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

Second Report to Congress

Prepared for

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SECOND REPORT TO CONGRESS

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ABSTRACT

The Centers for Medicare & Medicaid Services funded six demonstration projects to test the effectiveness of patient navigation (PN) in reducing ethnic/racial disparities in cancer screening and treatment. Although the demonstration began on October 1, 2006, the sites experienced difficulties in enrolling participants and in starting the actual process of navigation. As a result, definitive findings on the demonstration's effectiveness will not be available until 2012. This report presents preliminary data based on site visits, document review, baseline (pre-demonstration) Medicare claims and participant surveys, and satisfaction surveys of participants in the intervention group.

At the time of this report, sites had made substantial progress in enrolling participants into the screening arm of the demonstration, but enrollments in the treatment arm remain very low. Participants in the screening arm who were randomized to receive PN were generally satisfied with those services in 5 of the 6 sites. However, services were generally limited to help with setting up appointments and making referrals. The lay navigator model used by most of the sites suffers from a lack of day-to-day clinical supervision, which may have limited the services provided. Using Medicare claims, demonstration participants were compared with non-participants in order to ascertain whether the results from the demonstration could be applied to the Medicare population at large. Demonstration participants were significantly more likely to be younger and female. They were also more likely to have received cancer screening services and an influenza vaccine before the start of the demonstration.

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SECTION 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 two years after the date of implementation of the initial demonstration projects. The first Report to Congress was submitted in September 2008. This is the second report, and a final report will be submitted September 2012. The demonstration report is required to evaluate the demonstration project's cost-effectiveness, the quality of the health care services provided under the demonstration, and beneficiary and provider satisfaction under the demonstration. Beneficiary satisfaction will be determined through responses from the Cancer Screening Assessment (CSA), while provider satisfaction was ascertained via interviews conducted at site visits. 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]

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

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], 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). PNs have been used primarily to help cancer patients (Dohan and Schrag, 2005; Hede, 2006); their use for cancer screening and diagnosis is more limited, although some recent studies are promising (Battaglia et al., 2007; Nguyen et al., 2006).

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, Asian and Native Hawaiian or Other Pacific Islander (ANHOPI), 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 were as follows:

- University of Utah Huntsman Cancer Institute, Salt Lake City, UT: American Indians (tribes included Chippewa Cree, Assinniboine, Gros Ventre, Blackfeet and Navajo).
- Johns Hopkins University, Baltimore, MD: African Americans.
- Josephine Ford Cancer Center (Henry Ford Health System), Detroit, MI: African Americans.
- University of Texas M.D. Anderson Cancer Center, Houston, TX: Hispanics (primarily of Mexican and Central American origin).
- University of Medicine and Dentistry of New Jersey (UMDNJ), Newark, NJ: Hispanics (primarily of Puerto Rican origin).
- Moloka'i General Hospital, Moloka'i, HI: ANHOPI (largely Native Hawaiians and Filipinos).

1.1 Overview of Report

This report consists of the following four sections. Section 2 provides an overview of the CPTD demonstration design. Section 3 summarizes findings from the first Report to Congress, while Section 4 presents new findings from the past 2 years of the demonstration. Section 5 provides an overview of the scope of the third and final Report to Congress.

SECTION 2
OVERVIEW OF THE CPTD DESIGN

2.1 Eligibility

Participation in the demonstration is voluntary, and beneficiaries may drop out at any time. Participants are automatically dropped if they become ineligible. For example, beneficiaries in managed care plans are not eligible for this demonstration, and those who later enroll in a managed care plan also lose eligibility for the CPTD. Additionally, beneficiaries who are institutionalized or who have elected hospice are ineligible for the demonstration. All participants in the CPTD must be enrolled in Medicare Parts A and B.

2.2 Design Parameters

As previously noted, each site focuses on Medicare beneficiaries from a single racial or ethnic minority group. This greatly strengthens the experimental design because intervention and control participants share the same racial or ethnic background and are drawn from the same community.

Each site has two study arms: a screening arm and a treatment arm. Each study arm has one intervention group and one control group. Each participant recruited into the study completes a baseline CSA survey that includes questions on cancer risk factors, utilization of screening tests, and cancer history. This baseline CSA survey serves several purposes: (1) the CSA is used to assign participants to either the screening or treatment arm, (2) screening history data can be used to help schedule appointments for intervention participants in the screening arm, and (3) sites receive a fixed payment from CMS for each survey administered. These payments have proven to be an important source of additional start-up funding for the sites.

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

The study design is based on intent to treat; therefore, participants enrolled in the screening arm remain in that arm, even if they are diagnosed with cancer over the course of the study. (Intervention group participants will continue to receive navigation services for their cancer treatment. However, the evaluation will continue to treat them as participants in the screening arm.)

2.3 Randomization Method

Participants within each arm are randomized by a third party to either the intervention (i.e., PN) or control group. Four of the sites randomize at the individual level so that patients are randomly assigned to either group. The remaining two sites, Moloka'i and Huntsman, have variations on the randomization design. Because of the close-knit nature of the community on the small island of Moloka'i, CMS granted permission to assign all island residents in the treatment arm to the intervention group, and then assign people living in similar communities on the nearby island of Oahu to the control group.

