt relief. Four of these five sites (all but Josephine Ford) continued to receive additional cash payments in each subsequent year of the demonstration. None of these additional amounts had been anticipated by CMS. Total CMS spending on the CPTD remained unchanged,

however; that is, it did not exceed the $25 million obligated by Congress. Cumulative demonstration financing information for each site is presented in Table ES-4.

Table ES-4
Cumulative financing by site, in dollars

Site	Start-up fee	CSA Fee + capitation	Additional funding	Total
Huntsman Cancer Institute	50,000	2,646,730	1,023,375	3,720,105
Johns Hopkins University	50,000	3,743,249	1,609,021	5,402,270
Josephine Ford Cancer Center (Henry Ford Health System)	50,000	5,072,019	349,727	5,471,746
The University of Texas, M.D. Anderson Cancer Center	50,000	1,941,574	2,274,813	4,266,387
The University of Medicine and Dentistry of New Jersey	50,000	1,765,710	1,037,168	2,852,878
Moloka'i General Hospital	50,000	682,202	0	732,202
Total	300,000	15,851,484	6,294,104	22,445,588

NOTES: CSA = Cancer Status Assessment. The first column is the start-up fee each site received. The second column is the sum of the CSA and capitation fees that each site received. The third column is the amount of additional funding each site received, and the fourth column is the total amount of funding that each site received. RTI did not have the level of detail necessary in the data to approximate funding for CSA and capitation fees separately.

SOURCE: Centers for Medicare & Medicaid Services, 2011.

ES.5 Patient Navigation Interventions

The screening intervention group participants received navigation services to help ensure that they were administered the appropriate screenings for breast, cervical, colorectal, and prostate cancer in accordance with Medicare coverage policy for preventive services (CMS, 2011) and clinical practice guidelines. Guidelines were consistent through the demonstration period from 2006-2011. Sites varied in the specific screening guidelines they adopted, resulting in some variation in participant eligibility—for example, Josephine Ford did not recommend Pap smears for female beneficiaries aged 70 and older if they had a prior history of normal tests. Screening intervention group participants who had positive test results also received navigation services to help them obtain any necessary follow-up diagnostic tests. Sites varied in whether participants were contacted by phone or in person. Phone contact was more common, with the exception of Huntsman which did more patient navigation in person. Table ES-5 presents data on the type of activities that PNs offered intervention group participants.

Table ES-5
Reports of services provided by patient navigators from the screening arm, by demonstration site

Screening participants' reports	Huntsman	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i
Sample size	1,290	1,797	3,239	1,533	969	376
Often or sometimes…*						
…provided me with information about cancer-related services, resources, or support groups in my community.	77.6	41.8	47.2	64.5	72.5	95.9
…helped to schedule my medical appointments for me.	50.9	16.4	16.1	9.0	42.4	75.7
…helped me to talk with medical staff and doctors.	7.0	8.1	4.5	5.5	28.6	13.0
…talked to medical staff and doctors on my behalf so they could explain things to me.	4.3	8.8	2.3	3.9	20.2	9.9
…helped me fill out medical paperwork.	24.9	6.5	4.0	4.8	16.9	13.5
…helped me arrive at scheduled medical appointments on time and prepared.	19.6	7.7	4.4	3.0	23.2	37.8
…helped me find ways to pay for my medical care.	1.8	5.9	1.0	4.1	6.9	10.4
…helped me find transportation to get to my medical appointments.	24.3	9.9	4.1	3.3	17.2	9.3
...helped me arrange for someone to take care of my spouse or other family members so I could go to my medical appointments.	1.6	46.8	0.5	1.5	4.8	1.0
...contacted me by mail to remind me to make an appointment for my cancer follow-up.	23.7	13.8	51.3	28.1	41.9	97.9
...contacted me by telephone to remind me to make an appointment for my cancer follow-up.	53.5	37.4	42.8	50.3	42.0	96.4
…helped me to make additional follow-up medical appointments if I needed them.	25.8	11.6	11.9	12.4	19.9	71.0

NOTES: *Often and Sometimes are response categories that we combined for presentation. The excluded category is the "Never" response category.

UMDNJ = University of Medicine and Dentistry of New Jersey.

The intervention group in the treatment arm consisted of participants who had already been diagnosed with cancer. These participants received navigation services to ensure completion of all primary and secondary cancer treatments and all necessary follow-up and monitoring.

Control groups in each arm received relevant educational materials. The materials varied across sites, but typically described cancer risk factors, the importance of screening, and the importance of adhering to treatment protocols. CMS reviewed and approved all educational materials in advance.

CMS did not specify a standard patient navigation intervention to be used by all six sites. Instead, CMS recognized that each site would need to develop its own navigation model to ensure that the intervention was culturally sensitive to the needs of each minority community. The variation in both PN models and target populations across the sites introduced complexities to the evaluation of the CPTD demonstration.

Because the concept of patient navigation was relatively new to cancer care at the time the demonstration began, many aspects of it had not been well established in the literature. Even finding an agreed-upon definition of what patient navigation entails was challenging. Recent articles describe it as a "type of care management that encompasses a wide-range of advocacy and coordination activities" (Battaglia, et al., 2007). What these activities entail for PNs varied quite dramatically across programs, with differences in their roles and responsibilities, the background and training required of the them, and the point during care that they were to provide their services.

Sites' models of patient navigation in this demonstration varied in the extent of clinical oversight by a nurse. Three sites (Josephine Ford, Moloka'i , and M.D. Anderson) had nurses supervising lay navigators at the start of the demonstration, but Moloka'i and M.D. Anderson dropped nurse involvement during the demonstration. As nurses left the program, they felt that patient navigation activities could be conducted by lay navigators. At Ford, the nurses focused on assessing participants' service needs, interacting with health care providers as needed, and ensuring that care was received, whereas the advocates focused on scheduling appointments for the patients and ensuring that participants had access to any related services. At the time of the second site visits, these sites explained that they believe their decisions not to fill the vacant nurse positions was ideal for the program and allowed them to better support those working as lay navigators. All of these sites said that the clinical oversight provided by the senior staff affiliated with the program was sufficient. The Ford program still operated with a nurse/lay navigator model but had reduced the number of teams working with patients from seven to five. This reduction was precipitated by people leaving their positions and the site opting not to fill the vacancies.

The second model, used by five sites, relied almost entirely on lay navigators who provided the bulk of services directly to participants. For all of the programs, although clinical expertise was evident among key staff members, such as the principal investigator or another lead program staff member, the lay-only navigator model provided less direct access to this expertise than the nurse/lay navigator model. In these five programs, those with clinical expertise did not provide day-to-day oversight of the work of the PNs; instead, mostly physicians were available to the PNs as needed. One advantage to using this type of model was that by having only lay navigators, whose salaries were significantly less than those of nurses, the programs were able to afford more PNs to reach more participants.

In both models, the lay navigators worked to address participant barriers to attending appointments. Interestingly, PNs at all six sites reported similar barriers among their participants, including fears of being diagnosed with cancer and a lack of transportation. A general lack of understanding regarding cancer screening and a distrust of the health care system were also reported among patients across the sites. Three sites also said that patient comorbidities were a major issue in providing services. Patients with multiple chronic diseases often needed additional services to address their needs specific both to cancer and to their other illnesses. One site (M.D. Anderson) had a protocol in place to actively navigate these patients so that they obtained care for their other diseases. Another site (Johns Hopkins) navigated these patients for the other services only if lack of other services interfered with their receipt of cancer screening or treatment services. For these patients, Johns Hopkins provided more limited navigation for comorbidities. The third site (UMDNJ) did not navigate these patients to address the needs specific to their other health concerns. Two other sites (Moloka'i and the Montana reservations for Huntsman) tended to provide this service incidentally and had no protocol in place with respect to comorbidities. Because the PNs at these sites were so integrally involved in the communities, they knew most of their patients personally and shared stories of how they were often asked to provide transportation or other assistance in obtaining care for other diseases.

ES.6 The Screening Arm

In each site, the bulk of the participants were in the screening arm. Meeting enrollment goals proved more time-consuming than sites had anticipated for both study arms but was far more difficult in the treatment arm relative to the screening arm. The screening arm was also always intended to be bigger. In addition to difficulties reaching and enrolling participants in the demonstration, once participants had enrolled, many became ineligible for the demonstration because of their enrollment in managed care. As a percentage of the overall enrollment across all sites, about 15.1 percent voluntarily disenrolled from the demonstration and was in managed care the next month. Because of this, recruitment and enrollment were ongoing site concerns. As shown in Table ES-3, Moloka'i enrolled 488 screening arm participants, Ford enrolled 5,398, and the other sites enrolled between 1,100 and 2,600 participants each. Once participants were enrolled, PNs established contact with them, conducted the baseline CSA, assessed their needs, and tried to reduce barriers to screening. (We note that the sample sizes for the baseline data (Table ES-6) are not the same as the final enrollment numbers from CMS (Table ES-3) because we limited the analytic sample to those with at least 6 months of enrollment in the demonstration. This exclusion was to allow participants the time in the demonstration to receive services or screenings, and it did not change the demographic composition of the sample. Other data issues, like removing duplicate records and unmatchable identification numbers, also reduced the sample size of the analytic file.)

All six sites relied primarily on participants telling the PN what their screening results were and whether follow-up care was needed. If participants seemed confused or uncertain about what they should do, PNs would try to help patients understand their results and follow-up plans when they could, but in general, each site had established procedures so that the PNs would help patients contact their health care providers to answer any questions. The primary reason for this procedure was that respondents expressed concerns about the lay PNs providing any type of medical advice or answering questions because they had no clinical training. Even at Josephine

Ford, the one site that maintained a nurse/lay navigator model, a number of physicians had expressed concern about nurse navigators influencing what patients did for their treatment or follow-up care. Once participants were up to date with their screenings, all of the sites were to maintain ongoing contact with them.

Table ES-6
Demographic characteristics of screening arm participants, by demonstration site

Screening participant	Huntsman	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i
Sample size	1,540	2,313	4,809	1,915	1,071	377
Female (%)	58.5	73.4	68.4	60.0	62.8	51.7
Age (%)						
< 65	26.3	0.1	22.7	20.7	24.6	21.8
65–69	24.4	35.0	24.6	25.8	26.2	28.4
70–74	23.8	29.6	19.3	24.4	24.0	21.8
75–79	14.1	19.2	16.2	15.3	16.3	14.1
80–84	7.8	10.6	11.4	9.3	6.2	9.3
85+	3.6	5.5	5.9	4.6	2.7	4.8
Dual eligibility status (%)	54.1	18.3	30.5	36.3	68.4	23.6
Education (%)						
High school or more	48.7	66.7	63.6	37.8	35.8	63.1
Marital status (%)						
Married/living with partner	48.1	28.8	30.3	57.8	36.0	52.5
Living arrangements (%)						
Alone	22.7	43.0	46.1	23.9	45.6	19.1
Have children (% yes)	90.2	87.8	85.8	91.5	89.1	85.6
Income (%)						
Less than $10,000	44.2	23.6	25.6	21.4	48.6	27.8
$10,000–$19,999	25.1	27.8	28.9	37.8	36.1	23.8
$20,000+	30.7	48.6	45.4	40.8	15.3	48.4
Speak mainly English at home (%)	73.1	98.3	99.1	45.3	5.2	83.3

NOTE: The sample sizes for the baseline data are not the same as the final enrollment numbers from the Centers for Medicare & Medicaid Services because we limited the analytic sample to those with at least 6 months of enrollment in the demonstration. Other data issues, like removing duplicate records and unmatchable identification numbers, also reduced the sample size of the analytic file. UMDNJ = University of Medicine and Dentistry of New Jersey.

SOURCE: RTI analysis of baseline Cancer Status Assessments completed at time of enrollment in the demonstration. (Program: cptd009)

ES.7 Demographics of Screening Arm Participants at Baseline

Participants enrolled in the screening arm completed a baseline survey. This group constituted the main study sample. Although their characteristics varied considerably between sites, the intervention and control groups were remarkably similar within sites because of the random assignment procedures used. At Huntsman, where participants were not randomly assigned, there were some differences in characteristics between intervention and control groups (detailed in the final report). This was also true of Moloka'i, where initial implementation included control groups from the island of Oahu.

Table ES-6 shows the demographic characteristics of the screening arm participants. In general, the participants in this demonstration were women between the ages of 65 and 80, who had at least a high school education, spoke mainly English at home, had children, did not live alone, and had annual incomes below $20,000. Percentages of dually eligible beneficiaries varied from 18% at the Johns Hopkins site to 68% at UMDNJ. UMDNJ was also an outlier in the percentage of participants (95%) who reported that they spoke mainly a language other than English at home. These characteristics may have had implications for the type of support that participants wanted from their PNs, with participants who lived alone needing more help with transportation and those who spoke less English needing help communicating with physicians.

An earlier analysis that was part of the second Report to Congress examined whether demonstration participants were similar to other eligible local Medicare beneficiaries who were nonparticipants. Within each site, participants and nonparticipants were compared along several dimensions: age, gender, original reason for Medicare entitlement, dual eligibility for Medicaid, Medicare expenditures before the start of the demonstration, Medicare risk score,[2] the use of cancer screening tests in the year before the start of the demonstration, and vaccination for influenza before the start of the demonstration.

These analyses showed significant differences between participants and nonparticipants in their demographic characteristics and use of preventive services. In most sites, demonstration participants were younger, more likely to be female, and more likely to have received cancer screening services and an influenza vaccine before the start of the demonstration. However, the results for Huntsman and Moloka'i indicate that participants were less likely to use certain preventive services. In the other four sites (i.e., Josephine Ford, Johns Hopkins, M.D. Anderson, and UMDNJ), individuals who had received cancer screening tests in the past were more likely to participate in the demonstration than those who had not had previous cancer screenings. Participants and nonparticipants did not have significantly different overall Medicare expenditures or Medicare risk scores in most sites. At most sites, there were also no differences between participants and nonparticipants in original reason for Medicare entitlement or dual eligibility for Medicaid. However, at UMDNJ, participants were markedly more likely than nonparticipants to be dually eligible. These differences may affect the generalizability of the evaluation results, although it is difficult to predict how impacts in a broader population would differ from those in the demonstration population. Because participants were generally more

[2] The Medicare risk score, also known as the hierarchical condition categories score or HCC, is an expenditure-weighted index of a beneficiary's diagnoses that predicts the relative risk for future Medicare expenditures.

likely to have been receiving cancer screening tests even before the demonstration was implemented, patient navigation may have been more likely to increase use of cancer screening services if it had been offered to populations with lower baseline use of these services. However, it is also possible that individuals who enrolled may have been more receptive to using these services, so that results of the demonstration could show increases in screening.

ES.8 Did Demonstration Activities Reduce Disparities for Racial and Ethnic Minorities?

Reductions in screening disparities under the demonstration were measured by comparing screening rates for the intervention group with those for the control group. By design, both groups within the screening arm were from the same priority (racial or ethnic minority) population.

The site-provided identifying information was used to create an analytic sample using Medicare claims data. Using procedure codes for each type of cancer screening, for each participant we created variables that reflected screening status before and after demonstration enrollment. Group means for screening rates are presented by site. Screening rates presented in Table ES-7 reflect the individual's entire period of enrollment in the demonstration, compared with that same length of time before demonstration enrollment. The average length of time that participants remained enrolled in the demonstration ranged from a low of 16 months to a high of 23 months; on average across all sites, it was 20.4 months. To determine whether any of the changes in screening rates between intervention and control group were statistically significant, we used logistic regression and controlled for pre-enrollment screening rates and demographic differences between intervention and control groups. Although controlling for differences in demographic characteristics between intervention and control groups would not be necessary if randomization were perfect, we wanted to be sure that underlying demographic differences were not responsible for intervention effects. In addition, randomization was not perfect in Huntsman and Moloka'i, as these sites had received CMS approval to implement variations of randomization. In Table ES-7, asterisks indicate significant differences between intervention and control participants in screening rates after enrollment in the demonstration.

Mammography was the screening test most likely to show statistically significant intervention impacts, with increases in four of the six sites. Pap smears showed statistically significant increases in three sites and prostate-specific antigen test (PSA) and colonoscopy in two. None of the sites showed improvement in fecal occult blood test (FOBT) testing, but note the very low levels of testing. Of the six sites, only Moloka'i demonstrated improvements in screening for all four study cancers. UMDNJ showed improvements in three screening tests, whereas Johns Hopkins and Josephine Ford both showed increases in two. Huntsman and M.D. Anderson did not demonstrate any statistically significant improvement in any of the screening tests.

Table ES-7
Cancer screening rates for screening arm participants before and after enrollment in the demonstration, by group and by site

Screening test	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter	Control	Inter.	Control	Inter.
Sample size	813	727	1,103	1,210	2,337	2,472	968	947	526	545	182	195
Pap smear (%)												
Pre	6.8	7.2	23.2	22.0	27.6	27.7	19.5	22.2	30.9	31.5	25.3	20.8
Post	8.3	10.3	21.2	26.0*	24.4	25.4	17.3	17.5	30.6	44.5*	23.2	49.0*
Mammogram (%)												
Pre	19.7	16.8	58.0	62.0	65.8	64.2	44.6	44.7	56.3	58.2	37.4	21.1
Post	24.6	24.1	60.4	68.1*	62.4	69.3*	44.0	45.7	57.4	72.1*	44.4	62.1*
Prostate-specific antigen test (%)												
Pre	23.2	11.1	49.1	46.7	73.6	68.2	50.0	47.3	58.2	59.4	35.5	33.7
Post	22.1	15.0	51.9	57.3	69.6	74.8*	48.8	45.0	72.4	64.5	35.9	54.4*
Colonoscopy (%)												
Pre	12.3	10.2	17.9	17.6	23.0	23.0	11.8	13.6	23.5	23.2	8.7	7.9
Post	13.6	13.9	19.1	21.2	23.1	23.8	13.8	15.2	27.6	31.6*	9.8	28.3*
Fecal occult blood test (%)												
Pre	0.7	0.8	5.4	6.0	6.5	6.2	5.9	5.1	2.2	2.5	1.7	1.7
Post	0.4	1.4	4.1	5.4	5.3	4.6	5.3	6.0	2.4	4.0	1.7	1.7

NOTES: Percentages were calculated on the basis of gender-specific Ns where appropriate. Inter. = intervention; Pre = before enrollment in the demonstration, where pre-enrollment is time equal to individual duration of enrollment; Post = after enrollment in the demonstration, including entire duration of enrollment; UMDNJ = University of Medicine and Dentistry of New Jersey.