Huntsman is focusing on American Indians spread across numerous remote reservations in Montana and the Four Corners area of Arizona, Colorado, New Mexico, and Utah. Because these communities are also 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. These variations on the original design may cause problems in the final analysis of the CPTD because it will be difficult to analyze data consistently across sites.

2.4 Interventions

The screening intervention group participants receive navigation services to help ensure that they receive the appropriate screenings for breast, cervical, colorectal, and prostate cancer in accordance with Medicare coverage policy for preventive services (CMS, 2007) and clinical practice guidelines. Sites varied in the specific screening guidelines they adopted, resulting in some variation in participant eligibility, e.g., Josephine Ford did not recommend Pap tests for female beneficiaries aged 70 and older, if they had a prior history of normal tests. When screening intervention group participants received positive test results, they also received navigation services to help them obtain any necessary follow-up diagnostic tests.

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

CMS did not specify a standard PN 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 is culturally sensitive to the needs of each minority community. The PN models adopted by each site are described later in this report. The variation in both PN models and target populations across the sites introduce complexities to the evaluation of the CPTD demonstration.

Control groups in each arm receive relevant educational materials. The materials vary 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.

2.5 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 receive a fixed payment for each baseline CSA survey they complete on participants in both the intervention and control groups. They also receive payments for administering an annual survey to all intervention group participants. CMS requires these annual surveys as a means of validating that navigation services are actually being provided. Sites will also receive 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 receive a capitated monthly payment for each intervention group participant. This payment covers the cost of navigation services and varies across sites. The sites proposed payment rates on the basis of their expected costs and then negotiated these amounts with CMS. The same rate is used for intervention participants in both the site's screening arm and its treatment arm, despite the presumably higher navigation intensity for treatment participants.

Both the capitation payments and the CSA payments were negotiated in advance separately by each site with CMS. Sites bill CMS for the CSA surveys using special demonstration billing codes. Monthly capitation payments are made to the sites automatically, once participants are enrolled in the intervention group, and continue as long as they remain eligible. There is no beneficiary liability (i.e., no coinsurance or deductible) for these demonstration navigation services. All clinical screening, diagnosis, and treatment services are 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), generally because staffing and other costs were not quickly offset by capitation payments because of slower-than-expected enrollments. 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. The amounts reimbursed by CMS ranged from a low of $181,335 at Huntsman to a high of $624,717 at M.D. Anderson (Table 1). 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 remains unchanged, however; that is, it is not to exceed the $25 million obligated by Congress.

Table 1
Additional financing by site, in dollars

Site	Year 1 (2006–2007)	Year 2 (2007–2008)	Year 3 (2008–2009)	Year 4 (2009–2010)	Total
Huntsman Cancer Institute	181,335	433,500	247,944	160,596	1,023,375
Johns Hopkins University	409,021	400,000	400,000	400,000	1,609,021
Josephine Ford Cancer Center (Henry Ford Health System)	350,000	0	0	0	350,000
The University of Texas, M.D. Anderson Cancer Center	624,717	608,520	520,788	520,788	2,274,813
The University of Medicine and Dentistry of New Jersey	188,000	65,891	447,985	282,589	984,735
Moloka'i General Hospital	0	0	0	0	0

SOURCE: CMS, 2009.

SECTION 3
SUMMARY OF FINDINGS FROM THE FIRST REPORT TO CONGRESS

The first Report to Congress was submitted in September 2008. It summarized the experience of all six sites during their first 15 months of demonstration implementation (through January 2008). Data were collected during in-person site visits and from CMS records. This report also included claims-based analyses of disparities in cancer screening across the six sites.

3.1 Early Enrollment into the Demonstration

Four of the six sites (all but Josephine Ford and Moloka'i) encountered difficulties with identifying eligible beneficiaries and enrolling them in the demonstration, resulting in substantially fewer participants than initially projected. Projected enrollment at the end of Year 1 was 6,484 in the screening arm. After 15 months, the number of screening participants totaled 4,138, over half of whom were enrolled at Josephine Ford. Enrollment in the treatment arm fared even worse, with none of the sites meeting their Year 1 goals. After 15 months, only 300 treatment participants were enrolled, compared with the originally projected 1,276 for Year 1.

Josephine Ford's vertically integrated delivery and electronic medical record systems were key to its early success. Josephine Ford was able to draw upon an initial list of every African American Medicare beneficiary who had received services anywhere within its health care system. However, this method also had its drawbacks; since most participants were drawn from the health care system, they were more likely to be engaged in their own health care and thus less likely to be in need of screenings, as compared to persons outside of the Josephine Ford health care system. Moloka'i was able to take advantage of its small size and close-knit community to enroll participants.

Challenges for the other sites included a larger-than-expected proportion of the population enrolled in managed care (an exclusion criteria for CPTD); limited electronic medical record systems or linkages between existing systems; a lack of existing partnerships with community agencies serving the targeted minority population; and lack of identification, recruitment, and retention of qualified staff. For some sites, actual implementation did not begin until well after the start date of October 1, 2006, partly due to delays in institutional review board (IRB) approval and staff recruitment.

Because of these difficulties in enrollment, CMS renegotiated the enrollment goals for many of the sites. Some sites lowered their total enrollment goals, while others altered the mix of projected enrollees between the screening and treatment arms.

Sites also had realized that they could not recruit a sufficient number of incident (new) cancer cases. With CMS and IRB approval, they began to recruit prevalent cancer cases (i.e., participants who had already been diagnosed with one of the five study cancers, regardless of when the diagnosis was made). The result was a mix of treatment arm participants at various stages of their treatment, including many whose treatment was completed and who simply required surveillance. This change also introduced considerable variation into the type and timing of PN services required for those in the treatment arm.

3.2 Patient Navigation Models

By design, each site developed its own intervention tailored to the needs of its community. Three of the sites (Moloka'i, Josephine Ford, and M.D. Anderson) adopted a navigation model in which nurses play a leadership and oversight role, supported by lay navigators from the community. We will refer to this as a "nurse/lay navigation model." The other three sites (Huntsman, UMDNJ, and Johns Hopkins) relied almost entirely on lay navigators (community health workers) to provide the bulk of services to intervention group participants. Differences in these models may potentially affect relative program effectiveness. Sites using the nurse/navigator model, for example, had more thoroughly developed patient flow algorithms that may result in better monitoring of care over time. This model also included more direct clinical oversight of lay navigators that may result in more appropriate screening, interpretation of test results, and so on.

3.3 Baseline Disparities in Cancer Screening

Reductions in screening disparities under the demonstration will ultimately be measured by comparing screening rates for the intervention group with those for the control group. By design, both groups within the screening arm are from the same priority (racial or ethnic minority) population. As a result, the magnitude of pre-existing (baseline) disparities between White Medicare beneficiaries and the minority population in the target area served by each demonstration site will not be known. Therefore, Medicare claims data were used to construct baseline screening rates in each area. To put these local disparities in context, national screening rates were constructed for Whites and all racial and ethnic minority groups included in the demonstration.

National screening rates for mammograms, Papanicolaou (Pap) tests, colonoscopies, and prostate-specific antigen (PSA) tests, calculated using 2005 Medicare claims, confirm the racial and ethnic disparities reported in the literature. African American, Hispanic, ANHOPI, and American Indian/Alaska Native Medicare beneficiaries were all significantly less likely to have received these tests during the year than were White Medicare beneficiaries.

Similar disparities were observed in four of the six geographic areas covered by the CPTD: Baltimore, Detroit, Houston, and the parts of Montana and Utah included in the Huntsman site. However, the targeted minority groups in the other two sites—ANHOPI in Moloka'i and Hispanics in Newark—were found to have significantly higher screening rates than their White counterparts in the same geographic area for at least three of the four tests. Possible factors include differences in the ethnic mix or country of origin of minority groups in these two locations compared with those nationally, or differences in their socioeconomic status compared with white Medicare beneficiaries in those locations.

SECTION 4
NEW FINDINGS FROM THE CPTD DEMONSTRATION

This section presents updated findings from the past 2 years of the demonstration. A second round of in-person site visits ranging from 1 to 5 days was conducted between May and July 2009, supplemented by document review. During the site visits, individual and small group interviews were conducted with 6–15 key program staff, senior management and patient navigators. In addition, we conducted analyses of baseline CSAs, annual CSAs, and Medicare claims data for participants from each site.

4.1 Roles and Responsibilities of Patient Navigators

As noted earlier, CMS did not standardize the PN intervention to be implemented, believing that each site needed to develop the model that would work best for its own minority community. Initially, three sites (Josephine Ford, Moloka'i, and M.D. Anderson) adopted a "nurse/lay navigator" model in which nurses served in the PN role or in an oversight role and were teamed with a community health worker or other lay person who focused on more administrative aspects of the process (e.g., scheduling appointments). The other three sites (UMDNJ, Huntsman, and Johns Hopkins) adopted a "lay navigator" model in which lay staff provide the bulk of PN services to participants. None of the sites varied their approach by type of cancer screening. By the time of this report, two of the three sites that originally used a nurse/lay navigator model (Moloka'i and M.D. Anderson) had changed their approaches and used only lay navigators because their nurse navigators departed from the program. This change was due primarily to staff turnover with their nurse navigators and a subsequent need to revise roles to reduce costs. The lay navigator model has the primary advantage of being less expensive to operate, potentially allowing the program to serve more participants. The primary disadvantage is the lack of day-to-day clinical supervision. Lay navigators need clear protocols for each step in the PN process so that they know what to do in every scenario, especially when clinical input is not readily available.

At the start of the demonstration, much of the PNs' and other staff's time was spent on recruitment. The difficulties with enrolling eligible participants into the demonstration were discussed in detail in the first Report to Congress. By the time of the second round of site visits in 2009, PNs at most of the sites were able to focus their time on providing PN services. The majority of participants at all sites were enrolled in the screening arm, and PNs concentrated most of their activities on these cases. PNs are responsible for:

- Determining when each intervention group participant needs a given cancer screening test by obtaining their medical records and/or using the CSA to determine when their last screening test was for each of the four cancer types.
- Addressing barriers to participants' keeping their appointments.
- Assisting with any recommended diagnostic tests.
- Helping participants diagnosed with cancer to obtain the timely and necessary treatment.