*Significantly different from control group at 0.05 level.

SOURCE: RTI analysis of Medicare claims (2002–2010) of screening arm participants answering baseline Cancer Status Assessments. (Program: CPTD037)

Reductions in disparities in quality of life are also of interest in this demonstration. Beneficiary function was monitored through repeated administrations of the EQ-5D™—at baseline, in the annual surveys, and in the exit survey. The EQ-5D™ is a preference-based measure of health status that combines responses to five questions about physical function and emotional well-being into a summary score. Higher scores represent better function levels. In older adults, EQ-5D™ scores generally decline slowly over time. The mean score for 65- to 74-year-olds in the United States is 81.1, and it drops to 75.5 in those over 75 years of age (Nyman, 2007). Demonstration participants had lower scores than the national means, and they showed slight declines over the demonstration period. At Josephine Ford, the post-enrollment EQ-5D™ score was significantly better for the intervention group than for the control group. For the other sites, no differences were statistically significant.

ES.9 Did Demonstration Activities Reduce Medicare Expenditures of Participants?

Although Medicare expenditures may decline over a longer time period due to early detection and treatment associated with patient navigation, we did not expect to observe any reductions during the relatively short time horizon of this demonstration. At the same time, we hypothesized that Medicare spending for intervention group participants might actually increase, if, for example, PNs successfully steered these participants to other health care providers for treatment of comorbid diseases. In fact, we found no significant differences between intervention and control group participants, based on their total Medicare Part A and Part B claims (see Table ES-8). (Part D claims were not available for this study.) Adding in the capitation payments each site received for its intervention group participants does not change the basic findings, except for one site (Johns Hopkins). Once we account for these payments, intervention group participants become more costly than their control group counterparts only in the Hopkins site.

Our calculation of total expenditures for each individual is for the entire duration of their enrollment in the demonstration, and it is compared with the same amount of time before their demonstration enrollment. There is large variability around Medicare expenditures in general, and the lack of significant changes could reflect this variability. Intervention-related changes would need to be very large indeed to be detected as significant.

ES.10 Were Participants Satisfied With the Patient Navigation Experiences?

The final Congressional question is whether members of the intervention group were satisfied with the services they received as part of the demonstration. Because the control group did not receive services, this analysis can be descriptive only. Ideally, satisfaction would be assessed at the end of the demonstration through the exit CSA. Unfortunately, exit CSAs were missing for a large number of participants. Where possible, we used annual CSA data to provide information on satisfaction with patient navigation services.

Table ES-8
Medicare expenditures for screening arm participants before and after enrollment in the demonstration, by group, by demonstration site

	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
Expenditures	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.
Sample size	813	727	1,103	1,210	2,337	2,472	968	947	526	545	182	195
Total expenditures												
Pre	$14,264	$11,534	$11,696	$10,359	$13,944	$15,698	$9,423	$11,207	$12,784	$11,967	$4,336	$6,697
Post	$19,530	$16,753	$17,421	$16,482	$22,747	$23,376	$12,508	$14,387	$19,073	$18,709	$10,413	$10,405
Difference (post − pre)	$5,266	$5,219	$5,725	$6,123	$8,803	$7,677	$3,085	$3,180	$6,289	$6,742	$6,077	$3,708
Total expenditures post including capitation payments	$19,530	$18,410	$17,421	$18,529*	$22,747	$24,978	$12,508	$15,778	$19,073	$20,901	$10,413	$12,462
Difference (post − pre)	$5,266	$6,876	$5,725	$8,170*	$8,803	$9,280	$3,085	$4,571	$6,289	$8,934	$6,077	$5,765

NOTES: Inter. = intervention; Pre = before enrollment in the demonstration, where pre-enrollment is time equal to individual duration of enrollment; Post = after enrollment in the demonstration, including entire duration of enrollment; UMDNJ = University of Medicine and Dentistry of New Jersey.

*Significantly different from control group at 0.05 level.

SOURCE: RTI analysis of Medicare claims (2002–2010) of screening arm participants answering baseline Cancer Screening Assessments. (Program: CPTD037 and 039.)

Table ES-9 presents the experiences of the intervention group with PNs. Intervention group members reported considerable satisfaction with the educational materials they received, as well as with referrals and support services. At least 75% in each site agreed or somewhat agreed that they valued working with a PN and would recommend this service to others. Similarly, 70%-95% of participants at each site reported their experience as excellent or very good. It is worth noting that in many cases the person asking about participant satisfaction with patient navigation was, in fact, their patient navigator.

Although control group participants did not receive patient navigation services through the demonstration, it is possible that they still received similar facilitation services from others (e.g., from family, friends, health care worker). We had planned to compare use of such services between intervention and control group participants, using the exit CSAs. However, given the large number of missing exit CSAs, and the systematic differences in exit CSA response rates between intervention and control groups, we could not conduct this analysis. It is worth noting, however, that at least one-third of participants reported at baseline that they did not need help with setting up medical appointments, transport to them, or coordination support more generally.

ES.11 The Treatment Arm

Enrollment in the treatment arm of the CPTD demonstration was very difficult for sites, and not one site met its enrollment goals for the treatment arm. As shown in Table ES-10, the sample sizes are very small—not even reportable for three sites. On the basis of guidelines used by the National Center for Health Statistics, we have determined that no treatment arm data can be reported for Moloka'i, Huntsman, or UMDNJ, as intervention or control group sample sizes are less than 30.

In addition, patient navigation in the treatment arm was meant to support those who were newly diagnosed with cancer, to increase their adherence to guidelines for diagnostics and treatment during the most intense time. The average length of time with cancer is 3–5 years, which no longer reflects the active treatment phase that could benefit most with patient navigation support. This length of time with cancer reflects a surveillance phase, where Medicare and National Comprehensive Cancer Network guidelines suggest that periodic screening and physician visits are paramount. In examining screening rates, because of sample size constraints, we were not able to limit the sample to look at mammography rates in breast cancer survivors or PSA rates in prostate cancer survivors. Instead, we report all cancer screenings that are relevant to men or women, in addition to numbers of physician visits and emergency room visits. Breast cancer for women and prostate cancer for men were the most prevalent cancers at each site, followed by lung cancer. The average length of enrollment across all sites for the treatment arm was 19.3 months. There were no statistically significant differences in screening rates or physician visits between intervention and control groups. This result may be due in part to small sample sizes and to the fact that within the small samples, intervention and control groups in each site had different mixes of cancers.

We cannot address satisfaction questions because of the small samples responding to the exit CSAs. The only satisfaction measure that we can report is that approximately 77% of the intervention group at Josephine Ford and M.D. Anderson reported excellent or very good ratings of their experiences with the PNs.

Table ES-9
Satisfaction with PNs from the screening arm (intervention group only), by demonstration site

Screening participants' reports	Huntsman	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i
Sample size	445	717	1,707	571	395	193
The education materials I received were helpful.						
Agree or somewhat agree	67.7	68.6	53.9	77.4	89.1	99.0
Neither agree or disagree	27.8	13.3	43.8	14.5	3.5	1.0
Somewhat disagree or disagree	4.5	2.0	2.4	1.9	0.0	0.0
The support services referrals met my needs.						
Agree or somewhat agree	65.2	58.8	40.5	65.1	80.5	94.3
Neither agree or disagree	29.6	15.5	56.5	20.0	4.1	5.7
Somewhat disagree or disagree	5.2	2.8	3.1	1.2	0.0	0.0
I would recommend this service to others.						
Agree or somewhat agree	77.0	88.9	84.1	85.4	97.2	99.5
Neither agree or disagree	19.8	8.7	15.6	13.2	2.8	0.5
Somewhat disagree or disagree	3.2	2.4	0.2	1.4	0.0	0.0
I valued working with the navigator.						
Agree or somewhat agree	79.0	85.3	74.8	79.0	93.9	97.9
Neither agree or disagree	18.1	12.3	24.3	19.4	5.8	2.1
Somewhat disagree or disagree	2.9	2.4	0.9	1.6	0.3	0.0
Rating of experience with a PN						
Excellent or very good	70.0	80.2	69.9	75.7	86.8	95.3
Good	24.1	15.1	26.7	22.5	12.7	3.6
Fair or poor	5.9	4.6	3.5	1.8	0.5	1.0

NOTE: PN = patient navigator; UMDNJ = University of Medicine and Dentistry of New Jersey.

SOURCE: RTI analysis of exit Cancer Status Assessments (CSAs), supplemented by annual CSAs when exit CSAs were not completed. (Program cptd027.)

Table ES-10
Sample characteristics, screening rates, visit rates, and expenditures for treatment arm participants, before and after enrollment

	Johns Hopkins		Josephine Ford		M.D. Anderson	
Treatment participants	Control	Inter.	Control	Inter.	Control	Inter.
Sample size	77	78	185	196	126	137
Female (%)	41.6	44.9	41.1	43.4	58.7	42.3
Length of time with cancer (years)	4.6	3.2	3.7	3.4	3.5	4.2
Type of cancer (%)						
Breast	28.6	29.5	29.7	32.7	44.4	27.7
Cervix	0.0	1.3	0.5	2.6	6.4	9.5
Colon or rectum	7.8	11.5	7.6	9.2	11.9	13.9
Lung	18.2	11.5	11.9	5.6	6.4	2.9
Prostate	45.5	46.2	50.3	50.0	31.0	46.0
Colonoscopy (%)						
Pre	11.7	10.3	25.9	27.0	20.6	16.8
Post	10.4	11.5	23.2	27.0	23.8	21.2
Mammogram (%)						
Pre	18.2	24.4	30.8	34.7	31.0	26.3
Post	19.5	19.2	31.4	32.1	35.7	24.1
Pap smear (%)						
Pre	13.0	10.3	12.4	15.3	25.4	15.3
Post	2.6	3.8	10.3	12.2	18.3	16.8
Prostate-specific antigen test (%)						
Pre	39.0	41.0	53.5	48.0	30.2	46.0
Post	45.5	42.3	53.0	49.0	27.8	43.1
Physician visit (N)						
Pre	6.2	7.1	15.0	15.9	12.6	13.8
Post	6.1	7.2	15.8	16.7	15.5	16.8
Oncology visit (%)						
Pre	1.2	0.5	2.1	2.4	2.0	3.6
Post	1.4	0.5	0.8	0.8	2.6	2.7
Emergency room visit (%)						
Pre	0.6	0.6	1.4	1.5	0.7	0.7
Post	0.4	0.5	1.7	2.1	1.1	0.9

NOTES: Percentages were calculated on the basis of gender-specific Ns where appropriate. Inter. = intervention; Pre: before enrollment in the demonstration, where pre-enrollment is time equal to individual duration of enrollment; Post: after enrollment in the demonstration, including entire duration of enrollment.

SOURCE: RTI analysis of baseline Cancer Status Assessments and Medicare claims (2002–2010). (Program cptd031.)

ES.12 Economic Evaluation of the Demonstration: Cost and Activities

RTI performed a detailed assessment of the cost incurred by the demonstration sites to understand the key activities required for a patient navigation program and the funding necessary to sustain such a program in the future. We utilized the Cost Assessment Tool (CAT), an Excel-based data collection tool, to collect detailed activity-based costs from the demonstration sites for both the start-up and the implementation periods. The start-up time period was defined as the time from the initiation of the demonstration to when the first beneficiary was enrolled in the program; it ranged from 5 to 12 months across the six sites. In addition to the CAT, RTI also developed an Excel-based tool to collect and report details on the activities and time spent by PNs to understand the types of tasks performed by these individuals during the course of the demonstration.

The sites performed a large variety of activities to implement patient navigation during both start-up and implementation. In both periods, about a quarter of the funding was spent on program management. Other resource-intensive activities during the start-up period included planning for patient recruitment, undergoing professional development, and planning for patient navigation tasks. During the implementation period, large cost categories included patient recruitment, data collection and CSA administration, and patient navigation.

On average, the total cost for each person enrolled in the intervention group was $3,591, but sites varied widely, with a range from $1,239 to $6,127. Overall the sites spent $288 per person on recruitment and outreach; $247 per person on data collection and CSA administration; and $368 per person for patient navigation. Other high-cost activities were program management and administrative or overhead costs, which averaged $1,157 and $1,142 per person, respectively.

Across all the programs, on average about 30% of the PNs' time was spent on screening navigation activities. Other activities with significant hours expended included planning and administrative tasks; data collection, tracking, and CSA administration; addressing comorbidities; and outreach and recruitment. Overall, 11% of the total time available was devoted to treatment navigation for those in the screening and treatment arms combined.

The findings from this cost study highlight that, to ensure a successful navigation program, a variety of activities ranging from patient recruitment to quality assurance are required and need to be supported. Because the sites were implementing programs within a demonstration, they did incur additional costs related to evaluation activities and perhaps performed more intensive data collection than would otherwise be required. Nevertheless, the cost estimates reported from these demonstration sites provide valuable information on the resources required to start and implement navigation programs in the future.

ES.13 Conclusions and Implications for Future Demonstrations

The CPTD was designed to reduce racial/ethnic disparities in cancer prevention and treatment by improving cancer screening rates and completion rates of cancer treatment. Unfortunately, recruitment into the treatment arm of the demonstration was difficult, and no impact was found for PNs, possibly because of the very small sample sizes. Enrollment into the

screening arm was considerably larger, but we found that the impact of patient navigation varied by site. One site (Moloka'i) succeeded in improving screening for all four cancers (breast, cervix, colon, and prostate). Two sites (Huntsman and M.D. Anderson) failed to show any statistically significant impact whatsoever. The remaining three sites were more variable, with one site demonstrating improvement in three of the four screening rates (UMDNJ) and two showing improvement in two rates (Johns Hopkins, Josephine Ford). These results are based on the entire duration of enrollment in the demonstration (an average of 16–23 months, depending on site). When we limited the analysis to the first year of enrollment, UMDNJ and Johns Hopkins demonstrated improvement for only two and one screening tests, respectively.

What accounts for these mixed results across sites? Although it may be difficult to pinpoint exactly, we can use our two prior rounds of site visits, as well as the PN activity surveys completed by each site, to shed some light on these differences:

- Variations in design and implementation of the patient navigation model—CMS did not specify a standardized PN model, allowing each site to design the approach it deemed most appropriate for its target population. As a result, the demonstration cannot serve as a test of patient navigation per se. The sites also varied considerably in the amount of planning and model development they did before implementing the demonstration. More time spent developing relationships with local partners, understanding the target population and the barriers they faced, and learning about the characteristics of the Medicare population in their communities would have greatly benefitted those sites that had difficulties enrolling participants (all but Josephine Ford and Moloka'i).

- Difficulties in enrollment and retention—Four of the six sites encountered difficulties in identifying eligible Medicare beneficiaries and enrolling them in the demonstration. This resulted in a slower-than-anticipated start-up for these sites, especially for Johns Hopkins and M.D. Anderson, so that there was less time actually to navigate intervention group participants. Some sites found that some participants unexpectedly dropped from the demonstration (because of managed care enrollment), also shortening the time for navigation and increasing the time that sites spent focused on enrollment.

- Geography—Moloka'i is a small, self-contained island with a single 15-bed hospital. The site's PNs could easily reach its small group of intervention participants and even drive them to screening appointments. By contrast, participants in the Huntsman site were spread across vast areas of isolated Native American reservation land. Many participants did not have telephones, requiring PNs to travel long distances only to find them not at home.

- Limited time for patient navigation activities—On average, PNs spent about half their time in non-navigation activities. These included such things as recruitment, CSA administration, and training—activities that were important but that took time away from actual patient navigation.

- Non-randomization of Huntsman site—Because of cultural concerns, the Huntsman demonstration randomized clusters of communities, rather than randomizing individuals, as was done in the other five sites. As a result, there were some demographic differences between the intervention and control group participants, thereby compromising the randomization. "Contamination" of the control group also occurred, as Huntsman navigators reported that they provided services to control group participants when asked to do so.

The CPTD provides some valuable lessons learned for future demonstrations of this type, both for future sites to consider and for CMS.

Lessons learned for future demonstration sites

- *Understand your target population and local community ahead of time.* Sites need to determine what barriers to screening actually exist for their targeted racial/ethnic group before designing the intervention. Sites also need to assess whether there is local distrust of their institution that might hinder enrollment.

- *Identify local partners and begin working with them prior to implementation*. Sites need to learn what community-based organizations already exist in the local community that might be providing similar, or complementary, services. Sites also need to gain the trust of local primary care physicians in order to enlist their support and cooperation with the demonstration.

- *Understand the Medicare program as it affects the targeted racial/ethnic group*. All of the sites failed to recognize the Medicare Advantage (managed care) penetration rate in their communities. As a result, they under-estimated how many beneficiaries would be eligible for the demonstration. Sites also need to determine how many of their targeted beneficiaries are dual eligible and the special challenges posed by this population.

- *Develop the patient navigation model ahead of time*. Some sites developed the intervention "on the fly" without ensuring it was targeted to the needs of their community.

- *Do not start enrollment until the intervention is ready to be launched*. Many sites began enrolling participants into the demonstration before patient navigators were hired, trained, and ready to begin services.

- *Determine cancer incidence rates for the target population ahead of time*. Sites did not realize how few eligible participants would be diagnosed with new study cancers over the course of the demonstration. As a result, far fewer than expected beneficiaries were recruited into the treatment arm of the demonstration. The inclusion of cancer patients who had already finished their course of treatment further weakened this arm of the demonstration.

Lessons learned for CMS

- *Consider a more standardized patient navigation model for testing.* Each site was allowed to develop their own model in order to ensure cultural appropriateness for the local community. However, this greatly limited the ability to evaluate patient navigation as a tool to reduce racial/ethnic disparities.

- *Ensure that sites submit an implementation plan before they begin enrollment.* Sites rushed to enroll participants before they had clearly thought through all the steps associated with providing patient navigation services. A detailed implementation plan would have provided valuable guidance to both CMS and the sites themselves.

CHAPTER 1
INTRODUCTION

Racial and ethnic disparities in cancer screening and treatment have been well documented. Minority populations are less likely to receive cancer screening tests than Whites and, as a result, are more likely to be diagnosed with late-stage cancer (Agency for Healthcare Research and Quality [AHRQ], 2004; National Institutes of Health/National Cancer Institute [NIH/NCI], 2001). Racial and ethnic minorities with positive test results are more likely to experience delays in receiving the diagnostic tests needed to confirm cancer diagnoses (Battaglia et al., 2007; Ries et al., 2003). Similarly, differences in primary cancer treatment and appropriate adjuvant therapy have been shown to exist between White and minority populations (AHRQ, 2004). Although the ability to pay is one of the explanatory factors, similar disparities have been found among Medicare beneficiaries. To address this problem, Congress mandated that the U.S. Department of Health and Human Services conduct demonstrations aimed at reducing disparities in screening, diagnosis, and treatment of cancer among racial and ethnic minority Medicare-insured beneficiaries (Section 122 of the Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000).