Once a participant was enrolled into the program, the navigators could rely on either the participant's memory of their prior cancer screenings (as reported on the baseline CSA) or request medical records from their primary providers to know exactly when the tests were obtained. Early on, PNs realized that participants' memories often were not an accurate depiction of their screening history. As a result, all sites began requesting medical records from providers. This proved extremely difficult when the necessary medical records were outside the sites' own health care systems. Community physicians were often deeply suspicious of the demonstration and feared losing their patients to CPTD providers, especially those that were associated with large teaching hospitals.

This difficulty in assessing when screenings were due meant that some participants may have received screenings either earlier or later than actually needed. In addition, only one site had clinical oversight of the navigators by a nurse; all the other sites had physicians serving in leadership roles for the program, but these staff rarely had the time to provide daily oversight to the delivery of navigation services. This general lack of clinical oversight for lay navigators likely resulted in inconsistencies across cases such that some participants due for screening or follow-up did not always receive navigation.

PNs at all six sites reported similar barriers faced by their participants, including fears of being diagnosed with cancer, a general lack of knowledge about cancer screening, distrust of the health care system, and a lack of transportation. Three of the sites specifically mentioned that patient comorbidities were a major barrier, as these participants needed medical services in addition to cancer screening. Only one site had a protocol in place to actively navigate participants for these other services. Other sites provided navigations for noncancer services on an incidental basis or not at all. The latter mentioned the time-consuming nature of the additional navigation, and high PN caseloads, as the reason for not doing so.

Once screening tests are completed, all six sites rely primarily on participants informing the PN of their screening results 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 try to help patients understand their results and follow-up plans. All of the sites have established protocols so that the PNs can help patients contact their health care providers to answer any questions and do their best not to interfere with the patient's care. At the five sites with lay navigator models, staff indicated that this policy grew out of 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 (Josephine Ford), this process had developed because a number of physicians at different clinics had expressed concern about navigators' influencing what patients did for their treatment or follow-up care.

At the time of this report, only 46 intervention group participants in the screening arm had been diagnosed with one of the study cancers. (Over one-half of these new cancer cases were identified at Josephine Ford.) Sites reported that these participants were very time-intensive to navigate, because of their multiple appointments to different providers for their cancer treatment.

Participants in the treatment arm include a small number who had been recently diagnosed with cancer, but the majority had completed cancer treatment. PNs at all sites provide

assistance with cancer screening tests for intervention group participants. They also help with scheduling appointments, obtaining transportation to appointments, ensuring that participants understand treatment plans among other activities. However, sites varied considerably in the extent to which they provided these additional PN services.

Table 2 summarizes the strengths and limitations of PN across the six demonstration sites. Moloka'i and Josephine Ford had the greatest number of strengths. These sites include staff who have been working in the program for the duration of the program. They seem to work effectively together to address patient needs (e.g., they have processes in place to identify roles and responsibilities when a team member is absent, they cover for each other as needed). They have clearly distinct roles and responsibilities among team members such that their skills complement each other well; the programs have well-developed protocols for tracking participants. Although the Moloka'i program has limited clinical oversight, it is generally a well-organized, highly integrated program that seems to be functioning very well.

UMDNJ, M.D. Anderson, and Johns Hopkins also had some notable strengths. The program at UMDNJ includes staff members who have been with the program from the start and who understand their roles and responsibilities. The program also has a strong community presence. M.D. Anderson has a well-developed tracking system to follow participants, has defined the role of the PN fairly broadly (to include additional PN services beyond those for cancer screening), and has a staff with skills that complement one another. Johns Hopkins staff seemed to work well together and had clearly defined roles to best meet participants' needs.

The Huntsman program has relatively fewer strengths. Their PNs are from the communities in which they work and (in the case of the Montana reservations) they have worked with the program from the start. This program has a number of notable limitations, although these limitations may not apply to each individual reservation. These limitations include: (1) an inadequate data system for tracking participants, with limited participant contact in some areas; (2) limited clinical oversight; and (3) lack of clearly defined PN responsibilities, e.g., on at least two of the reservations PNs are not aware of the need to contact participants over time and ensure they are rescreened annually.

Huntsman PNs expressed concern about not being able to navigate participants in the control communities, as this violated their respect for elders which was deeply rooted in cultural norms. Some PNs reported that they did, in fact, provide help to control group participants when asked, thus compromising the study design.

Although other programs also had limitations, they were fewer in number. UMDNJ has a mixed electronic and paper data system for monitoring or tracking patients; the partial reliance on hard copy records may make the system difficult to maintain over time. Johns Hopkins has multiple electronic data systems that are not integrated, requiring redundant input of the same information. Johns Hopkins has also experienced difficulties in hiring and maintaining staff and in locating or obtaining screening information for enrolled participants. Both Josephine Ford and M.D. Anderson have high caseloads for their PNs. M.D. Anderson was also experiencing difficulty in navigating participants in their expanded geographic areas where the PNs had little knowledge of available services. All of the sites except Moloka'i have experienced challenges engaging physicians to enroll participants into one or both arms of the study.