Section 122(c)(1) requires a report to Congress not later than 2 years after the date of implementation of the initial demonstration projects. The first Report to Congress was submitted in September 2008. The second Report to Congress was submitted in October 2010, and a final report will be submitted September 2012. The report is required to evaluate the demonstration project's effectiveness at reducing cancer screening disparities as well as the costs of the projects and the beneficiary satisfaction with the services provided through the demonstrations. In addition, the report is to include any other information regarding the demonstration as the Secretary of the U.S. Department of Health and Human Services determines to be appropriate. An appropriation of $25 million was designated to support the demonstration and its evaluation, and the legislation stipulated that at least nine sites be awarded.

When reviewing the budgets of the proposals submitted for consideration, the Centers for Medicare & Medicaid Services (CMS) concluded that it could award either six projects for 4 years or nine projects for 3 years. Given the start-up time needed to implement and accrue participants, a 3-year demonstration would not yield data needed to provide sufficient findings to Congress before the projects would have to be terminated. Therefore, CMS determined that a 4-year demonstration would enable a more comprehensive study of cost-effectiveness based on at least 2 full years of intervention data. It was originally thought that this longer period would permit CMS to determine whether the projects should be extended before they are terminated because CMS would no longer have a mandated appropriation for their continued operation.[3]

CMS contracted with the Schneider Institute for Health Policy at Brandeis University, which, together with the Boston University Center of Excellence in Women's Health and other consultants, was directed to "identify concepts and models that have a high probability of

[3] As discussed later in this report, sites experienced far more difficulty than expected in recruiting participants into the demonstration. As a result, the sites did not begin providing patient navigation services until the demonstration had been operational for a year or more.

reducing risk factors [for cancer], increas[e] use of Medicare-covered services, and improv[e] health and related outcomes for elder of color Medicare beneficiaries" (Brandeis University, 2003). The team developed recommendations for the design of the demonstrations, and CMS decided to assess the use of patient navigators (PNs) to help steer Medicare beneficiaries through the health care system (Brandeis University, 2003).

The American Cancer Society (ACS) was the first organization to introduce a PN program to a hospital in 1990; in 2005, it formally launched the ACS Patient Navigator program. The PNs are full-time employees, are nationally trained, and provide a variety of services to underserved patients. As of 2007 there were 60 program sites across the United States (IAF, 2007). Services range from arranging transportation to providing information on financial assistance programs.

The National Cancer Institute (NCI) has three research projects to evaluate the cost-effectiveness and efficacy of patient navigation. The main research project (PNRP) is a $25-million, 5-year study of eight sites looking at four types of cancer. Each of the sites individually partners with local organizations to serve underserved populations. This program has a variety of types of navigators—paid professionals and volunteers, social workers and nurses, and laypersons and community health workers. The study is examining whether the type of navigator, the location of the navigator, and language matching affects outcomes, as well as whether the type of navigator impacts cost-effectiveness.

The Health Resources and Services Administration (HRSA) funded six projects for the 2-year demonstration, beginning in September 2008, to support patient navigation programs in communities with significant health disparities and barriers to health services. The PNs are responsible for helping patients learn about chronic disease, such as cancer, diabetes, cardiovascular disease, obesity, and asthma, and helping them access screening and treatment (HRSA, 2012).

The Clinical Directors Network (CDN), a nonprofit network of primary care clinicians in community and migrant health centers, published a study of 1,413 women across 11 health centers. The women participated in a telephone-based PN program designed to improve cancer screening. All of them were overdue for screenings; they were provided with information on screening and given assistance in arranging appointments. Screening rates for three cancers (breast, cervical, and colorectal) increased in the intervention group.

Although these studies began at approximately the same time as the CMS demonstration project, the CMS study included patient navigation interventions aimed at cancer screening and treatment and focused on specific minority population that had Medicare coverage. Another key difference in terms of the design is that the patient navigation intervention was randomly assigned so comparing the intervention and control group yields unbiased impacts of patient navigation. In addition, the CMS study included a detailed assessment of the activities and the costs of patient navigation, which allow a more detailed understanding of what patient navigation might include in the different sites. Table ES-1 compares the PN programs.

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treatment and focused on specific minority populations that had Medicare coverage. Another key difference in terms of the design is that the patient navigation intervention was randomly assigned, so comparing the intervention and control group yields unbiased impacts of patient navigation. In addition, the CMS study included a detailed assessment of the activities and the costs of patient navigation, which allows a more detailed understanding of what patient navigation might include in the different sites. Table 1-1 compares the PN programs.

Table 1-1
Comparison chart:
multi-site patient navigation program overview

Name	Target population	Sites	Focus area	Navigator type
American Cancer Society Patient Navigator Program	Mostly medically underserved	More than 50	Cancer (various types)	Trained PNs
Medicare Cancer Prevention and Treatment	Demonstration for racial and ethnic minorities; minority Medicare fee-for service beneficiaries	6	Breast, cervical, colorectal & prostate cancer	Community health workers, sometimes supervised by nurses or medical social workers
Center to Reduce Cancer Health Disparities Patient Navigator Research Program	Racial/ethnic minorities; low income and underserved	9	Breast, cervical, colorectal & prostate cancer	Various
Clinical Directors Network	Underserved women	11	Screening for breast cancer	Trained care managers

SOURCE: Institute for Alternative Futures, 2007.

Available results from these and other efforts show that patient navigation can improve screening rates and reduce time to treatment in some cases, although there are limitations to the study designs implemented. One retroactive case study found that PN services reduced the time between presentation of breast cancer and initial treatment in an urban setting (Haideri et al., 2011). Patient navigation was also shown to improve mammography adherence among a similar population after a 9-month intervention (Phillips et al., 2010). In several studies with smaller sample sizes (Loreley et al., 2011; Ferrante et al., 2010), the authors concluded that PN services are beneficial to patients with special needs or barriers to treatment, but further research was necessary to generalize more broadly. Similarly, it is well documented that cancer patients value the assistance provided by PNs; many patients cite the emotional support, information, and logistical assistance they receive as evidence of the PNs' effectiveness (Carroll et al., 2010; Hendren et al., 2010). A thorough literature review [Hopkins et al., 2009) of recent research emphasized that 16 of 45 published studies provided data on efficacy of patient navigation services in improving timeliness and receipt of cancer screening, diagnostic follow-up care, and treatment. However, most of these trials had significant methodological limitations, including lack of control group, small sample sizes, and contamination with other interventions, and the

authors conclude that further rigorous research is necessary to determine the exact benefits of PN services.

CMS issued an announcement on December 23, 2004, soliciting cooperative agreement proposals for the Cancer Prevention and Treatment Demonstration (CPTD) for Ethnic and Racial Minorities. In particular, the announcement sought demonstration projects that targeted four legislatively mandated minority populations: American Indians; Asians and Native Hawaiians or Other Pacific Islanders; African Americans; and Hispanics. By law, CMS was also required to include at least one rural site, one inner-city site, and one site in the Pacific Islands, which CMS limited to the State of Hawaii. Applications were due March 23, 2005. After reviewing all applications and negotiating with individual sites, CMS announced the selection of six CPTD sites on April 3, 2006. Enrollment of beneficiaries began October 1, 2006.

CHAPTER 2
DEMONSTRATION PROJECTS

Four of the six sites were based in academic medical centers that house major cancer treatment centers. The fifth (Josephine Ford Cancer Center [Henry Ford Health System]) is a cancer center based in a large, vertically integrated delivery system, which greatly facilitated the center's access to potential demonstration participants. The sixth (Moloka'i General Hospital) is based in a small general hospital on the island, but is part of the larger Queen's Hospital System.

Two of the sites are located in rural areas. The Moloka'i site is on a small, relatively undeveloped island that is accessible only by small plane because the ocean currents are too strong for ferries to travel from the nearest developed island of Oahu, Hawaii. Huntsman originally targeted American Indian reservations in remote and mountainous sections of Montana and Utah. The final sites included three reservations in Montana (representing four tribes—the Chippewa Cree, the Assinniboine, the Gros Ventre, and the Blackfeet) and several Navajo communities in the Four Corners area of Arizona, Colorado, New Mexico, and Utah.

Table 2-1
Description of demonstration sites

Site	Location	Lead organizational unit	Priority population
Huntsman Cancer Institute	Arizona and Montana	Huntsman Cancer Institute in Utah, Sletten Cancer Institute, Montana (sub to HCI)	American Indians
Johns Hopkins University	Baltimore City, Maryland	Bloomberg School of Public Health	African Americans
Josephine Ford Cancer Center (Henry Ford Health System)	Detroit, Michigan (Wayne County)	Josephine Ford Cancer Center–Henry Ford Health System	African Americans
The University of Texas, M.D. Anderson Cancer Center	Houston, Texas (Harris County), later expanded to surrounding countries	Center for Research on Minority Health	Hispanic/Mexican Americans
The University of Medicine and Dentistry of New Jersey (UMDNJ)	Newark, New Jersey, later expanded to surrounding countries	New Jersey Medical School	Latinos
Moloka'i General Hospital	Moloka'i (island), Hawaii (Maui County)	Moloka'i General Hospital	Asian, Pacific Islanders (primarily Filipinos, Native Hawaiians)

SOURCE: RTI's first round of site visits, 2006–2007.

The remaining four sites are all located in the inner cities of major metropolitan areas. Because of difficulties recruiting eligible participants, two of the sites (M.D. Anderson and The

University of Medicine and Dentistry of New Jersey [UMDNJ]) later expanded their areas to encompass surrounding counties.

All sites received institutional review board (IRB) approval before implementing their initiatives. Each site's IRB reviewed and approved the scripts and consent procedures so that the sites could contact beneficiaries, administer the Cancer Status Assessments (CSA), access beneficiaries' medical records, and contact their primary care providers, if applicable.

2.1 Demonstration Design

The CPTD was designed to reduce racial/ethnic disparities in cancer prevention and treatment by improving cancer screening rates and completion rates of cancer treatment. Each of the six sites had two study arms: a screening arm and a treatment arm. Each study arm had one intervention group and one control group. The random assignment of participants to intervention and control groups allows unbiased estimates of the impacts of patient navigation, since participant characteristics are not related to assignment to groups. Each participant recruited into the study completed a baseline cancer status assessment survey (CSA) that includes questions on cancer risk factors, utilization of screening tests, and cancer history. This baseline survey served several purposes: (1) the survey was used to assign participants to either the screening or treatment arm, (2) screening history data could be used to help schedule appointments for intervention participants in the screening arm, and (3) sites received a fixed payment from CMS for each survey administered. In addition to CSA payments, sites were paid a capitated amount per enrollee in the intervention group. More detailed information about site payments is presented in Table 2-3.

Participants with a diagnosis of breast, cervical, colorectal, lung, or prostate cancer who had received some form of treatment within the past 5 years were assigned to the treatment arm. Participants who had received treatment in the past 5 years for another type of cancer were excluded from the study. All other participants were assigned to the screening arm.

The study design was based on intent to treat; therefore, participants enrolled in the screening arm remained in that arm, even if they were diagnosed with cancer over the course of the study. Intervention group participants who were diagnosed with cancer received navigation services for their cancer treatment. However, the evaluation continued to treat them as participants in the screening arm.

The main sources of data for this study were surveys administered by the sites to study participants and Medicare claims data from 2002-2010. The Cancer Status Assessments (or CSAs) were administered by site personnel at baseline when a study participant enrolled, and at exit, or when a study participant left the study. Sites also administered an annual survey to study participants, though most focused on the intervention group. The baseline CSA was required for someone to be considered a study participant, and the exit CSA was important for measuring program-related change on elements measured in the surveys. Survey data were sent from each site to Thomson Reuters and then on to RTI for analysis. The response rates for the exit CSAs were not ideal, and differed by study site and participant status (intervention or control). The CSA data was therefore most useful for answering questions related to satisfaction with the intervention for the intervention group, and for providing identifiers that allowed matching to the

claims data. Using the identifying information from the baseline CSA, we matched each study participant to Medicare claims data, which allowed us to address outcomes for all study participants (not just the ones who had responded to the exit CSA). The Medicare claims data was the basis for analysis of changes in screening rates and spending in response to patient navigation interventions. The claims data from 2002-2010 allowed us to examine utilization and spending patterns before study enrollment, during study enrollment, and even after study enrollment. Because each site implemented its own patient navigation intervention, and because the target populations in each site were so different, all analysis was site specific.

Several other data sources were used for this report. RTI collected data from the sites. Annually, sites submitted to RTI a Cost Assessment Tool (CAT); quarterly, sites submitted PN activity surveys. (More information is provided on these in Chapter 7.) CMS provided RTI with enrollment and payment data. In addition, RTI conducted two rounds of site visits with each of the demonstration sites and delivered to CMS a site visit report for each site and each round.

2.2 Demonstration Enrollment

Participation in the demonstration was voluntary, and beneficiaries could drop out at any time. Participants were automatically dropped if they became ineligible during the course of this demonstration. For example, beneficiaries in managed care plans were not eligible for this demonstration, and those who later enrolled in a managed care plan also lost eligibility for the CPTD. Additionally, beneficiaries who were institutionalized or who had elected hospice were ineligible for the demonstration. All participants in the CPTD must be enrolled in Medicare Parts A and B throughout their enrollment in the demonstration.

At the start of the demonstration, sites had projected their expected enrollment into the screening and treatment arms of the study. Table 2-2 displays projected, revised, and actual enrollment for the screening and treatment arms for each site. Enrollment goals varied across sites; the much lower numbers for Moloka'i reflected the small target population on the island. All of the sites expected to enroll more participants into the screening arm of the study than into the treatment arm. Screening enrollment came much closer to meeting site goals, even exceeding it in certain sites. No sites met their goals for treatment arm enrollment.

Table 2-2
Enrollment in the demonstration screening and treatment arms, by demonstration site

	Original total projected enrollment[1]		Revised total enrollment goals[1]		Cumulative enrollment[2]	
Site	Screening	Treatment	Screening	Treatment	Screening	Treatment
Huntsman Cancer Institute	1,800	140	1,635	140	1,743	54
Johns Hopkins University	2,874	200	1,975	200	2,595	172
Josephine Ford Cancer Center (Henry Ford Health System)	1,900	1,150	2,876	274	5,398	440

(continued)

Table 2-2 (continued)
Enrollment in the demonstration screening and treatment arms, by demonstration site

Site	Original total projected enrollment[1]		Revised total enrollment goals[1]		Cumulative enrollment[2]	
	Screening	Treatment	Screening	Treatment	Screening	Treatment
The University of Texas, M.D. Anderson Cancer Center	3,240	360	1,887	900	2,038	299
The University of Medicine and Dentistry of New Jersey	1,284	100	1,259	100	1,190	85
Moloka'i General Hospital	528	50	528	50	488	34
Total	11,626	2,000	10,160	1,664	13,452	1,084

[1] Data provided by the Centers for Medicare & Medicaid Services, 2009.

[2] RTI Analysis of Cancer Status Assessments (Program csa_n_v2).

2.3 Randomization Method

Once participants completed the baseline survey and were assigned to the screening arm, they were randomized to either the control or the intervention (or navigation) group. Participants within each arm were randomized by a third party to either the intervention (i.e., Patient Navigation) or control group. The intervention group in the treatment arm consisted of participants who had already been diagnosed with cancer. These participants received navigation services to ensure completion of all primary and secondary cancer treatments and all necessary follow-up and monitoring.

Control groups in each arm received relevant educational materials. The materials varied across sites, but typically describe cancer risk factors, the importance of screening, and the importance of adhering to treatment protocols. CMS reviewed and approved all educational materials in advance.

Four of the sites randomized at the individual level so that patients are randomly assigned to either group. The remaining sites, Huntsman and Moloka'i, implemented variations on the randomized design. Huntsman focused on American Indians who were spread across numerous remote reservations in Montana and the Four Corners area of Arizona, Colorado, New Mexico, and Utah. Because these communities are closely knit, Huntsman was concerned with assigning individuals living in the same community to different groups. Therefore, Huntsman designed a randomization scheme by clusters of individuals, so that equal numbers of individuals living within a defined geographic area on a reservation are assigned to the intervention group, while the same proportion of people living in a different cluster or area of the same reservation are assigned to the control group. Moloka'i had also been granted permission to implement a variation on the randomization design, because of the close-knit nature of the community on the small island. CMS had granted permission to assign all island residents in the screening and

treatment arms to the intervention group, and then assign people living in similar communities on the nearby island of Oahu to the control group. During implementation the site decided not to recruit screening participants from Oahu and used a Moloka'i-based nutrition education program for the control group. The treatment arm control group on Oahu also faced difficulties and recruitment in Oahu stopped half-way through the project. Moloka'i did end up closer to a randomized design than they had originally anticipated for the screening arm.

The fact that each site focused on Medicare beneficiaries from a single racial or ethnic minority group greatly strengthened the experimental design because intervention and control participants shared the same racial or ethnic background and were drawn from the same communities. However, in each site, this limited our ability to examine changes in screening rate disparities between groups. We were able to document changes in screening rates for the target group in each site.

2.4 Demonstration Funding

This demonstration was designed to have three sources of funding for each project site: (1) start-up payments, (2) payment for administration of CMS-mandated participant surveys, and (3) capitated payments for navigation services. An additional source of emergency funding was also made available during the course of the project.

First, the initial source of demonstration funding was a one-time $50,000 payment at the beginning of each project to help cover start-up costs.

Second, the sites received a fixed payment for each baseline Cancer Status Assessment (CSA) survey they completed on participants in both the intervention and control groups. They also received payments for administering an annual survey to all intervention group participants. CMS required these annual surveys as a means of validating that intervention group members remained enrolled in the demonstration. Sites received payment for similar exit surveys administered at the end of the demonstration period for all participants, both intervention and control. Payments for all surveys were negotiated individually with sites and vary considerably.

Third, sites received a capitated monthly payment for each intervention group participant per month of enrollment. This payment covered the cost of navigation services and varied across sites. The sites proposed payment rates on the basis of their expected costs and then negotiated these amounts with CMS. The same rate was used for intervention participants in both the site's screening arm and its treatment arm, despite the potentially higher navigation intensity for treatment participants. Because treatment participants were not in the initial active phases of treatment, as most had been diagnosed 3–5 years before the demonstration baseline, this was not a concern.