Table 2
Strengths and limitations of patient navigation across demonstration sites

	Huntsman[1]	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i
Strengths						
PNs come from the community.	X				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	X
There are well-developed protocols for providing navigation.		X	X	X		X
Staff work effectively together to meet participant needs (e.g., readily substitute for one another).		X	X			X
There is a well-developed database for tracking participants throughout all phases of navigation.			X	X		
The skills of the staff complement each other well.			X	X		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 services).				X		X
Limitations						
The data system (or lack thereof) makes it difficult to track participants.	X	X			X	
Follow-up of participants over time seems limited or unorganized (e.g., PNs are unclear about when to contact participants and what to provide).	X					
There are difficulties in hiring or maintaining staff (i.e., high turnover rate).	X	X				
There is limited clinical oversight of cases.	X					X
Some PNs seem unclear about their roles and responsibilities.	X					

(continued)

Table 2 (continued)
Strengths and limitations of patient navigation across demonstration sites

	Huntsman[1]	Johns Hopkins	Josephine Ford	M.D. Anderson	UMDNJ	Moloka'i
It is difficult to locate or obtain screening information for enrolled participants from their medical records.	X	X		X[2]		
There is a high caseload, given the role and number of staff or PNs relative to cases.			X	X		
There is limited engagement among physicians in enrolling participants in the screening arm.	X	X	X[3]	X	X	
There is limited engagement among physicians in enrolling participants in the treatment arm.	X		X[3]	X	X	
It is difficult to navigate participants in areas where there is limited knowledge of local services or health care providers.	X			X		
There are inconsistencies among PNs about how they are tracking and monitoring participants.	X		X			

NOTES:

[1] Each location within this program operates somewhat differently. Reservations in Montana have much more organized staff, with greater oversight of 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 the three Montana reservations.

[2] Difficulty is limited to patients seen outside the M.D. Anderson system. M.D. Anderson does not attempt to obtain medical records for patients served outside their system.

[3] 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.

4.2 Recruitment, Training, and Payment of Patient Navigators

Recruitment of lay navigators proved to be quite challenging for all of the sites. Generally, these workers needed to be hired directly from the community, and not all programs had firsthand knowledge of their communities at the start of the demonstration. In addition, many sites did not have clearly specified PN roles and responsibilities, which further complicated recruitment.

Navigators at all sites, except Huntsman, had attended the formal PN training provided by the American Cancer Society. The Huntsman program developed its own training for PNs. Follow-up training of PNs has been quite variable across the six sites.

PNs at four of the sites (Moloka'i, UMDNJ, M.D. Anderson, and Johns Hopkins) were all salaried, whereas those at Josephine Ford were paid hourly. Reimbursement for PN services at Huntsman varied by reservation, with some salaried and others paid on a per-CSA basis. The latter proved particularly problematic for PNs on the Navajo reservation, who had to travel long distances without a guarantee that they would actually locate a potential participant and be able to enroll them into the demonstration. This difficulty was compounded by the fact that Huntsman did not reimburse PNs for mileage (nor did Moloka'i or Josephine Ford).

4.3 Enrollment into the CPTD

As noted earlier, with the exception of Josephine Ford and Moloka'i, the sites had made limited progress toward their screening enrollment goals by the time the first Report to Congress was submitted. As a result, all of the sites (except Moloka'i) renegotiated their total enrollment goals with CMS. The revised goals for both the screening and treatment arms are shown in the first two columns of Table 3.

The second pair of columns in Table 3 shows the most current enrollments during the time when this second Report to Congress (December 31, 2009) was being drafted. All of the sites have made dramatic gains in enrollment, particularly in the screening arm, in the past two years. The total number of screening participants has more than doubled, from 4,138 to 8,934 beneficiaries. These figures represent total enrollment at a specific point in time (December 31, 2009). Cumulative enrollments over the course of the demonstration are larger, as can be seen in the final two columns of the table. Sites can lose participants over time for a number of reasons: loss of eligibility (generally because of enrollment in Medicare Advantage), voluntary dropout, death, or failure of some in the intervention arm to complete the annual CSA.[2] Because our evaluation is based on an intent to treat design, we will include all participants in the analysis, subject to a minimum duration of enrollment requirement. Sites reported that, because of outdated information on managed care enrollment, a sizeable number of ineligible participants were mistakenly signed up for the demonstration. These participants were disenrolled from the demonstration within a few months and should not be included in the demonstration.

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[2] As of May 27, 2010, a total of 4,253 participants, representing 30% of the entire demonstration population, had been disenrolled from the CPTD. Of these, one-half were disenrolled because of managed care enrollment, while 28% were disenrolled due to failure to complete the annual CSA. Other reasons for disenrollment included participants entering hospice or dying, participants quitting the demonstration or not complying with the demonstration, and loss of Medicare eligibility.

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

Site	Original total projected enrollment		Revised total enrollment goals		Current enrollment[1]		Cumulative enrollment[1]	
	Screening	Treatment	Screening	Treatment	Screening	Treatment	Screening	Treatment
Huntsman Cancer Institute	1,800	140	1,635	140	1,257	23	1,677	51
Johns Hopkins University	2,874	200	1,975	200	1,904	135	2,514	145
Josephine Ford Cancer Center (Henry Ford Health System)	1,900	1,150	2,876	274	3,081	223	5,413	293
The University of Texas, M.D. Anderson Cancer Center	3,240	360	1,887	900	1,556	197	1,954	273
The University of Medicine and Dentistry of New Jersey	1,284	100	1,259	100	761	42	1,132	76
Moloka'i General Hospital	528	50	528	50	375	21	474	32
Total	11,626	2,000	10,160	1,664	8,934	641	13,164	838

[1] As of December 31, 2009.

SOURCE: CMS, 2009.

Josephine Ford has certainly exceeded its total screening target. Depending on the number of mistakenly enrolled participants who will not be counted for the evaluation, Johns Hopkins, Huntsman, and M.D. Anderson have probably reached their screening goals as well. The remaining two sites (UMDNJ and Moloka'i) are close and may well attain their screening goals by the time enrollment ends on March 31, 2010. The following are several reasons for the big increase in screening enrollment at the four sites (Johns Hopkins, Huntsman, M.D. Anderson, and UMDNJ) that were having the most difficulty 2 years ago:

- Three of the sites (Johns Hopkins, UMDNJ, and M.D. Anderson) said that the accuracy of the CMS-provided lists of potential participants had greatly improved. The availability of telephone numbers on these new lists also helped.

- M.D. Anderson and UMDNJ expanded their catchment areas well beyond Houston, Texas, and Newark, New Jersey, respectively, as originally planned, to include multiple surrounding counties. This expansion increased the pool of potentially eligible participants. Both sites had experienced smaller-than-expected numbers of Hispanic Medicare beneficiaries in general and of those enrolled in fee for service in particular.

- As the demonstration programs grew more mature and additional financing was received from CMS, staff recruitment and retention improved at all four sites.

Although enrollment in the treatment arm also improved over the past 2 years, the figures remain disappointingly low at all sites and well below the revised targets (except for Josephine Ford). To improve enrollment, all of the sites had changed their recruitment from incident to prevalent cancer cases. Initially, sites had planned to recruit patients into the treatment arm at the time of diagnosis. This would have allowed PNs to work with patients over the full course of their primary and adjuvant therapies (the standard navigation approach for cancer patients). Very early on in the demonstration, sites realized that they simply could not recruit a sufficient number of incident (new) cancer cases. With CMS and IRB approval, they began to recruit prevalent cancer cases (i.e., patients who had been diagnosed with one of the five study cancer sites, regardless of when the diagnosis had been made). The result was a mix of patients at various stages of their treatment, including many whose treatment was completed and who simply required surveillance. Even with this change, recruitment into the treatment arm has remained difficult. This change also introduced considerable variation into the type and timing of navigation services required for those in the treatment arm.

Because the target populations and PN interventions vary across sites, most evaluation questions will be addressed on a site-specific basis. It is estimated that each site's arm must enroll at least 450 participants to have sufficient power to detect meaningful differences between intervention and control groups. Judging by cumulative enrollment, a test of patient navigation for screening should be possible in all of the sites. A test of patient navigation for cancer treatment will not be possible at any of the sites.

4.4 Participant Satisfaction with Patient Navigation Services

One of the three questions posed by Congress for this demonstration was whether patients were satisfied with the intervention services (i.e., the navigation services). A definitive answer to this question cannot be provided until the Final Report to Congress, which is when RTI will compare exit CSA responses for both the intervention and control groups. However, some preliminary information can be obtained from the annual CSAs, which are administered only to the intervention group on each anniversary of their enrollment into the demonstration. This is a CMS requirement to help ensure that the sites are, in fact, providing navigation services, and CMS reimburses the sites for administering this questionnaire. If an annual CSA is not administered within a specified time period, then CMS automatically disenrolls that participant. Once the annual CSA has been administered, the participant can be re-enrolled. Sites reported that this frequently occurs.

Intervention group participants in the screening arm were asked to assess the usefulness of various PN services and to rate their satisfaction with their PN (Table 4). The majority of participants at all sites, except Johns Hopkins, reported that they "agreed" or "somewhat agreed" that the educational materials they received were helpful and that the referrals for support services met their needs. Johns Hopkins participants were more likely to be neutral on these two statements, neither agreeing nor disagreeing. The majority of participants at all sites agreed that they would recommend this service to others, although the percentage at Johns Hopkins was noticeably lower, 53 percent versus 78–99 percent at the other sites.

Intervention group participants were asked to rate their experience with their PNs along the traditional five-part scale (excellent, very good, good, fair, or poor). Ratings of excellent or very good ranged from 48 percent among Johns Hopkins participants to 95 percent among those at Moloka'i. Most striking is the very large percentage of Johns Hopkins participants who rated their PN experience as fair or poor (30 percent), compared with only 0–9 percent at the other sites. This low rating is not an artifact of combining fair and poor into a single category for presentation purposes. One-fifth of Johns Hopkins participants rated their PN experience as poor.