Capitation payments and the CSA payments were negotiated in advance between each site and CMS. Capitation and CSA payments therefore varied by site. Sites billed CMS for the CSA surveys using special demonstration billing codes. Monthly capitation payments were made to the sites automatically, once participants were enrolled in the intervention group, and continued as long as they remained eligible. There was no beneficiary liability (i.e., no coinsurance or deductible) for these demonstration navigation services. All clinical screening,

diagnosis, and treatment services were billed and paid through the normal Medicare claims process.

Five of the six sites (all but Moloka'i) incurred substantial debt in the first year (above and beyond the $50,000 in start-up funding), generally because slower-than-expected enrollments meant that staffing and other costs were not quickly offset by capitation payments. In response to these mounting financial obligations, CMS renegotiated with individual sites, increasing capitation payments, CSA payments, lump sum payments, or some combination of these for debt relief. Four of these five sites (all but Josephine Ford) continued to receive additional cash payments in each subsequent year of the demonstration. None of these additional amounts had been anticipated by CMS. Total CMS spending on the CPTD remained unchanged, however; that is, it did not exceed the $25 million obligated by Congress. Cumulative demonstration financing information for each site is presented in Table 2-3.

Table 2-3
Cumulative financing by site, in dollars

Site	Start-up fee	CSA Fee + capitation	Additional funding	Total
Huntsman Cancer Institute	50,000	2,646,730	1,023,375	3,720,105
Johns Hopkins University	50,000	3,743,249	1,609,021	5,402,270
Josephine Ford Cancer Center (Henry Ford Health System)	50,000	5,072,019	349,727	5,471,746
The University of Texas, M.D. Anderson Cancer Center	50,000	1,941,574	2,274,813	4,266,387
The University of Medicine and Dentistry of New Jersey	50,000	1,765,710	1,037,168	2,852,878
Moloka'i General Hospital	50,000	682,202	0	732,202
Total	300,000	15,851,484	6,294,104	22,445,588

NOTES: CSA = Cancer Status Assessment. The first column is the start-up fee each site received. The second column is the sum of the CSA and capitation fees that each site received. The third column is the amount of additional funding each site received, and the fourth column is the total amount of funding that each site received. RTI did not have the level of detail necessary in the data to approximate funding for CSA and capitation fees separately.

SOURCE: Centers for Medicare & Medicaid Services, 2011.

2.5 Patient Navigation Interventions

The screening intervention group participants received navigation services to help ensure that they were administered the appropriate screenings for breast, cervical, colorectal, and prostate cancer in accordance with Medicare coverage policy for preventive services (CMS, 2011) and clinical practice guidelines. Guidelines were consistent through the demonstration period from 2006-2011. Sites varied in the specific screening guidelines they adopted, resulting in some variation in participant eligibility—for example, Josephine Ford did not recommend Pap smears for female beneficiaries aged 70 and older if they had a prior history of normal tests.

Screening intervention group participants who had positive test results also received navigation services to help them obtain any necessary follow-up diagnostic tests. Sites varied in whether participants were contacted by telephone or in person. Telephone contact was more common, with the exception of Huntsman, which did more patient navigation in person.

CMS did not specify a standard patient navigation intervention to be used by all six sites. Instead, CMS recognized that each site would need to develop its own navigation model to ensure that the intervention was culturally sensitive to the needs of each minority community. The variation in both PN models and target populations across the sites introduced complexities to the evaluation of the CPTD demonstration.

Because the concept of patient navigation was relatively new to cancer care, many aspects of it had not been well established in the literature at the time this demonstration began. Even finding an agreed-upon definition of what patient navigation entails was challenging.

Sites' models of patient navigation in this demonstration, presented in Table 2-4, varied in the extent of clinical oversight by a nurse. Three sites (Josephine Ford, Moloka'i , and M.D. Anderson) had nurses supervising lay navigators at the start of the demonstration, but Moloka'i and M.D. Anderson dropped nurse involvement during the demonstration. As nurses left the program, they felt that patient navigation activities could be conducted by lay navigators. At Ford, the nurses focused on assessing participants' service needs, interacting with health care providers as needed, and ensuring that care was received, whereas the advocates focused on scheduling appointments for the patients and ensuring that participants had access to any related services. At the time of the second site visits, these sites explained that they believe their decisions not to fill the vacant nurse positions was ideal for the program and allowed them to better support those working as lay navigators. All of these sites said that the clinical oversight provided by the senior staff affiliated with the program was sufficient. The Ford program still operated with a nurse/lay navigator model but had reduced the number of teams working with patients from seven to five. This reduction was precipitated by people leaving their positions and the site opting not to fill the vacancies.

The second model, used by five sites, relied almost entirely on lay navigators who provided the bulk of services directly to participants. For all of the programs, although clinical expertise was evident among key staff members, such as the principal investigator or another lead program staff member, the lay-only navigator model provided less direct access to this expertise than the nurse/lay navigator model. In these five programs, those with clinical expertise did not provide day-to-day oversight of the work of the PNs; instead, mostly physicians were available to the PNs as needed. One advantage to using this type of model was that by having only lay navigators, whose salaries were significantly less than those of nurses, the programs were able to afford more PNs to reach more participants.

In both models, the lay navigators worked to address participant barriers to attending appointments. Interestingly, PNs at all six sites reported similar barriers among their participants, including fears of being diagnosed with cancer and a lack of transportation. A general lack of understanding regarding cancer screening and a distrust of the health care system were also reported among patients across the sites. Three sites also said that patient comorbidities were a major issue in providing services. Patients with multiple chronic diseases often needed additional

services to address their needs specific both to cancer and to their other illnesses. One site (M.D. Anderson) had a protocol in place to actively navigate these patients so that they obtained care for their other diseases. Another site (Johns Hopkins) navigated these patients for the other services only if lack of other services interfered with their receipt of cancer screening or treatment services. For these patients, Johns Hopkins provided more limited navigation for comorbidities. The third site (UMDNJ) did not navigate these patients to address the needs specific to their other health concerns. Two other sites (Moloka'i and the Montana reservations for Huntsman) tended to provide this service incidentally and had no protocol in place. Because the PNs at these sites were so integrally involved in the communities, they knew most of their patients personally and shared stories of how they were often asked to provide transportation or other assistance in obtaining care for other diseases.

Table 2-4
Patient navigation models by site

Site	Dates of second site visit	Number of PNs at time of site visit	Type of navigation model (nurse/lay or lay)
Huntsman Cancer Institute	May 2009	6 (+4 site coordinators; 6 educators)	Lay
Johns Hopkins University	June 2009	5 (+8 interviewers; 5 recruiters)	Lay
Josephine Ford Cancer Center (Henry Ford Health System)	July 2009	10 (5 pairs of nurses and advocates)	Nurse/lay
The University of Texas, M.D. Anderson Cancer Center	May 2009	4 (+6 community health workers; 1 health referral specialist)	Lay
The University of Medicine and Dentistry of New Jersey	June 2009	3 (+3 interviewers)	Lay
Moloka'i General Hospital	June 2009	2 (+1 office manager)	Lay

SOURCE: RTI's second round of site visits, 2009.

As the PNs scheduled appointments, two of the sites (Josephine Ford and M.D. Anderson) maintained an electronic tracking system to follow participants and record information for each service encounter. Two sites (Moloka'i and Johns Hopkins) had a Microsoft Excel spreadsheet to track patient information, and two sites (UMDNJ and Huntsman) kept hard-copy logs of participant contacts.

Once screening tests were completed, all six sites rely primarily on participants telling the PN what their screening results are and whether follow-up care is needed. If participants seem confused or uncertain about what they should do, nurses at the one site with the nurse/lay navigator model would try and help patients understand their results and follow-up plans when they could, but in general, across the sites, they had each established protocols so that the PNs

would help patients contact their health care providers to answer any questions and do their best not to interfere with the patient's care. The primary reason for this protocol was that regarding the reliance on lay navigator models across five sites, respondents expressed concerns about the PNs providing any type of medical advice or answering questions because they have no clinical training. At the one site with the nurse/lay navigator model (i.e., Josephine Ford), this process had developed because a number of physicians at different sites had expressed concern about navigators influencing what patients did for their treatment or follow-up care. Once participants are up to date with their screenings, all of the sites were to maintain ongoing contact with patients.

A summary of the strengths and limitations of the patient navigation models that each site implemented is presented in Table 2-5. The table illustrates the differences in site interpretation and implementation of patient navigation. The only 2 strengths shared by 4 of the sites is the continuity of staff and the distinction between roles and responsibilities. Similarly, there are few shared limitations across sites. Across 3 of the 6 sites, a noted limitation is in the level of engagement of the physicians in recruiting and enrolling study participants.

Table 2-5
Strengths and limitations of patient navigator models

Strengths and limitations	Huntsman[1]	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i
Strengths						
The staff are well grounded in the community.	X					X
Most staff have served in their role for the duration of program.	X		X		X	X
The program has a strong community presence.					X	X
There is a clear distinction between roles and responsibilities.		X	X		X	X
There are well-developed protocols for providing navigation		X	X			X
The staff work effectively together to meet patient needs (e.g., readily substitute for one another).		X	X			X
There is a well-developed database for tracking patients throughout all phases of navigation	—	—	—	X	—	—

(continued)

Table 2-5 (continued)
Strengths and limitations of patient navigator models

Strengths and limitations	Huntsman[1]	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i
The skills of the staff complement each other well.	—	—	—	X	—	—
There is an expansive view of the PN role (i.e., will navigate other social, financial, and medical needs to remove barriers to receiving cancer services).	—	—	—	X	—	—
Limitations						
The data system(s) (or lack thereof) makes it difficult to track patients.	X	—	—	—		—
Follow-up of patients over time seems limited and/or unorganized (e.g., PNs are unclear of when to contact them and what to provide).	X	—	—	—	X	—
There are difficulties in hiring and/or maintaining staff (i.e., high turnover rate).	X	X	—	—	—	—
There is limited clinical oversight of patient cases.	X	—	—	—	—	X
Some PNs seem unclear about their roles and responsibilities.	X	—	—	—	—	—
It is difficult to locate and/or obtain screening information for enrolled patients.	X	X	—	—	—	—
There is a high caseload, given their role and/or number of staff relative to cases.	—	—	X	X	—	—
There is limited engagement among physicians in enrolling patients in the screening arm.	X	—	X[2]	X	—	—

(continued)

Table 2-5 (continued)
Strengths and limitations of patient navigator models

Strengths and limitations	Huntsman[1]	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i
There is limited engagement among physicians in enrolling patients in the treatment arm.	X	—	X	X	—	—
It is difficult to navigate patients in areas where there is limited knowledge of local services and/or health care providers.	X	—		X	—	—
There are inconsistencies among PNs about how they are tracking and monitoring patients (i.e., making comparisons across sites are problematic).	X	—	X	—	—	—

NOTES:

[1] Each location within this program operates somewhat differently. Reservations in Montana have much more organized staff, with oversight of patient cases, than on the Navajo Reservation. Strengths and limitations noted here are for the program overall, although some of the limitations do not apply to any of the three Montana reservations.

[2] Difficulty with physicians at Josephine Ford is limited to those outside the Henry Ford Health System for the screening arm. For the treatment arm, physicians at Josephine Ford have been reticent to allow its patients to be enrolled in the CPTD. Of the treatment arm patients enrolled, most have been recruited from within the Henry Ford Health System.

SOURCE: RTI's analysis of site visit data, 2009.

2.6 The Screening Arm

In each site, the bulk of the participants were in the screening arm. In fact, meeting enrollment goals was more time-consuming than sites had anticipated. Furthermore, because some participants enrolled in managed care and were lost to the demonstration, recruitment and enrollment were ongoing site concerns. As a percentage of the overall enrollment across all sites, about 15.1 percent voluntarily disenrolled from the demonstration and was in managed care the next month. As shown in Table 2-2, Moloka'i enrolled 488 screening arm participants, Ford enrolled 5,398, and the other sites enrolled between 1,100 and 2,600 participants each. PNs established contact with participants, conducted the baseline CSA, assessed participant needs, and tried to reduce barriers to screening. We note that the sample sizes for the baseline data (Table 2-6) are not the same as the final enrollment numbers from CMS (Table 2-2) because we limited the analytic sample to those with at least 6 months of enrollment in the demonstration. Other data issues, like removing duplicate records and unmatchable identification numbers, also reduced the sample size of the analytic file.

2.7 Demographics of Screening Arm Participants at Baseline

Participants enrolled in the screening arm completed a baseline survey. This group constituted the main study sample. Although their characteristics varied considerably between sites, the intervention and control groups were remarkably similar within sites because of the random assignment procedures used. At Huntsman, where participants were not randomly assigned, there were some differences in characteristics between intervention and control groups (detailed in the final report). This was also true of Moloka'i, where initial implementation included control groups from the island of Oahu. The two sites that implemented variations in randomization showed demographic differences between their intervention and control groups that were not present in other sites, as shown in Table 2-6.

In general, the participants in this demonstration were women between the ages of 65 and 80, who had at least a high school education, spoke mainly English at home, had children, did not live alone, and had annual incomes below $20,000. Percentages of dually eligible beneficiaries, including those under 65 years of age, varied from 18% at the Johns Hopkins site to 68% at UMDNJ. UMDNJ was also an outlier in the percentage of participants (95%) who reported that they spoke mainly a language other than English at home. These characteristics may have had implications for the type of support that participants wanted from their PNs, with participants who lived alone needing more help with transportation and those who spoke less English needing help communicating with physicians.

An earlier analysis that was part of the second Report to Congress examined whether demonstration participants were similar to other eligible local Medicare beneficiaries who were nonparticipants. Within each site, participants and nonparticipants were compared along several dimensions: age, gender, original reason for Medicare entitlement, dual eligibility for Medicaid, Medicare expenditures before the start of the demonstration, Medicare risk score,[4] the use of cancer screening tests in the year before the start of the demonstration, and vaccination for influenza before the start of the demonstration.

These analyses showed significant differences between participants and nonparticipants in their demographic characteristics and use of preventive services. In most sites, demonstration participants were younger, more likely to be female, and more likely to have received cancer screening services and an influenza vaccine before the start of the demonstration. However, the results for Huntsman and Moloka'i indicate that participants were less likely to use certain preventive services. Except at Huntsman and Moloka'i, it appears that the sites did not enroll individuals with the greatest need for assistance in accessing cancer screening services. In the four sites (i.e., Josephine Ford, Johns Hopkins, M.D. Anderson, and UMDNJ), individuals who had received cancer screening tests in the past were more likely to participate in the demonstration than those who had not had previous cancer screenings. Participants and nonparticipants did not have significantly different overall Medicare expenditures or Medicare risk scores in most sites. At most sites, there were also no differences between participants and nonparticipants in original reason for Medicare entitlement or dual eligibility for Medicaid.

[4] The Medicare risk score, also known as the hierarchical condition categories score or HCC, is an expenditure-weighted index of a beneficiary's diagnoses that predicts the relative risk for future Medicare expenditures.

However, at UMDNJ, participants are markedly more likely than nonparticipants to be dually eligible. These differences may affect the generalizability of the evaluation results, although it is difficult to predict how impacts in a broader population would differ from those in the demonstration population. Because participants were generally more likely to have been receiving cancer screening tests even before the demonstration was implemented, PN may have been more likely to increase use of cancer screening services if it had been offered to populations with lower baseline use of these services. However, it is also possible that individuals who enroll may be more receptive to using these services, so that results of the demonstration could show increases in screening.

Table 2-6
Demographic characteristics of screening arm participants, by group and by demonstration site

Screening participants	Huntsman		John Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.
Sample size	813	727	1,103	1,210	2,337	2,472	968	947	526	545	182	195
Female (%)	58	59	73	73	68	69	57	63	65	61	54	49
Age (%)												
< 65	24.2	28.6	0.1	0.1	21.8	23.6	22.6	20.2	25.7	23.5	19.2	24.1
65–69	24.4	24.5	35.0	35.0	24.7	24.5	28.5	26.2	26.8	25.7	26.9	29.7
70–74	25.7	21.7	30.4	28.9	19.4	19.3	17.8	22.9	22.2	25.7	25.3	18.5
75–79	15.9	12.1	17.9	20.4	16.9	15.5	15.9	16.5	13.9	18.7	13.7	14.4
80–84	7.6	8.0	10.8	10.5	11.2	11.6	9.7	10.0	7.8	4.6	9.9	8.7
85+	2.2	5.1	5.9	5.1	6.1	5.7	5.5	4.2	3.6	1.8	5.0	4.6
Dual eligibility status	54.9	53.2	19.2	17.4	29.1	31.8	34.7	38.0	71.1	65.7	24.2	23.1
Health insurance (%)												
Medicare supplemental	52.3	35.7	55.0	54.9	40.4	41.4	22.1	23.0	15.4	12.5	59.0	63.1
Medicaid	49.5	47.9	12.0	15.2	22.4	25.9	30.0	29.1	80.2	60.5	22.6	21.8
TRICARE	3.3	2.7	4.0	3.5	2.1	2.4	2.4	1.6	0.6	0.9	7.7	4.1
Veterans Affairs	8.6	9.3	5.9	6.6	4.4	3.0	4.9	3.7	1.3	0.9	7.1	9.7
Other public	39.5	30.9	8.5	9.5	5.6	5.1	9.7	9.7	10.4	10.7	16.6	22.7
Prescription assistance	52.0	48.4	87.0	87.2	90.1	89.9	69.0	73.0	81.1	78.2	88.4	88.1
Part D	87.6	81.0	29.2	27.2	27.3	29.2	53.6	51.2	81.6	78.7	45.5	44.5
Education (%)												
High school or more	51.6	48.5	67.4	67.9	62.9	64.8	38.2	38.9	37	35.3	65.4	61.6
Marital status (%)												
Married/living with partner	52.3	45.9	28.3	30.2	30.4	30.5	57.6	58.4	37.8	34.8	49.5	55.3

(continued)

Table 2-6 (continued)
Demographic characteristics of screening arm participants, by group and by demonstration site

	Huntsman		John Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
Screening participants	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.
Living arrangements (%)												
Alone	23.1	23.5	45.6	42.2	46.6	47.4	24.9	23.0	43.5	48.4	18.1	20.0
Have children (%)	89.7	90.7	88.5	87.2	86.3	85.3	91.5	91.5	89.3	88.9	85.6	85.6
Income (%)												
Less than $10,000	34.9	53.4	25.3	22.0	24.7	26.6	20.6	22.2	48.0	49.2	24.5	30.8
$10,000–$19,999	24.1	26.1	27.9	27.7	29.7	28.1	38.1	37.6	38.3	34.2	23.0	24.6
$20,000+	41.0	20.5	46.8	50.3	45.6	45.3	41.3	40.2	13.7	16.7	52.5	44.6
Speak mainly English at home (%)	66.2	80.9	98.0	98.6	99.1	99.1	44.1	46.5	5.1	5.1	83.0	83.6

NOTE: UMDNJ = University of Medicine and Dentistry of New Jersey.