RTI identified several different reasons that might explain the generally lukewarm assessment of PN services by Johns Hopkins participants and the relatively negative rating of their experience with PNs. First, the Johns Hopkins PNs reported that, until a fairly short time before the June 2009 site visit, they had been focused on recruitment rather than navigation. Thus, it is possible that Johns Hopkins participants had received little, or no, PN services at the time of their annual CSA. Second, the Johns Hopkins PNs also reported that some intervention group participants said that they did not need PN services. However, this was equally true at several of the other sites (data not shown). Third, Johns Hopkins participants may have been generally less receptive to this support. PNs reported that many participants were resistant to annual contact, and Johns Hopkins participants did have the lowest rate of self-reported contact with PNs of any site (data not shown). However, this does not explain why participants were resistant. Program staff reported that there was a fair amount of hostility toward Johns Hopkins among the minority community, but similar sentiments were expressed at Josephine Ford and the M.D. Anderson. Finally, it is possible that PNs received more positive ratings when the annual CSA was administered by the PNs themselves, as opposed to interviewers as was the case at

Table 4
Intervention group (screening arm) reports of satisfaction with patient navigators through June 30, 2009

	Huntsman (%) n = 291	Johns Hopkins (%) n = 224	Josephine Ford (%) n = 959	M.D. Anderson (%) n = 100	UMDNJ (%) n = 166	Moloka'i (%) n = 103
The education materials I received were helpful.						
Agree or somewhat agree	74.3	27.8	67.7	71.0	58.4	98.0
Neither agree or disagree	19.9	67.5	31.8	21.5	40.4	2.0
Somewhat disagree or disagree	5.9	4.7	0.5	7.5	1.2	0.0
The support services referrals met my needs.						
Agree or somewhat agree	62.6	24.0	49.2	69.0	48.8	90.2
Neither agree or disagree	28.2	67.7	50.0	31.0	50.0	9.8
Somewhat disagree or disagree	9.3	8.3	0.8	0.0	1.2	0.0
I would recommend this service to others.						
Agree or somewhat agree	77.7	53.1	93.5	81.1	96.4	99.0
Neither agree or disagree	19.1	42.3	6.0	16.8	3.6	1.0
Somewhat disagree or disagree	3.3	4.6	0.5	2.1	0.0	0.0
Rating of experience with a PN						
Excellent or very good	61.3	47.6	67.0	78.0	81.2	95.1
Good	29.9	22.1	26.5	13.2	18.1	4.9
Fair or poor	8.8	30.3	6.3	8.8	0.8	0.0

SOURCE: Analysis of annual CSAs through June 30, 2009.

Johns Hopkins. However, interviewers also administered the CSAs at M.D. Anderson (and in some instances at UMDNJ and Josephine Ford), and ratings at those other sites were consistently higher than at Johns Hopkins.

4.5 Generalizability of Demonstration Findings

Some sites have raised concerns that individuals who agree to participate in the demonstration are not representative of the overall population eligible to participate. In particular, these sites believe that people who participate are healthier than those who do not and would be more likely to receive cancer screening services even in the absence of the demonstration. Analyses were conducted to determine whether there is evidence of systematic differences between participants and nonparticipants in the screening arm of the CPTD. Systematic differences between participants and nonparticipants could affect the generalizability of findings from the CPTD evaluation, and effects measured in the demonstration might not

reflect those that would be expected if PN services were extended to a broader population of Medicare beneficiaries.

Medicare claims analyses compare participants in the screening arm of the CPTD to Medicare beneficiaries in the catchment area of each demonstration site who were eligible for the demonstration but not participating in it. The analyses include screening arm participants (both intervention and control group) who first enrolled in the demonstration through June 2008. Eligible nonparticipants were selected from Medicare beneficiaries who resided in the ZIP codes that defined each demonstration site's catchment area and were of the specific race group targeted by the site.[3] Sites vary in the age requirement for participating in the demonstration. The results reported are for individuals 65 years of age and over, who represent the vast majority of the population eligible to participate in the demonstration.

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 show significant differences between participants and nonparticipants in their demographic characteristics and use of preventive services (Table 5). In most sites, participants are 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. 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 are markedly more likely than nonparticipants to be dually eligible.

Participants and nonparticipants differ along a number of dimensions that could be associated with expected outcomes of PN, including age, gender, and prior use of preventive services. 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 overstate the effect of PN in a broader population.

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[3] RTI included in this analysis expanded areas for Huntsman and NJ. MD Anderson expanded its catchment area after this analysis began.

[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.

Table 5
Characteristics of CPTD participants and nonparticipants, aged 65 years or older