SOURCE: RTI analysis of baseline Cancer Status Assessments completed at time of enrollment in the demonstration. (Program: cptd009).

CHAPTER 3
DID DEMONSTRATION ACTIVITIES REDUCE DISPARITIES FOR RACIAL AND ETHNIC MINORITIES?

Reductions in screening disparities under the demonstration were measured by comparing screening rates for the intervention group with those for the control group. By design, both groups within the screening arm were from the same priority (racial or ethnic minority) population.

Site-provided identifying information (a HICNO patient identification number crosswalk) was used to create an analytic sample using Medicare claims data. Using procedure codes for each type of cancer screening, for each participant we created variables that reflected screening status before and after demonstration enrollment. Any screenings conducted in the Indian Health Service facilities for the Huntsman site would not be captured in Medicare claims data. If there was differential use of Indian Health Service facilities by the intervention and control groups in the Huntsman site, the full extent of the measurable intervention impact may be affected.

Group means for screening rates are presented by site. Screening rates presented in Table 3-1 reflect the individual's entire period of enrollment in the demonstration, compared with that same length of time before demonstration enrollment. The average length of time that participants remained enrolled in the demonstration ranged from a low of 16 months to a high of 23 months; on average across all sites, it was 20.4 months. To determine whether any of the changes in screening rates between intervention and control groups were statistically significant, we used logistic regression and controlled for pre-enrollment screening rates and demographic differences between intervention and control groups. Although controlling for differences in demographic characteristics between intervention and control groups would not be necessary if randomization were perfect, we wanted to be sure that underlying demographic differences were not responsible for intervention effects. In addition, randomization was not perfect in Huntsman and Moloka'i, as these sites had received CMS approval to implement variations of randomization. In Table 3-1, asterisks indicate significant differences between intervention and control participants in screening rates after enrollment in the demonstration.

Mammography was the screening test most likely to show statistically significant intervention impacts, with increases in four of the six sites. Pap smears showed statistically significant increases in three sites and prostate-specific antigen test (PSA) and colonoscopy in two. None of the sites showed improvement in fecal occult blood test (FOBT) testing, but note the very low levels of testing. Of the six sites, only Moloka'i demonstrated improvements in screening for all four study cancers. UMDNJ showed improvements in three screening tests, whereas Johns Hopkins and Josephine Ford both showed increases in two. Huntsman and M.D. Anderson did not demonstrate any statistically significant improvement in any of the screening tests.

Table 3-1
Cancer screening rates for screening arm participants before and after enrollment in the demonstration, by group and by site

Screening test	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter	Control	Inter.	Control	Inter.
Sample size	813	727	1,103	1,210	2,337	2,472	968	947	526	545	182	195
Pap smear (%)												
Pre	6.8	7.2	23.2	22.0	27.6	27.7	19.5	22.2	30.9	31.5	25.3	20.8
Post	8.3	10.3	21.2	26.0*	24.4	25.4	17.3	17.5	30.6	44.5*	23.2	49.0*
Mammogram (%)												
Pre	19.7	16.8	58.0	62.0	65.8	64.2	44.6	44.7	56.3	58.2	37.4	21.1
Post	24.6	24.1	60.4	68.1*	62.4	69.3*	44.0	45.7	57.4	72.1*	44.4	62.1*
Prostate-specific antigen test (%)												
Pre	23.2	11.1	49.1	46.7	73.6	68.2	50.0	47.3	58.2	59.4	35.5	33.7
Post	22.1	15.0	51.9	57.3	69.6	74.8*	48.8	45.0	72.4	64.5	35.9	54.4*
Colonoscopy (%)												
Pre	12.3	10.2	17.9	17.6	23.0	23.0	11.8	13.6	23.5	23.2	8.7	7.9
Post	13.6	13.9	19.1	21.2	23.1	23.8	13.8	15.2	27.6	31.6*	9.8	28.3*
Fecal occult blood test (%)												
Pre	0.7	0.8	5.4	6.0	6.5	6.2	5.9	5.1	2.2	2.5	1.7	1.7
Post	0.4	1.4	4.1	5.4	5.3	4.6	5.3	6.0	2.4	4.0	1.7	1.7

NOTES: Percentages were calculated on the basis of gender-specific Ns where appropriate. Inter. = intervention; Pre = before enrollment in the demonstration, where pre-enrollment is time equal to individual duration of enrollment; Post = after enrollment in the demonstration, including entire duration of enrollment; UMDNJ = University of Medicine and Dentistry of New Jersey.

*Significantly different from control group at 0.05 level.

SOURCE: RTI analysis of Medicare claims (2002–2010) of screening arm participants answering baseline Cancer Screening Assessments. (Program: CPTD037)

Table 3-2
Cancer screening rates for screening arm participants 1 year before and 1 year after enrollment in the demonstration, by group and by site

	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
Screening test	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.
Sample size	813	727	1,103	1,210	2,337	2,472	968	947	526	545	182	195
Pap smear												
Year before (%)	3.4	4.4	17.3	17.0	19.3	19.9	16.4	19.5	22.4	24.8	17.2	14.6
Year after (%)	4.9	5.8	17.9	21.1	17.6	19.9	16.1	15.5	21.0	36.4**	17.2	43.8**
Mammogram												
Year before (%)	12.3	16.5	57.0	57.0	53.9	53.7	40.1	41.8	49.6	52.7	25.3	17.9
Year after (%)	17.4	15.1	56.7	65.2**	50.9	61.0**	41.0	42.5	48.4	67.0**	38.4	56.8**
Prostate-specific antigen test												
Year before (%)	18.3	7.9	43.3	38.4	61.7	59.7	45.6	43.9	52.4	54.6	31.5	31.0
Year after (%)	13.4	10.3	48.8	52.9	57.2	64.0**	47.1	42.1	67.9	61.4	30.3	49.4*
Colonoscopy												
Year before (%)	7.2	7.7	12.2	12.1	14.2	13.0	9.5	10.2	15.7	17.0	4.2	2.3
Year after (%)	5.7	6.6	12.9	15.3	14.4	15.3	11.3	11.2	19.2	20.9	5.2	21.3**
Fecal occult blood test												
Year before (%)	0.3	0.2	3.7	3.8	3.6	3.6	3.9	4.3	1.2	2.4	1.2	0.6
Year after (%)	0.4	1.1	2.8	4.0	2.9	2.4	4.7	4.7	1.4	2.9	1.7	0.6

NOTES: Percentages were calculated on the basis of gender-specific Ns where appropriate. Inter. = intervention; UMDNJ = University of Medicine and Dentistry of New Jersey. Year before: This period is 1 year before enrollment. Year after: This period is 1 year after enrollment.

*Significantly different from control group at 0.05 level, ** significantly different from control group at 0.01 level

SOURCE: RTI analysis of Medicare claims (2002–2010) of screening arm participants answering baseline CSAs. (Program: CPTD009)

Because annual rates are more prevalent in the literature, especially for screenings that are recommended to be conducted each year, we have also analyzed screening rates for participants one year before and after their enrollment dates (see Table 3-2 on previous page). This approach has some limitations. For example, we would not capture a screening test conducted 13 months after enrollment. To be able to measure any patient navigation activity, even activity that may have taken place more than a year after enrollment in the demonstration, we present screening rates for the entire period of demonstration enrollment as well as those for the first year of enrollment. The findings are not very different, but capturing the entire enrollment period does result in significant differences between intervention and control groups at UMDNJ for colonoscopy and at Hopkins on Pap screening.

Additional detail on hours and activities of PNs in each site shows that, on average, navigators spent 24.1 hours on each person in an intervention group in the demonstration. The sites vary both in the average number of hours spent on each person and in the mix of activities. Across all sites a significant proportion of demonstration activity was not related directly to patient care or navigation. More detail is provided in Chapter 7.

Reductions in disparities in quality of life are also of interest in this demonstration (Table 3-3). The Physical Health Composite and Mental Health Composite are components of a multipurpose overall health rating measure called the RAND Short Form Health Survey 12. PHC captures physical health, and MHC captures mental health. Each component is normed to have an average of 50 and a standard deviation of 10. Although these scores vary by site, they are similar within site for control and intervention groups. The scores are also within the expected range for beneficiaries in this age group. Because the PHC and MHC were not a part of the annual CSA, the low exit CSA response rates preclude looking at change in these measures.

Beneficiary function was also monitored through repeated administrations of the EQ-5D™—at baseline, in the annual surveys, and in the exit survey. The EQ-5D is a preference-based measure of health status that combines responses to five questions about physical function and emotional well-being into a summary score. Higher scores represent better function levels. In older adults, EQ-5D scores generally decline slowly over time. The mean score for 65- to 74-year-olds in the United States is 81.1, and it drops to 75.5 in those over 75 years of age (Nyman et al., 2007). Demonstration participants had lower scores than the national means, and they showed slight declines over the demonstration period. At Josephine Ford, the post-enrollment EQ-5D score was significantly better for the intervention group than for the control group. For the other sites, no differences were statistically significant.

Table 3-3
Health status of the screening arm, by group and by demonstration site

Health status measures	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.
Sample size	813	727	1,103	1,210	2,337	2,472	968	947	526	545	182	195
Baseline												
Physical Health Composite at Baseline	36.135	36.206	39.636	39.544	37.51	37.368	38.003	37.833	34.188	34.386	42.935	42.051
Mental Health Composite at Baseline	41.311	40.945	43.83	43.838	42.168	42.112	43.883	43.741	39.96	40.436	46.928	46.418
EuroQuol5D_Baseline	0.748	0.75	0.801	0.802	0.789	0.789	0.768	0.762	0.662	0.646	0.843	0.841
Exit												
EuroQuol5D_Exit_Annual	0.737	0.754	0.832	0.826	0.767	0.798	0.756	0.755	0.741	0.732	0.823	0.833
Difference (exit-baseline)												
EuroQuol5D	-0.011	0.004	0.031	0.024	-0.022	0.009	-0.012	-0.007	0.079	0.086	-0.02	-0.008

NOTES: Inter. = intervention; UMDNJ = University of Medicine and Dentistry of New Jersey. RTI reports PHC and MHC only from the baseline data because of loss of sample in the exit Cancer Status Assessments (CSAs).

SOURCE: RTI analysis of baseline CSAs completed at time of enrollment in the demonstration and exit surveys completed upon end of demonstration. (Program: cptd007)

The EuroQol Group (1990). EuroQol—a new facility for the measurement of health-related quality of life. Health Policy 16(3):199-208.

Hays RD. RAND-36 Health Status Inventory. San Antonio, TX: The Psychological Corporation, 1998.

CHAPTER 4
DID DEMONSTRATION ACTIVITIES REDUCE MEDICARE EXPENDITURES OF PARTICIPANTS?

Although Medicare expenditures may decline over a longer time period due to early detection and treatment associated with patient navigation, we did not expect to observe any reductions during the relatively short time horizon of this demonstration. At the same time, we hypothesized that Medicare spending for intervention group participants might actually increase, if, for example, PNs successfully steered these participants to other health care providers for treatment of comorbid diseases. In fact, we found no significant differences between intervention and control group participants, based on their total Medicare Part A and Part B claims (see Table 4-1). (Part D claims were not available for this study.) Adding in the capitation payments each site received for its intervention group participants does not change the basic findings, except for one site (Johns Hopkins). Once we account for these payments, intervention group participants at Johns Hopkins become more costly than their control group counterparts.

Our calculation of total expenditures for each individual is for the entire duration of their enrollment in the demonstration, and it is compared with the same amount of time before their demonstration enrollment. There is large variability around Medicare expenditures in general, and the lack of significant changes could reflect this variability. Intervention-related changes would need to be very large indeed to be detected as significant.

Table 4-1
Medicare expenditures for screening arm participants before and after enrollment in the demonstration, by group, by demonstration site

	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
Expenditures	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.
Sample size	813	727	1,103	1,210	2,337	2,472	968	947	526	545	182	195
Total expenditures												
Pre	$14,264	$11,534	$11,696	$10,359	$13,944	$15,698	$9,423	$11,207	$12,784	$11,967	$4,336	$6,697
Post	$19,530	$16,753	$17,421	$16,482	$22,747	$23,376	$12,508	$14,387	$19,073	$18,709	$10,413	$10,405
Difference (post-pre)	$5,266	$5,219	$5,725	$6,123	$8,803	$7,677	$3,085	$3,180	$6,289	$6,742	$6,077	$3,708
Total expenditures post including capitation payments	$19,530	$18,410	$17,421	$18,529*	$22,747	$24,978	$12,508	$15,778	$19,073	$20,901	$10,413	$12,462
Difference (post-pre)	$5,266	$6,876	$5,725	$8,170*	$8,803	$9,280	$3,085	$4,571	$6,289	$8,934	$6,077	$5,765

NOTES: Inter. = intervention; Pre = before enrollment in the demonstration, where pre-enrollment is time equal to individual duration of enrollment; Post = after enrollment in the demonstration, including entire duration of enrollment; UMDNJ = University of Medicine and Dentistry of New Jersey.

*Significantly different from control group at 0.05 level,

SOURCE: RTI analysis of Medicare claims (2002–2010) of screening arm participants answering baseline Cancer Status Assessments. (Program: CPTD037) and 039.)

CHAPTER 5
WERE PARTICIPANTS SATISFIED WITH THE PATIENT NAVIGATION EXPERIENCES?

The final Congressional question is whether members of the intervention group were satisfied with the services they received as part of the demonstration. Because the control group did not receive services, this analysis can be descriptive only. Ideally, satisfaction would be assessed at the end of the demonstration through the exit CSA. Unfortunately, exit CSAs were missing for a large number of participants. Because we were concerned about the size and representativity of the group that responded to the exit surveys, we used two approaches to address this issue. In particular, if the responses to the exit CSAs were different between intervention and control groups within each site, it would be possible to mistake the group composition differences for actual differences in satisfaction. In general, we did find that the control group had a higher response rate to the exit CSA, so using just the exit CSAs was not possible.

The simplest approach to addressing the lack of exit CSA responses was to bolster them, using annual CSA data, where participants responded to the annual CSA but not the exit CSA. This reduced the differential response between intervention and control groups, except for M.D. Anderson, where only a small number of additional annual CSAs were available. In this section we present exit CSA data, augmented by available annual data for those who did not respond to an exit CSA. To strengthen this approach we also used propensity score matching. These results are presented in Appendix 1.

Table 5-1 reports participant needs at baseline, by group. At least three-fourths of the sample members across sites and groups had no problem finding personal doctors they were happy with. Slightly fewer in the Huntsman site and slightly more in the other sites reported having no trouble finding referrals to specialists they needed, and similar numbers reported no problems getting access to the care that was recommended. Health plan approvals appeared to be a concern only for Huntsman participants. The second part of Table 5-1 shows great satisfaction with doctors' listening, respect, explanation, and time spent with them. At least 75% reported that doctors always or usually did the right thing.

Table 5-2 describes those who assisted enrollees with various facilitation and support services. Overall, most enrollees across sites indicated that they did not need help with scheduling and keeping appointments, getting to appointments, understanding physician instructions, making decisions about health care, or addressing questions or concerns about medical bills and insurance. When enrollees did need help, they most often turned to friends and family. Enrollees at Huntsman reported the most need for assistance, as only about 40% of enrollees indicated that they did not need help. Transportation to visits and billing concerns were more common at Huntsman, and UMDNJ.

Table 5-1
Participant needs as reported at baseline for the screening arm, by group and by demonstration site

Screening participants' reports	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter.
Sample size	806	722	1089	1200	2326	2463	961	941	523	544	182	195
How much of a problem was it to get… (%)												
A personal doctor you are happy with?												
Big	8.3	11.9	2.9	3.0	2.9	3.0	4.1	5.5	6.7	4.6	2.2	1.0
Small	18.2	13.3	6.4	5.8	5.7	5.8	9.1	8.5	7.1	8.3	3.3	4.1
Not	73.5	74.8	90.6	91.3	91.4	91.2	86.9	86.0	86.2	87.1	94.5	94.9
A referral to a specialist you needed?												
Big	10.1	15.7	1.8	1.4	1.6	2.0	3.5	4.1	3.6	3.9	1.7	1.0
Small	19.3	10.6	2.5	1.8	2.6	2.9	5.9	4.6	3.8	5.0	3.3	3.6
Not	70.7	73.8	95.8	96.7	95.9	95.2	90.5	91.4	92.5	91.2	95.1	95.4
The care your doctor believed necessary?												
Big	7.0	11.0	2.1	2.3	1.8	2.1	3.9	4.1	3.6	2.6	1.1	1.0
Small	14.9	10.8	3.9	3.9	3.2	3.6	6.1	6.4	7.1	5.9	3.9	3.6
Not	78.2	78.2	94.0	93.8	95.0	94.3	90.1	89.6	89.3	91.6	95.0	95.4
Timely approval from your health plan?												
Big	11.6	13.8	1.8	2.0	1.5	1.6	3.5	2.3	3.2	3.0	1.7	2.1
Small	19.9	15.1	3.3	3.0	1.7	1.6	4.7	4.8	7.1	7.0	1.1	3.6
Not	68.6	71.1	95.0	95.0	96.8	96.8	91.8	92.9	89.7	90.1	97.3	94.4
How often did your doctors… (%)												
Listen carefully to you?												
Always	54.9	59.0	80.5	81.3	80.2	80.2	76.3	78.1	85.1	86.4	85.7	87.7
Usually	28.4	21.5	12.3	10.8	12.2	11.7	17.3	14.0	9.1	7.2	9.3	8.7
Sometimes	13.6	14.2	5.8	6.0	6.7	6.9	4.8	6.7	5.0	5.3	4.4	2.1
Never	3.2	5.3	1.5	1.8	0.9	1.1	1.7	1.2	0.8	1.1	0.6	1.5
Explain things in a way you could understand?												
Always	48.7	58.8	81.8	84.1	73.1	73.4	75.9	77.2	83.1	85.7	86.8	88.7
Usually	32.5	21.8	10.8	8.4	19.2	19.1	17.4	15.6	8.8	7.2	8.8	5.6
Sometimes	14.3	12.9	5.4	5.8	6.5	5.9	5.3	5.9	6.3	5.7	4.4	4.1
Never	4.5	6.5	2.0	1.7	1.2	1.6	1.5	1.3	1.9	1.5	0.0	1.5
Show respect for what you had to say?												
Always	53.7	65.8	88.0	87.0	75.9	76.5	78.9	81.2	91.6	91.9	88.5	90.8
Usually	27.0	17.7	7.4	7.4	17.5	17.1	15.7	12.9	6.3	4.1	6.6	5.6
Sometimes	15.6	12.2	3.5	3.9	5.6	5.0	4.1	5.1	1.5	3.1	3.9	1.5
Never	3.7	4.3	1.1	1.6	1.0	1.4	1.4	0.8	0.6	0.9	1.1	2.1
Spend enough time with you?												
Always	49.2	58.2	75.9	78.3	72.5	73.0	73.6	75.3	74.5	76.6	87.4	87.2
Usually	23.2	19.3	13.7	10.9	19.3	17.6	16.4	16.1	15.2	14.4	8.8	6.2
Sometimes	21.2	14.1	7.7	7.8	6.6	6.9	7.7	7.0	8.2	7.2	3.3	4.1
Never	6.3	8.5	2.6	3.1	1.6	2.4	2.3	1.7	2.1	1.8	0.6	2.6

NOTE: Inter. = intervention group; UMDNJ = University of Medicine and Dentistry of New Jersey.

SOURCE: RTI analysis of screening arm participants answering baseline Cancer Status Assessments. (Program: cptd048)

Table 5-2
Reports of who provided facilitation and support services for the screening arm, by group and by demonstration site

	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
Screening participants' reports	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter	Control	Inter.	Control	Inter.
Sample size	669	621	869	928	1,463	1,776	810	723	463	506	181	195
Who helps schedule and keep appointments? (%)												
Do not need help	37.2	40.4	74.0	75.9	72.8	71.2	56.8	57.7	48.3	45.9	53.9	43.6
Doctor/health care center/clinic staff	15.2	8.9	6.8	7.3	6.0	10.0	10.6	7.6	11.3	9.1	10.8	24.7
Family/friend/neighbor	40.2	44.7	18.5	15.6	18.7	17.3	31.2	33.0	25.7	24.5	32.8	29.1
Other	7.4	6.0	0.7	1.2	2.5	1.6	1.4	1.8	14.8	20.5	2.6	2.6
Who helps with transportation to appointments? (%)												
Do not need help	32.1	38.0	64.2	66.7	55.3	48.7	56.8	57.7	39.7	40.7	60.6	66.2
Doctor/health care center/clinic staff	5.0	7.3	0.8	1.0	2.5	2.4	10.6	7.6	2.0	1.8	4.2	4.4
Family/friend/neighbor	45.4	45.7	23.9	25.5	31.9	34.2	31.2	33.0	28.0	28.3	31.1	25.1
Other	17.5	9.0	11.0	6.9	10.4	14.6	1.4	1.8	30.3	29.2	4.1	4.4
Who helps you to better understand what the doctor told you to do? (%)												
Do not need help	38.1	36.6	70.3	73.2	74.6	68.9	46.2	48.4	54.2	55.6	61.1	61.0
Doctor/health care center/clinic staff	13.8	13.9	7.9	6.2	3.0	5.6	0.5	0.5	16.1	13.9	6.2	8.3
Family/friend/neighbor	42.3	44.8	21.6	19.9	20.6	23.7	45.3	42.9	23.8	23.4	30.6	29.4
Other	5.8	4.7	0.2	0.8	1.8	1.8	8.0	8.3	5.9	7.3	2.1	1.4
Who helps you make decisions about health care and treatment? (%)												
Do not need help	41.2	38.8	71.4	75.2	74.8	70.0	54.7	53.8	53.2	56.5	59.8	57.6
Doctor/health care center/clinic staff	10.8	14.8	6.8	4.3	3.3	5.0	7.3	6.0	4.4	5.6	7.2	11.2
Family/friend/neighbor	42.6	43.9	21.6	20.1	20.5	23.9	36.9	39.1	38.2	31.9	31.4	29.9
Other	5.4	2.6	0.2	0.4	1.5	1.2	1.2	1.1	4.3	6.0	1.6	1.3
Who helps you to follow your doctor's treatment recommendations? (%)												
Do not need help	39.8	37.8	76.8	79.1	76.2	71.3	56.1	56.2	52.0	54.6	61.8	58.0

(continued)

Table 5-2 (continued)
Reports of who provided facilitation and support services for the screening arm, by group and by demonstration site

	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
Screening participants' reports	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter	Control	Inter.	Control	Inter.
Doctor/health care center/clinic staff	10.7	13.4	2.6	1.6	2.0	2.6	4.8	2.8	4.4	5.2	6.8	9.4
Family/friend/neighbor	43.2	43.9	20.3	18.7	19.9	24.9	38.1	40.3	36.7	31.4	29.8	30.8
Other	6.3	4.9	0.3	0.6	1.9	1.2	1.0	0.7	6.9	8.8	1.6	1.8
Who helps you with questions/concerns about insurance/ medical bills? (%)												
Do not need help	36.3	35.9	70.7	77.7	75.4	74.4	59.4	60.2	38.8	42.0	55.3	50.2
Doctor/health care center/clinic staff	12.2	10.7	3.0	1.9	1.4	2.4	1.8	1.4	1.5	1.9	6.3	16.9
Family/friend/neighbor	41.3	43.9	21.3	18.1	17.9	21.0	37.0	37.3	42.2	36.6	37.4	31.1
Other	10.3	9.5	4.9	2.4	5.2	2.2	1.5	1.1	17.4	19.5	1.1	1.8

NOTE:

Other is combination of Community Organizations, No Help Available, and Other.

SOURCE: RTI analysis of exit CSAs supplemented by annual CSAs when exit CSAs were not completed (Program cptd027).

The frequency of services provided by PNs to enrollees varied by site (Table 5-3). A large percentage of enrollees across sites reported that PNs provided them with information regarding cancer-related services, resources, or support groups in the community. This ranged from 69% in Moloka'i to 40% at Johns Hopkins. Enrollees also reported that PNs made reminder phone calls to make appointments, ranging from 96% at Molokai to 37% at Johns Hopkins, or mailed them to do so (ranging from 98% at Moloka'i to 14% at Johns Hopkins). Other activities varied widely within categories. For example, 47% of enrollees at Johns Hopkins indicated that PNs arranged for someone to take care of spouses or family members while the enrollee went to medical appointments. However, this was reported by less than 5% of enrollees at the other sites. Nearly one-quarter of enrollees at Huntsman reported that PNs assisted with finding transportation services for medical appointments, but this was reported by less than 10% of enrollees at four of the sites.

Table 5-3
Reports of services provided by patient navigators from the screening arm, by demonstration site

Screening participants' reports	Huntsman	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i
Sample size	1,290	1,797	3,239	1,533	969	376
Often or sometimes…*						
…provided me with information about cancer-related services, resources, or support groups in my community.	77.6	41.8	47.2	64.5	72.5	95.9
…helped to schedule my medical appointments for me.	50.9	16.4	16.1	9.0	42.4	75.7
…helped me to talk with medical staff and doctors.	7.0	8.1	4.5	5.5	28.6	13.0
…talked to medical staff and doctors on my behalf so they could explain things to me.	4.3	8.8	2.3	3.9	20.2	9.9
…helped me fill out medical paperwork.	24.9	6.5	4.0	4.8	16.9	13.5
…helped me arrive at scheduled medical appointments on time and prepared.	19.6	7.7	4.4	3.0	23.2	37.8
…helped me find ways to pay for my medical care.	1.8	5.9	1.0	4.1	6.9	10.4
…helped me find transportation to get to my medical appointments.	24.3	9.9	4.1	3.3	17.2	9.3
...helped me arrange for someone to take care of my spouse or other family members so I could go to my medical appointments.	1.6	46.8	0.5	1.5	4.8	1.0
...contacted me by mail to remind me to make an appointment for my cancer follow-up.	23.7	13.8	51.3	28.1	41.9	97.9
...contacted me by telephone to remind me to make an appointment for my cancer follow-up.	53.5	37.4	42.8	50.3	42.0	96.4
…helped me to make additional follow-up medical appointments if I needed them.	25.8	11.6	11.9	12.4	19.9	71.0

NOTES: * Often and Sometimes are response categories that we combined for presentation. The excluded category is the "Never" response category.

UMDNJ = University of Medicine and Dentistry of New Jersey.

SOURCE: RTI analysis of exit Cancer Status Assessments (CSAs), supplemented by annual CSAs when exit CSAs were not completed. (Program cptd027)

Table 5-4 presents the experiences of the intervention group with PNs. Intervention group members reported considerable satisfaction with the educational materials they received, as well as with referrals and support services. At least 75% in each site agreed or somewhat agreed that they valued working with a PN and would recommend this service to others. Similarly, 70%–95% of participants at each site reported their experience as excellent or very good. It is worth noting that in many cases the person asking about participant satisfaction with patient navigation was, in fact, their patient navigator.

Table 5-4
Satisfaction with patient navigators from the screening arm, by demonstration site

Screening participants' reports	Huntsman	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i
Sample size	445	717	1,707	571	395	193
The education materials I received were helpful.						
Agree or somewhat agree	67.7	68.6	53.9	77.4	89.1	99.0
Neither agree or disagree	27.8	13.3	43.8	14.5	3.5	1.0
Somewhat disagree or disagree	4.5	2.0	2.4	1.9	0.0	0.0
The support services referrals met my needs.						
Agree or somewhat agree	65.2	58.8	40.5	65.1	80.5	94.3
Neither agree or disagree	29.6	15.5	56.5	20.0	4.1	5.7
Somewhat disagree or disagree	5.2	2.8	3.1	1.2	0.0	0.0
I would recommend this service to others.						
Agree or somewhat agree	77.0	88.9	84.1	85.4	97.2	99.5
Neither agree or disagree	19.8	8.7	15.6	13.2	2.8	0.5
Somewhat disagree or disagree	3.2	2.4	0.2	1.4	0.0	0.0
I valued working with the navigator.						
Agree or somewhat agree	79.0	85.3	74.8	79.0	93.9	97.9
Neither agree or disagree	18.1	12.3	24.3	19.4	5.8	2.1
Somewhat disagree or disagree	2.9	2.4	0.9	1.6	0.3	0.0
Rating of experience with a PN						
Excellent or very good	70.0	80.2	69.9	75.7	86.8	95.3
Good	24.1	15.1	26.7	22.5	12.7	3.6
Fair or poor	5.9	4.6	3.5	1.8	0.5	1.0

NOTE: PN = patient navigator; UMDNJ = University of Medicine and Dentistry of New Jersey.

SOURCE: RTI analysis of exit Cancer Status Assessments (CSAs), supplemented by annual CSAs when exit CSAs were not completed. (Program cptd027.)

Although control group participants did not receive patient navigation services through the demonstration, it is possible that they still received similar facilitation services from others (e.g., from family, friends, health care worker). We had planned to compare use of such services between intervention and control group participants, using the exit CSAs. However, given the large number of missing exit CSAs, and the systematic differences in exit CSA response rates between intervention and control groups, we could not conduct this analysis. It is worth noting,

however, that at least one-third of participants reported at baseline that they did not need help with setting up medical appointments, transport to them, or coordination support more generally.

Table 5-5 presents enrollees' reports of communications with PNs. Across sites, more than 70% of enrollees reported that they had been in touch with a PN within the past year. This figure ranged from nearly 100% of enrollees on Moloka'i to 70% at M.D. Anderson. However, 11% of enrollees did not know whether they had communicated with a PN in the past year at M.D. Anderson, nor did 7% at Ford or 5% at UMDNJ.

Most of those who had been in touch with a PN had been contacted more than once but less than six times. One-fifth of the enrollees at Johns Hopkins and UMDNJ had been contacted six or more times in the past year, as had 40% of enrollees on Moloka'i. How the PNs communicated with enrollees varied by site: most enrollees at Johns Hopkins, Ford, M.D. Anderson, UMDNJ and Moloka'i were contacted by telephone, whereas at Huntsman, most were met in person.

Table 5-5
Reports of communication with a patient navigator, from the screening arm, by demonstration site

Screening participants' reports	Huntsman	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i
Sample size	445	717	1,707	571	395	193
Percentage with any communication with a PN in past year	94.1	82.0	71.38	70.27	80.87	99.48
Don't know	0.5	1.9	6.57	11.11	4.99	0.0
Number of times communicated with a PN during the past year	8.8	9.2	11.85	16.42	5.46	0.52
1 (When I signed up)						
2–3	50.35	41.54	69.54	46.42	45.91	18.23
4–5	32.86	24.63	4.73	17.36	21.09	41.15
6+	6.86	20.33	0.83	9.06	19.11	40.1
Don't know	0.47	4.3	12.98	10.75	8.44	0.0
Usual mode of communication with a PN	74.47	4.46	11.8	0.94	6.33	28.65
In person						
By telephone	24.82	93.31	47.66	87.19	78.73	69.27
By postal mail (through letters)	0.24	0.15	30.79	3.58	12.41	2.08
By electronic mail (e-mail)	0.0	0.15	0.08	0.56	0.25	0.0
Other	0.0	0.0	1.59	7.16	0.0	0.0
Don't know	0.0	1.93	7.94	0.56	2.28	0.0

NOTE: PN = patient navigator; UMDNJ = University of Medicine and Dentistry of New Jersey.

SOURCE: RTI analysis of exit Cancer Status Assessments (CSAs), supplemented by annual CSAs when exit CSAs were not completed. (Program cptd027)

CHAPTER 6
THE TREATMENT ARM

Enrollment in the treatment arm of the CPTD demonstration was very difficult for sites, and not one site met its enrollment goals for the treatment arm. As shown in Table 6-1, the sample sizes are very small—not even reportable for three sites. On the basis of guidelines used by the National Center for Health Statistics, we have determined that no treatment arm data can be reported for Moloka'i, Huntsman, or UMDNJ, as intervention or control group sample sizes are less than 30.

Table 6-1
Sample characteristics, screening rates, visit rates, and expenditures for treatment arm participants, before and after enrollment

	Johns Hopkins		Josephine Ford		M.D. Anderson	
Treatment participants	Control	Inter.	Control	Inter.	Control	Inter.
Sample size	77	78	185	196	126	137
Female (%)	41.6	44.9	41.1	43.4	58.7	42.3
Length of time with cancer (years)	4.6	3.2	3.7	3.4	3.5	4.2
Type of cancer (%)						
Breast	28.6	29.5	29.7	32.7	44.4	27.7
Cervix	0.0	1.3	0.5	2.6	6.4	9.5
Colon or rectum	7.8	11.5	7.6	9.2	11.9	13.9
Lung	18.2	11.5	11.9	5.6	6.4	2.9
Prostate	45.5	46.2	50.3	50.0	31.0	46.0
Colonoscopy (%)						
Pre	11.7	10.3	25.9	27.0	20.6	16.8
Post	10.4	11.5	23.2	27.0	23.8	21.2
Mammogram (%)						
Pre	18.2	24.4	30.8	34.7	31.0	26.3
Post	19.5	19.2	31.4	32.1	35.7	24.1
Pap smear (%)						
Pre	13.0	10.3	12.4	15.3	25.4	15.3
Post	2.6	3.8	10.3	12.2	18.3	16.8
Prostate-specific antigen test (%)						
Pre	39.0	41.0	53.5	48.0	30.2	46.0
Post	45.5	42.3	53.0	49.0	27.8	43.1
Physician visit (N)						
Pre	6.2	7.1	15.0	15.9	12.6	13.8
Post	6.1	7.2	15.8	16.7	15.5	16.8
Oncology visit (%)						
Pre	1.2	0.5	2.1	2.4	2.0	3.6

(continued)

Table 6-1 (continued)
Sample characteristics, screening rates, visit rates, and expenditures for treatment arm participants, before and after enrollment

	Johns Hopkins		Josephine Ford		M.D. Anderson	
Treatment participants	Control	Inter.	Control	Inter.	Control	Inter.
Post	1.4	0.5	0.8	0.8	2.6	2.7
Emergency room visit (%)						
Pre	0.6	0.6	1.4	1.5	0.7	0.7
Post	0.4	0.5	1.7	2.1	1.1	0.9

NOTES: Inter. = intervention; Pre: before enrollment in the demonstration, where pre-enrollment is time equal to individual duration of enrollment; Post: after enrollment in the demonstration, including entire duration of enrollment.

SOURCE: RTI analysis of baseline Cancer Status Assessments and Medicare claims (2002–2010). (Program cptd031)

In addition, patient navigation in the treatment arm was meant to support those who were newly diagnosed with cancer, to increase their adherence to guidelines for diagnostics and treatment during the most intense time. The average length of time with cancer is 3–5 years, which no longer reflects the active treatment phase that could benefit most with patient navigation support. This length of time with cancer reflects a surveillance phase, where Medicare and National Comprehensive Cancer Network guidelines suggest that periodic screening and physician visits are paramount. In examining screening rates, because of sample size constraints, we were not able to limit the sample to look at mammography rates in breast cancer survivors or PSA rates in prostate cancer survivors. Instead, we report all cancer screenings that are relevant to men or women, in addition to numbers of physician visits and emergency room visits. Breast cancer for women and prostate cancer for men were the most prevalent cancers at each site, followed by lung cancer. The average length of enrollment across all sites for the treatment arm was 19.3 months. There were no statistically significant differences in screening rates or physician visits between intervention and control groups. This result may be due in part to small sample sizes and to the fact that within the small samples, intervention and control groups in each site had different mixes of cancers.

We cannot address satisfaction questions because of the small samples responding to the exit CSAs. The only satisfaction measure that we can report is that approximately 77% of the intervention group at Josephine Ford and M.D. Anderson reported excellent or very good ratings of their experiences with the PNs.

CHAPTER 7
ECONOMIC EVALUATION OF THE DEMONSTRATION: COST AND ACTIVITIES

RTI performed a detailed assessment of the cost incurred by the demonstration sites to provide the screening and treatment facilitation services. This information will provide CMS with the cost of specific activities performed by the sites for the screening and treatment intervention groups. Assessment of the costs and activities will provide decision makers with a thorough understanding of the key activities required for a patient navigation program and the funding necessary to sustain such a program.

The demonstration costs and activities were analyzed to address the following research questions:

- What is the total cost of the facilitating services offered by the demonstration sites and the sources of funding?
- What is the average facilitation cost per person for those enrolled in the screening and treatment intervention groups?
- How are the costs distributed across the key activities performed by the demonstration sites?
- What are the specific types of tasks performed by the PNs?

The costs presented in this chapter include the cost incurred by the sites to provide both screening and treatment navigation. The analysis is also based on the program perspective, and therefore all resources (from CMS and other sources) required by the sites to operate the navigator program are included. The funding information provided in this chapter is based on the data reported directly by the sites to RTI.

7.1 Approach and Data Sources

RTI utilized the Cost Assessment Tool (CAT) to collect detailed activity-based costs from the demonstration sites. The CAT, an Excel-based data collection tool, is based on standard well-established methods for cost data collection (French et al., 1997; French et al., 2004; Salome et al., 2003) and has been administered successfully previously to collect costs from cancer programs (Subramanian et al., 2008). Sites use CAT to gather information electronically to eliminate data entry errors. The sites also received a user's guide that contains definitions and descriptions of the required cost data elements to ensure consistent reporting across all programs.

RTI tailored the information collected in the CAT to obtain cost data on services provided by the demonstration sites for both the start-up period and the implementation period. The start-up time period was defined as the time period from the initiation of the demonstration to when the first beneficiary was enrolled in the program. The start-up period ranged from 5 to 12 months. The Annual CAT collected information on implementation costs for each year of the demonstration. In both the Start-up and Annual CAT, RTI collected information on in-kind

contributions (donated labor and other resources) because these contributions can be a very significant proportion of the resources expended by programs (Subramanian et al., 2008).

To appropriately allocate the expenditures, RTI collected details on the distribution of both labor and non-labor costs for all activities performed. Program staff was asked to allocate costs to the following CPTD activities: program management, outreach/recruitment, professional development/quality assurance, data collection/CSA administration, patient support/navigation, program evaluation, administrative/overhead, and other activities. RTI estimated labor costs using the following information: (1) the number of hours worked by staff each month on various activities, (2) the proportion of staff salaries paid through CPTD funds, (3) data on the percentage of time that staff members worked, and (4) staff salaries. RTI computed the hourly rate for each staff member and used the hours spent on each program activity to allocate parts of the total salary to the activities performed. RTI then aggregated the labor costs for each activity and assigned in-kind labor contributions to each program activity. Similarly, RTI aggregated the costs of consultants, materials, equipment, and supplies for each activity, then derived the total overhead costs related to the service delivery period by using detailed information provided by the sites on rent, utility payments, and other indirect costs.

Cost and activities are provided for each site separately to assess potential differences between the sites that participated in the demonstration. To assess costs while accounting for the volume of individuals who were served at each site, RTI estimated the cost per person enrolled for each activity. RTI calculated the costs per person by dividing the cost for each program activity by the total number of individuals who received navigation services at each site (that is, the intervention group who completed baseline CSA). For some activities (outreach/recruitment and data collection/CSA administration), the sites incurred costs for both the intervention and the control groups. RTI used the ratio of intervention to control group in each site to allocate the cost specifically incurred by the intervention group to determine the cost per person. RTI presented the cost per person including and excluding in-kind contributions to account for any potential differences in the manner in which the sites may have reported in-kind contributions.

In addition to the CAT, RTI also developed an Excel-based tool to collect and report details on the activities and time spent by PNs to understand the types of tasks performed by these individuals during the course of the demonstration. RTI collected the hours spent by each navigator on planning and administrative tasks, screening-related navigation, treatment-related navigation (screening and treatment arms separately), addressing comorbidities such as diabetes and hypertension, outreach and recruitment, orientation and training, data collection and CSA administration, and other tasks (not reported in the other categories). The PN survey was completed quarterly to limit potential recall bias. RTI reported the aggregated hours by activity for each site and also the hours per person enrolled in the intervention group. The cost-per-person calculation was performed as described above for the CAT analysis; again, RTI excluded costs related to the control group.

7.2 Demonstration Cost and Activities

As reported in Table 7-1, the total funding reported by the sites during the demonstration period ranged from $959,968 to $4,901,506. The proportion of the total funding spent during the start-up period varied from 4.5% to 18.9%. All sites received most of their funding from CMS, but some sites had significant in-kind contributions as well.

Table 7-2 presents the cost of program activities for all sites pooled together during the start-up and the implementation period separately. In both periods, about a quarter of the cost was expended on program management activities. Other resource-intensive activities during the start-up period included planning for patient recruitment (15.1%), undergoing professional development (10.5%), and planning for patient navigation tasks (9.6%). During the implementation period, large cost categories included patient recruitment (16.3%), data collection/CSA administration (18.0%), and patient navigation (8.0%). The highest percentage of the funding in both periods was spent on administrative or overhead costs.

Table 7-3 provides the cost per person enrolled for each program activity and by site. Four of the six sites reported costs per person of between $3,000 and $4,000 for the entire demonstration period (includes start-up and implementation cost). The average across all the sites was $3,591, with a range from $1,239 to $6,127. On average, the sites spent $288 per person ($225–413) on recruitment and outreach; $247 per person ($117–335) on data collection and CSA administration; and $368 per person ($96–579) for patient navigation. Other high-cost activities were program management and administrative or overhead costs, which were, on average, $1,157 ($169–3,579) and $1,142 ($208–1,631) per person, respectively. Without in-kind contributions (Table 7-4), the average total cost was $3,238, with a range from $1,216 to $5,120. The distribution of the costs across the activities remained very similar whether in-kind contributions were included or excluded.

7.3 Patient Navigator Activities and Hours

On average across all the programs (Table 7-5), 30.5% of the PNs' time was spent on screening navigation activities. Other activities with significant hours expended included planning and administrative tasks (13.7%); data collection, tracking, and CSA administration (11.2%); addressing comorbidities (11.1%); and outreach/recruitment (9.3%). Overall, 11.2% of the total time available was devoted to treatment navigation for those in the screening and treatment arms combined.

The proportion of time spent on activities varied across the sites. For most of the sites, navigation activities related to the screening arm were the most time-consuming. In the case of Josephine Ford, though, the PNs spent the largest percentage of their time on data collection and tracking (25.2%) and other activities (27.9%), which included mailings, eligibility checks, and other nonspecific clerical duties. Screening arm-related navigation activities consumed 16.8% of the total time devoted by the PNs at Josephine Ford. Also, at Huntsman, most of the time (50.8%) was spent addressing comorbidities of the enrollees and only 8.5% of the time was spent on screening navigation.

Table 7-6 presents the average total hours and hours by specific activity for each person enrolled in the intervention arm. On average across all the sites, the navigators spent 24.1 hours on each person. M.D. Anderson had the lowest amount of time, at 10.5 hours, whereas Molokai reported the highest, 47.1 hours. The sites devoted 1.6–17.4 hours per person to screening navigation activities, with an average across all the sites of 7.6 hours per person.

7.4 Conclusions

The sites performed a large variety of activities to successfully implement patient navigation. In addition to direct patient navigation tasks, the sites expended significant time and resources in data collection, patient recruitment, and management. Overall, the PNs spent about 25 hours per person; the total cost for each person enrolled in the intervention group was about $3,500.

There are differences across the sites in terms of both the cost and the distribution of the activities performed. Some of the difference in the cost can be explained by variation in cost of living, but this does not account for the large variations seen. The patient population did differ among the sites; for example, Huntsman enrollees were American Indians who often had other comorbid conditions that needed to be addressed. Also, the mix of individuals requiring screening compared with treatment navigation did differ, but in all the sites the vast majority of the enrollees were those who received screening navigation. In addition, although the sites did have guidance from CMS as to what type of navigation to provide, there was variation in the intensity of the services provided.

The findings from this study highlight that, to ensure a successful navigation program, a variety of activities ranging from patient recruitment to quality assurance are required and need to be supported. Because the sites were implementing programs within a demonstration, they did incur additional costs related to evaluation activities and perhaps performed more intensive data collection than would otherwise be required. Nevertheless, the cost estimates reported from these demonstration sites provide valuable information on the resources required to start and implement navigation programs in the future.

Table 7-1
Cancer prevention and treatment demonstration funding, by source

Funding	Huntsman	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i	Total
Total funded	**$4,851,827**	**$4,901,506**	**$4,883,517**	**$4,226,647**	**$2,385,680**	**$959,968**	**$22,209,145**
Start-up	4.5%	5.7%	7.4%	18.9%	7.3%	17.6%	9.0%
Implementation	95.5%	94.3%	92.6%	81.1%	92.7%	82.4%	91.0%
Funding sources CPTD funded	82.8%	96.0%	98.7%	89.6%	99.9%	78.5%	89.1%
In-kind	16.9%	2.1%	1.3%	4.8%	0.1%	20.7%	9.2%
Other	0.3%	2.0%	0.0%	5.6%	0.0%	0.8%	1.6%

NOTE: UMDNJ = University of Medicine and Dentistry of New Jersey.

SOURCE: RTI Analysis of Cancer Prevention and Treatment Demonstration (CPTD) demonstration sites' Cost Assessment Tools, 2006–2010.

Table 7-2
Cost of program activities during the start-up and implementation periods

Program activities	Start-up period				Implementation period			
	Mean	Minimum	Maximum	%	Mean	Minimum	Maximum	%
Total	**$332,675**	**$168,818**	**$799,399**	—	**$3,368,849**	**$791,150**	**$4,634,829**	—
Program management	$85,929	$22,416	$273,724	25.8%	$770,634	$220,584	$2,584,742	22.9%
Outreach/recruitment	$50,213	$6,767	$116,498	15.1%	$549,947	$115,691	$1,392,182	16.3%
Professional development/quality assurance	$34,816	$4,661	$141,352	10.5%	$139,046	$45,936	$262,548	4.1%
Patient support/navigation	$32,029	$6,878	$97,506	9.6%	$270,532	$118,225	$465,868	8.0%
Data collection/tracking/CSA	$5,537	$0	$12,511	1.7%	$605,631	$95,559	$1,738,264	18.0%
Program evaluation	$6,616	$1,694	$18,612	2.0%	$77,268	$28,132	$203,260	2.3%
Administration/overhead	$111,815	$42,179	$292,459	33.6%	$87,443	$0	$278,723	2.6%
Other activities	$5,720	$0	$30,590	1.7%	$868,347	$148,883	$1,651,469	25.8%

NOTE: CSA = Cancer Status Assessment.

SOURCE: RTI analysis of Cancer Prevention and Treatment Demonstration (CPTD) demonstration sites' Cost Assessment Tools, 2006–2010.

Table 7-3
Cost per person enrolled for each program activity, by site (includes in-kind)

Program activities	Huntsman	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i	Average
Total	**$6,127**	**$3,287**	**$1,239**	**$3,333**	**$3,586**	**$3,974**	**$3,591**
Program management	$3,579	$400	$169	$729	$749	$1,317	$1,157
Outreach/recruitment	$225	$238	$291	$255	$413	$305	$288
Professional development/quality assurance	$172	$212	$128	$155	$96	$357	$187
Patient support/navigation	$269	$384	$96	$453	$429	$579	$368
Data collection/tracking/CSA	$117	$328	$335	$306	$150	$244	$247
Program evaluation	$298	$82	$12	$36	$111	$188	$121
Other activities	$43	$240	$0	$196	$6	$0	$81
Administration/overhead	$1,425	$1,403	$208	$1,203	$1,631	$983	$1,142

NOTE: CSA = Cancer Status Assessment; UMDNJ = University of Medicine and Dentistry of New Jersey.

SOURCE: RTI analysis of Cancer Prevention and Treatment Demonstration (CPTD) demonstration sites' Cost Assessment Tools, 2006–2010.

Table 7-4
Cost per person enrolled for each program activity, by site (excludes in-kind)

Program activities	Huntsman	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i	Average
Total costs	**$5,120**	**$3,216**	**$1,216**	**$3,184**	**$3,586**	**$3,108**	**$3,238**
Program management	$3,048	$383	$159	$673	$749	$995	$1,001
Outreach/recruitment	$175	$236	$285	$253	$413	$258	$270
Professional development/quality assurance	$130	$202	$127	$150	$96	$298	$167
Patient support/navigation	$246	$381	$96	$403	$429	$461	$336
Data collection/tracking/CSA	$85	$317	$331	$274	$150	$230	$231
Program evaluation	$183	$73	$11	$35	$111	$168	$97
Other activities	$43	$230	$0	$194	$6	$0	$79
Administration/overhead	$1,210	$1,395	$208	$1,203	$1,631	$698	$1,057

NOTE: CSA = Cancer Status Assessment; UMDNJ = University of Medicine and Dentistry of New Jersey.

SOURCE: RTI analysis of Cancer Prevention and Treatment Demonstration (CPTD) demonstration sites' Cost Assessment Tools, 2006–2010.

Table 7-5
Percentage distribution of activities performed by patient navigators, by site

Navigator activities	Huntsman	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i	Average
Planning & administrative tasks	11.9%	19.5%	6.9%	10.3%	16.5%	17.4%	13.7%
Screening arm only: Screening-related navigation activities	8.5%	44.0%	16.8%	33.9%	43.0%	36.8%	30.5%
Screening arm only: Treatment-related navigation activities	0.7%	0.3%	3.7%	8.8%	7.1%	5.8%	4.4%
Treatment arm only: Treatment-related navigation activities	0.2%	6.2%	3.1%	13.2%	9.4%	8.9%	6.8%
Addressing comorbidities such as diabetes & hypertension	50.8%	1.1%	2.6%	8.1%	2.7%	1.3%	11.1%
Outreach/recruitment	14.8%	3.5%	11.5%	2.6%	7.4%	15.8%	9.3%
Orientation and training	6.5%	4.7%	2.2%	6.3%	3.8%	10.1%	5.6%
Data collection/tracking/CSA	5.0%	11.8%	25.2%	11.6%	10.2%	3.2%	11.2%
Other activities	1.6%	8.9%	27.9%	5.2%	0.0%	0.7%	7.4%

NOTE: CSA = Cancer Status Assessment; UMDNJ = University of Medicine and Dentistry of New Jersey.

SOURCE: RTI analysis of Cancer Prevention and Treatment Demonstration (CPTD) demonstration sites' Navigator Activity Surveys, 2006–2010.

Table 7-6
Average hours per person enrolled for activities performed by patient navigators, by site

Navigator activities	Huntsman	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i	Average
Total hours	**14,060.9**	**19,934.3**	**65,048.9**	**11,380.3**	**16,244.5**	**10,183.9**	**22,808.8**
Hours per person (baseline N)							
Overall	18.9	15.5	24.4	10.5	28.2	47.1	24.1
By activity							
Planning & administrative tasks	2.2	3.0	1.7	1.1	4.6	8.2	3.5
Screening arm only: Screening-related navigation activities	1.6	6.8	4.1	3.6	12.1	17.4	7.6
Screening arm only: Treatment-related navigation activities	0.1	0.0	0.9	0.9	2.0	2.7	1.1
Treatment arm only: Treatment-related navigation activities	0.0	1.0	0.8	1.4	2.6	4.2	1.7
Addressing comorbidities such as diabetes & hypertension	9.6	0.2	0.6	0.8	0.8	0.6	2.1
Outreach/recruitment	2.8	0.5	2.8	0.3	2.1	7.5	2.7
Orientation and training	1.2	0.7	0.5	0.7	1.1	4.7	1.5
Data collection/tracking/CSA	0.9	1.8	6.2	1.2	2.9	1.5	2.4
Other activities	0.3	1.4	6.8	0.5	0.0	0.3	1.6

NOTE: CSA = Cancer Status Assessment; UMDNJ = University of Medicine and Dentistry of New Jersey.

SOURCE: RTI analysis of Cancer Prevention and Treatment Demonstration (CPTD) demonstration sites' Navigator Activity Surveys, 2006–2010.

CHAPTER 8
CONCLUSIONS

The CPTD was designed to reduce racial/ethnic disparities in cancer prevention and treatment by improving cancer screening rates and completion rates of cancer treatment. Unfortunately, recruitment into the treatment arm of the demonstration was difficult, and no impact was found for PNs, possibly because of the very small sample sizes. Enrollment into the screening arm was considerably larger, but we found that the impact of patient navigation varied by site. One site (Moloka'i) succeeded in improving screening for all four cancers (breast, cervix, colon, and prostate). Two sites (Huntsman and M.D. Anderson) failed to show any impact whatsoever. The remaining three sites were more variable, with one site demonstrating improvement in three of the four screening rates (UMDNJ) and two showing improvement in two rates (Johns Hopkins, Josephine Ford). These results are based on the entire duration of enrollment in the demonstration (an average of 16–23 months, depending on site). When we limited the analysis to the first year of enrollment, UMDNJ and Johns Hopkins demonstrated improvement for only two and one screening tests, respectively.

What accounts for these mixed results across sites? Although it may be difficult to pinpoint exactly, we can use our two prior rounds of site visits, as well as the PN activity surveys completed by each site, to shed some light on these differences:

- Variations in design and implementation of the patient navigation model—CMS did not specify a standardized PN model, encouraging innovation by allowing each site to design the approach it deemed most appropriate for its target population. As a result, the demonstration cannot serve as a test of patient navigation per se. The sites also varied considerably in the amount of planning and model development they did before implementing the demonstration. More time spent developing relationships with local partners, understanding the target population and the barriers they faced, and learning about the characteristics of the Medicare population in their communities would have greatly benefitted those sites that had difficulties enrolling participants (all but Josephine Ford and Moloka'i).

- Difficulties in enrollment and retention—Four of the six sites encountered difficulties in identifying eligible Medicare beneficiaries and enrolling them in the demonstration. This resulted in a slower-than-anticipated start-up for these sites, especially for Johns Hopkins and M.D. Anderson, so that there was less time actually to navigate intervention group participants. Some sites found that some participants unexpectedly dropped from the demonstration (because of managed care enrollment), also shortening the time for navigation and increasing the time that sites spent focused on enrollment.

- Geography—Moloka'i is a small, self-contained island with a single 15-bed hospital. The site's PNs could easily reach its small group of intervention participants and even drive them to screening appointments. By contrast, participants in the Huntsman site were spread across vast areas of isolated Native American reservation land. Many

participants did not have telephones, requiring PNs to travel long distances only to find them not at home.

- Limited time for patient navigation activities—On average, PNs spent about half their time in non-navigation activities. These included such things as recruitment, CSA administration, and training—activities that were important but that took time away from actual patient navigation.

- Non-randomization of Huntsman site—Because of cultural concerns, the Huntsman demonstration randomized clusters of communities, rather than randomizing individuals, as was done in the other five sites. As a result, there were some demographic differences between the intervention and control group participants, thereby compromising the randomization. "Contamination" of the control group also occurred, as Huntsman navigators reported that they provided services to control group participants when asked to do so.

The CPTD provides some valuable lessons learned for future demonstrations of this type, both for future sites to consider and for CMS.

Lessons learned for future demonstration sites

- *Understand your target population and local community ahead of time.* Sites need to determine what barriers to screening actually exist for their targeted racial/ethnic group before designing the intervention. Sites also need to assess whether there is local distrust of their institution that might hinder enrollment.

- *Identify local partners and begin working with them prior to implementation*. Sites need to learn what community-based organizations already exist in the local community that might be providing similar, or complementary, services. Sites also need to gain the trust of local primary care physicians in order to enlist their support and cooperation with the demonstration.

- *Understand the Medicare program as it affects the targeted racial/ethnic group*. All of the sites failed to recognize the Medicare Advantage (managed care) penetration rate in their communities. As a result, they under-estimated how many beneficiaries would be eligible for the demonstration. Sites also need to determine how many of their targeted beneficiaries are dual eligible and the special challenges posed by this population.

- *Develop the patient navigation model ahead of time*. Some sites developed the intervention "on the fly" without ensuring it was targeted to the needs of their community.

- *Do not start enrollment until the intervention is ready to be launched*. Many sites began enrolling participants into the demonstration before PNs were hired, trained, and ready to begin services.

- *Determine cancer incidence rates for the target population ahead of time*. Sites did not realize how few eligible participants would be diagnosed with new study cancers over the course of the demonstration. As a result, far fewer than expected beneficiaries were recruited into the treatment arm of the demonstration. The inclusion of cancer patients who had already finished their course of treatment further weakened this arm of the demonstration.

Lessons learned for CMS

- *Consider a more standardized patient navigation model for testing.* Each site was allowed to develop their own model in order to ensure cultural appropriateness for the local community. However, this greatly limited the ability to evaluate patient navigation as a tool to reduce racial/ethnic disparities.

- *Ensure that sites submit an implementation plan before they begin enrollment.* Sites rushed to enroll participants before they had clearly thought through all the steps associated with providing patient navigation services. A detailed implementation plan would have provided valuable guidance to both CMS and the sites themselves.

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APPENDIX A
PROPENSITY MATCHED SAMPLE

Because response rates to exit Cancer Status Assessment surveys were low, and differed for intervention and control group members, it was possible that results could be biased for outcomes that relied on the exit CSA data. Because screening rates and expenditure outcomes relied on claims data that were available for all who enrolled in the demonstration, these outcomes were not problematic.

Despite the initial randomization that most sites implemented, if the group that responded to exit CSAs was different from those responding to the baseline CSA, response bias could still be a problem. Using logistic regression, we modeled likelihood of responding to the exit CSA using demographic controls to see if there was a significant difference between intervention and control groups. Response bias was a problem across sites, except in Moloka'i, where exit CSA response rates were very high. In most sites, the control group had a higher response rate to the exit CSA because sites had a longer window of time to complete their interviews.

By supplementing the exit CSAs with the annual CSAs for those who were missing an exit CSA, response bias problems were reduced for all sites except MD Anderson, where annual CSA response rates were also low. To be sure that any outcomes reported from exit CSA data were unbiased, we used propensity score matching to create well-matched intervention and control groups for each site. To do this, some observations that were not well-matched were not used in the analysis. The demographics of the sample used in the propensity matched sample are presented in Table A-1.

The main information that comes from the exit CSA data relates to the health status of participants and their reported needs for facilitation and support services. With the propensity score adjustment, no health status changes were significantly different between intervention and control groups after the demonstration period.

Table A-2 presents health status scores. As indicated in the main report, the PHC and MHC are components of a multipurpose overall health rating measure called the Short Form Health Survey12. PHC captures physical health, and MHC captures mental health. Each component is normed to have an average of 50 and a standard deviation of 10. Because the PHC and MHC were not a part of the annual CSA, the low exit CSA response rates preclude looking at change in these measures. However, we were able to analyze them through propensity matching. The baseline PHC and MHC scores are similar between the exit-annual sample and the propensity matched sample. For the propensity matched sample, the changes in health status were small across sites from the baseline CSA to the exit CSA.

Beneficiary function was also monitored through repeated administrations of the EQ-5D—at baseline, in the annual surveys, and in the exit survey. The EQ-5D is a preference-based measure of functional status that combines responses to five questions about physical function and emotional well-being into a summary score. Higher scores represent better function levels. In older adults, EQ-5D scores generally decline slowly over time. The mean score for 65- to 74-year-olds in the United States is 81.1, and it drops to 75.5 in those over 75 years of age

(Nyman et al., 2007). Again, the results were similar to those in the exit-annual sample. The differences over time in the propensity matched sample were small.

Table A-3 reports participant needs at exit, for the propensity matched sample. At least three-fourths of the samples across sites and groups had no problem finding a personal doctor they were happy with. Slightly fewer in the Huntsman site and slightly more in the other sites report having no trouble finding referrals to specialists they need, and similar numbers report no problems getting access to the care that is recommended. Health plan approvals appear to be a concern only for Huntsman participants. The second part of Table 5-1a shows great satisfaction with doctors' listening, respect, explanation, and time spent with them. At least 75% report that doctors always or usually do the right thing.

Table A-4 describes who assisted enrollees with various facilitation and support services. The propensity matched sample had the same reports as the sample which used exit CSAs supplemented by annual CSAs. Overall, most enrollees across sites indicated that they did not need help with the following: scheduling and keeping appointments, getting to appointments, understanding physician instructions, making decisions about health care or with questions or concerns about medical bills and insurance. When enrollees did need help, they most often turned to friends and family. Enrollees at Huntsman reported the most need for assistance, as only about 40% of enrollees indicated that they did not need help. Transportation to visits and billing concerns were more common at Huntsman and UMDNJ.

The propensity matched sample confirms the findings from the analysis presented in the report for the information that is based on exit Cancer Status Assessment surveys.

Table A-1
Demographic characteristics of propensity matched sample, by demonstration site

Propensity matched sample	Huntsman	John Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i
Sample size	948	1,604	2,850	916	934	356
Female (%)	59.4	73.8	67.9	59.1	62.6	51.7
Age (%)						
< 65	25.4	0.1	22.9	21.1	24.5	21.1
65–69	24.0	36.1	23.7	27.0	26.8	28.4
70–74	24.3	29.6	19.8	25.7	24.5	22.2
75–79	14.4	18.5	16.3	14.1	17.1	14.0
80–84	8.7	10.8	11.7	7.4	5.1	9.6
85+	3.4	5.0	5.8	4.8	1.9	4.8
Dual eligibility status	53.2	19.8	30.1	33.5	69.8	23.9
Education (%)						
High school or more	50.3	67.7	63.2	39.8	36.5	63.5
Marital status (%)						
Married/living with partner	47.7	28.2	30.5	59.9	36.6	47.7
Living arrangements (%)						
Alone	22.1	44.8	47.1	22.6	45.7	19.1
Have children (% yes)	89.7	87.8	85.9	91.6	88.8	85.7
Income (%)						
Less than $10,000	46.7	25.0	25.6	19.9	49.0	26.3
$10,000–$19,999	27.0	27.9	29.0	36.7	37.3	23.7
$20,000+	26.2	47.1	45.4	43.4	13.7	50.0
Speak mainly english at home (%)	79.2	99.8	99.3	46.2	4.8	83.7

SOURCE: RTI analysis of propensity score sample. (Program: cptd028)

Table A-2
Health status indicators of propensity matched sample, by demonstration site and by group

Propensity matched sample	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter	Control	Inter.	Control	Inter.
Sample size	474	474	802	802	1,425	1,425	458	458	467	467	178	178
Enrollee age	69.6	65.9	73.7	72.2	71.2	67.8	71.2	67.0	67.3	69.2	69.3	67.7
Baseline												
PHC_Baseline	36.418	36.307	39.148	39.763	38.216	36.723	38.032	37.957	33.884	34.250	42.934	42.220
MHC_Baseline	41.173	40.898	43.592	43.966	42.810	41.587	44.213	43.365	39.731	40.125	46.982	46.539
EQ5D_Baseline	0.737	0.737	0.791	0.808	0.807	0.776	0.774	0.757	0.654	0.645	0.842	0.849
Exit												
PHC_Exit	35.247	37.403	40.724	40.952	37.466	37.037	38.434	38.339	34.567	35.196	41.422	41.243
MHC_Exit	40.995	41.493	44.412	44.128	42.372	41.340	43.505	43.031	40.378	39.869	46.145	45.902
EQ5D_Exit	0.727	0.742	0.827	0.828	0.787	0.789	0.756	0.759	0.737	0.729	0.826	0.834
Difference (after-before)												
PHC	–1.171	1.096	1.576	1.189	–0.750	0.314	0.402	0.382	0.683	0.946	–1.512	–0.977
MHC	–0.178	0.595	0.820	0.162	–0.438	–0.247	–0.708	–0.334	0.647	–0.256	–0.837	–0.637
EQ5D	–0.010	0.005	0.036	0.020	–0.020	0.013	–0.018	0.002	0.083	0.084	–0.016	–0.015

SOURCE: RTI analysis of propensity score sample. (Program: cptd028)

Significance testing was conducted for EQ5D; nothing significant at the .05 level.

Table A-3
Participant needs as reported at baseline for the screening arm of the propensity matched sample, by group and by demonstration site

	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
Propensity matched sample's reports	Control	Inter	Control	Inter	Control	Inter	Control	Inter	Control	Inter	Control	Inter
Sample	473	471	796	801	1,423	1,423	455	456	464	466	178	177
How much of a problem was it to get…												
A personal doctor you are happy with?												
Big	9.3	15.5	3.3	2.8	2.4	3.2	4.0	7.0	7.5	3.9	2.3	0.6
Small	17.3	12.3	6.7	6.1	5.2	6.3	10.3	8.6	7.3	8.2	3.4	4.5
Not	73.4	72.2	90.1	91.1	92.4	90.4	85.7	84.4	85.1	88.0	94.4	94.9
A referral to a specialist you needed?												
Big	8.7	18.1	2.1	1.4	1.2	2.0	3.5	5.3	4.1	3.9	1.7	1.1
Small	19.3	9.2	2.4	2.0	2.4	2.7	6.6	5.0	4.1	4.7	3.4	3.4
Not	72.0	72.8	95.5	96.6	96.4	95.4	89.9	89.7	91.8	91.4	94.9	95.5
The care your doctor believed necessary?												
Big	7.0	13.0	2.7	2.4	1.4	2.1	3.5	5.1	4.1	2.4	1.1	0.6
Small	15.2	9.4	4.0	3.9	2.7	3.8	7.3	6.8	7.5	5.6	4.0	3.9
Not	77.8	77.7	93.3	93.8	96.0	94.1	89.2	88.1	88.4	92.1	94.9	95.5
Timely approval from your health plan?												
Big	11.2	16.3	2.2	2.1	1.5	1.8	2.9	2.4	3.4	2.6	1.7	1.7
Small	20.6	13.2	3.5	2.9	1.2	1.5	4.9	5.7	7.3	7.3	1.1	3.9
Not	68.2	70.5	94.4	95.0	97.2	96.8	92.2	91.9	89.3	90.2	97.2	94.4

(continued)

Table A-3 (continued)
Participant needs as reported at baseline for the screening arm of the propensity matched sample, by group and by demonstration site

	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
Propensity matched sample's reports	Control	Inter	Control	Inter	Control	Inter	Control	Inter	Control	Inter	Control	Inter
How often did your doctors…												
Listen carefully to you? Always	56.3	60.2	79.8	82.8	82.1	79.6	75.6	77.9	83.9	86.3	85.4	88.2
Usually	27.4	18.5	12.5	10.2	11.1	12.0	18.9	13.9	10.1	7.3	9.6	8.4
Sometimes	13.8	14.9	5.9	5.1	6.2	7.4	3.7	7.1	5.2	5.1	4.5	1.7
Never	2.6	6.4	1.9	1.9	0.6	1.1	1.8	1.1	0.9	1.3	0.6	1.7
Explain things in a way you could understand? Always	52.7	60.1	79.5	86.0	72.3	75.6	74.6	78.2	82.0	85.7	86.5	89.3
Usually	29.7	21.3	11.8	7.9	20.6	16.8	18.2	14.4	9.2	7.3	9.0	5.1
Sometimes	14.0	11.5	6.2	4.7	6.2	6.1	5.7	6.8	6.9	6.0	4.5	3.9
Never	3.6	7.0	2.5	1.4	0.9	1.5	1.5	0.7	1.9	1.1	0.0	1.7
Show respect for what you had to say? Always	59.0	66.0	86.4	88.8	74.9	77.3	77.0	83.4	91.2	92.0	88.2	91.6
Usually	24.0	16.6	8.1	6.4	19.5	16.2	17.3	10.4	6.6	4.1	6.7	5.1
Sometimes	14.0	12.1	4.0	3.3	5.0	5.2	4.0	5.5	1.7	3.0	3.9	1.7
Never	3.0	5.3	1.5	1.6	0.6	1.3	1.8	0.7	0.4	0.9	1.1	1.7
Spend enough time with you? Always	54.7	60.9	74.4	80.3	71.7	74.0	70.6	74.8	73.8	75.5	87.1	87.6
Usually	21.6	17.0	13.5	9.9	21.0	16.4	19.6	16.4	15.5	15.2	9.0	5.6
Sometimes	18.0	13.6	8.8	7.1	5.9	7.0	7.5	6.9	8.6	7.5	3.4	4.5
Never	5.7	8.5	3.3	2.8	1.4	2.6	2.4	2.0	2.2	1.7	0.6	2.3

SOURCE: RTI analysis of propensity score sample (cptd028)

Table A-4
Reports of who provided facilitation and support services for the screening arm of the propensity matched sample, by group and by demonstration site

	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
Propensity matched sample's reports	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter	Control	Inter.	Control	Inter.
Who helps schedule and keep appointments?												
Do not need help	36.8	42.5	71.2	79.6	71.1	74.2	48.6	66.3	49.3	44.8	54.2	42.3
Doctor/health care center/clinic staff	13.6	9.5	7.8	6.2	6.1	8.9	12.6	5.7	11.1	9.3	10.4	26.4
Family/friend/neighbor	42.3	43.1	20.2	12.9	19.8	15.6	38.1	25.8	25.9	24.9	32.8	28.9
Other	7.3	5.0	1.0	1.3	3.0	1.4	0.7	2.3	13.7	21.1	2.6	2.4
Who helps with transportation to appointments?												
Do not need help	32.9	40.7	60.1	70.0	53.8	48.6	46.0	50.9	39.8	39.7	61.1	66.8
Doctor/health care center/clinic staff	5.1	7.1	1.0	1.0	2.9	2.2	1.2	0.2	2.2	1.7	4.2	4.7
Family/friend/neighbor	48.1	44.8	24.9	22.5	32.3	34.5	44.3	39.7	28.5	27.8	30.5	23.7
Other	14.1	7.5	13.9	6.5	11.1	14.8	8.6	9.1	29.4	30.8	4.2	4.8
Who helps you to better understand what the doctor told you to do?												
Do not need help	41.5	40.8	67.8	76.8	73.7	69.7	49.7	56.3	54.0	54.3	61.9	60.0
Doctor/health care center/clinic staff	10.1	12.5	8.6	5.4	2.5	6.0	6.6	5.8	16.2	14.8	5.8	8.5
Family/friend/neighbor	42.9	42.8	23.3	17.0	22.0	22.4	42.8	36.0	23.6	23.0	30.2	30.0
Other	5.5	4.0	0.2	0.9	1.9	1.9	0.9	1.9	6.2	7.9	2.2	1.5
Who helps you make decisions about health care and treatment?												
Do not need help	42.2	42.1	70.3	77.0	73.6	70.8	51.9	59.6	52.4	56.4	60.5	56.0
Doctor/health care center/clinic staff	8.8	14.3	7.4	3.7	3.1	4.3	5.6	2.8	4.8	5.4	6.8	11.6
Family/friend/neighbor	43.4	41.7	22.0	18.7	21.7	23.8	41.5	36.4	38.2	31.5	31.1	30.9
Other	5.6	2.0	0.2	0.5	1.5	1.1	0.9	1.1	4.6	6.7	1.6	1.5

(continued)

Table A-4 (continued)
Reports of who provided facilitation and support services for the screening arm of the propensity matched sample, by group and by demonstration site

	Huntsman		Johns Hopkins		Josephine Ford		M.D. Anderson		UMDNJ		Moloka'i	
Propensity matched sample's reports	Control	Inter.	Control	Inter.	Control	Inter.	Control	Inter	Control	Inter.	Control	Inter.
Who helps you to follow your doctor's treatment recommendations?												
Do not need help	41.1	42.8	75.6	81.4	76.0	72.8	53.8	64.1	51.5	54.3	62.6	57.1
Doctor/health care center/clinic staff	8.3	11.4	3.3	1.5	1.5	2.2	1.9	1.7	4.7	5.4	6.4	9.8
Family/friend/neighbor	44.4	41.9	20.9	16.5	20.4	23.8	42.7	32.5	36.9	30.6	29.4	31.2
Other	6.1	4.0	0.4	0.7	2.2	1.4	1.6	1.7	6.8	9.7	1.6	2.0
Who helps you with questions/concerns about insurance/medical bills?												
Do not need help	38.6	40.8	68.9	80.2	75.1	76.5	50.4	60.8	39.2	41.0	55.9	49.3
Doctor/health care center/clinic staff	8.9	8.8	3.4	2.4	1.1	2.0	2.1	2.1	1.5	2.0	5.9	17.9
Family/friend/neighbor	43.1	42.5	23.1	15.3	19.6	19.3	44.5	32.6	42.6	36.1	37.1	30.9
Other	9.4	7.9	4.6	2.2	4.2	2.3	3.0	4.6	16.7	20.9	1.0	2.0

SOURCE: RTI analysis of propensity score sample. (Program: cptd028)

Other is a combination of the possible responses: community organizations, no help available, and other.