	Huntsman participant (%) n = 561	Huntsman non-participant (%) n = 1,335	Johns Hopkins participant (%) n = 731	Johns Hopkins non-participant (%) n = 35,562	Josephine Ford participant (%) n = 2,196	Josephine Ford non-participant (%) n = 78,884	M.D. Anderson participant (%) n = 317	M.D. Anderson non-participant (%) n = 16,175	UMDNJ participant (%) n = 371	UMDNJ non-participant (%) n = 20,807	Moloka'i participant (%) n = 65	Moloka'i non-participant (%) n = 10,597
Demographics												
Female	63.8	56.1***	70.5	63.8***	65.5	61.8***	58.5	55.1	62.1	57.9	65.8	57.4
Age		***		***		***		***		***		**
65–69	38.4	34.7	30.5	27.2	28.0	26.4	32.3	33.0	35.3	32.6	39.7	22.9
70–74	33.7	25.0	30.6	26.1	26.6	24.9	32.5	26.3	36.1	27.3	21.1	23.6
75–79	15.3	20.3	20.7	20.6	22.2	20.7	22.8	19.9	22.5	20.3	18.1	25.1
80–84	8.3	12.7	11.4	14.8	16.3	15.3	10.0	12.5	4.4	12.0	14.9	17.4
85+	4.3	7.3	6.8	11.3	6.9	12.8	2.5	8.3	1.8	7.9	6.3	11.0
Medicare eligibility												
Originally entitled to Medicare based on age	81.6	83.5	84.9	87.7	83.6	82.6	92.3	93.1	75.9	85.8***	93.7	94.9
Dually eligible for Medicaid	47.8	46.0	21.3	22.9	21.1	23.0**	35.0	34.3	77.4	48.3***	19.5	23.1
Screening tests/vaccination												
Flexible sigmoidoscopy/ colonoscopy/FOBT	7.8	7.1	18.1	16.0	22.3	17.6***	22.5	12.4***	22.2	16.2***	18.8	21.6
Mammogram	14.7	13.2	49.9	40.9***	54.8	36.0***	43.1	26.8***	49.6	34.6***	32.0	37.5
Pap test	3.2	4.7	15.0	13.6	14.9	12.4***	32.3	11.5***	23.3	16.4***	15.7	21.4
PSA	4.1	11.3***	25.1	33.0**	59.6	46.3***	43.8	28.3***	55.0	47.8	20.9	44.8**
Influenza vaccine	8.0	15.0***	27.6	26.2	46.2	29.8***	40.0	28.7***	15.6	18.2	56.9	52.6
Mean												
Annualized expenditures	$8,983	$8,474	$10,376	$11,241	$10,494	$12,895	$15,328	$11,067	$15,770	$12,471**	$ 7,672	$6,235
Medicare risk score	1.25	1.25	1.24	1.36	1.37	1.54	1.31	1.18	1.51	1.32***	0.88	1.08**

NOTES:

** $p < 0.05$

*** $p < 0.01$

SOURCE: Analysis of Medicare denominator file data for 2007 and Medicare claims data for September 2005 – August 2006.

4.6 Validation of Self-Reported Cancer Screening Using Claims Data

Beneficiaries who participate in the CPTD are administered the CSA when they initially enroll in the demonstration. The initial CSA includes questions about whether the beneficiary had received various cancer screening tests (i.e., mammograms, Pap tests, flexible sigmoidoscopy or colonoscopy,[5] fecal occult blood tests [FOBTs], and PSA tests) before enrolling in the demonstration and the time frame in which the testing occurred. This information can be used by demonstration sites to determine whether participants in the intervention group are up to date on screening tests and when they need to be screened. However, a number of sites contend that participant self-report of receiving cancer screening tests is often inaccurate and they are not able to rely on CSA data to determine whether and when testing is needed. Analyses were undertaken to systematically validate participant self-report of having received cancer screening services against Medicare claims for these services. While it is possible that some participants may have received cancer screening tests that were not paid for by Medicare, Medicare claims are regarded as the "gold standard" for the purpose of these analyses.

The validation analyses are based on initial CSAs administered through December 31, 2007, and Medicare claims and denominator file data for 2002–2007. The analyses include all beneficiaries in the screening arm, both intervention and control group members. Beneficiaries who reported having received a test more than 5 years before the CSA administration date were excluded from the analysis because claims data to validate self-report were not available for time periods before 2002. Claims for screening tests were identified based on procedures codes and drawn from Part B claims and Part A inpatient and outpatient hospital claims. The date of the most recent claim for the cancer screening test was also identified. This was used to determine whether the date of the most recent screening test found in the claims data fell within the time frame when the beneficiary reported having received the test most recently in the CSA. For each test we report the percentage of CSA responses that were validated. Validation was defined as finding a claim within the time frame reported on the CSA for those who reported having the test, or not finding a claim for those who reported not having the test.

The validation rate for self-reported use of cancer screening tests in the CSA based on Medicare claims data varied considerably, both by screening test and by site (Table 6). Overall, validation rates were low. For many sites and tests, less than half the self-reported use in the CSA could be validated by Medicare claims. At all sites, Pap tests had the lowest validation rate, with about two-fifths or less of the CSA-reported use validated by the claims data. The validation rate for the other screening tests generally ranged from about 40% to 70%, although lower rates (from approximately one-quarter to one-third) were found for some sites and tests. Validation rates for participants who reported that they did not have a test were typically high for all tests. Validation rates for participants who reported that they had had a test were lower, although a large proportion of respondents reporting that they had received the test had a claim that fell outside the time frame reported on the CSA. However, even taking into account claims outside the reported time frame, validation rates remained lower for respondents who reported

[5] The CSA asks one question about receipt of flexible sigmoidoscopy or colonoscopy because participants cannot reliably distinguish between these tests.

receiving a test. The percentage of participants reporting they had a test for which a claim was found was

Table 6
Percentage of self-reported cancer screening tests validated by Medicare claims, by site

Cancer screening test	Huntsman (%)	Johns Hopkins (%)	Josephine Ford (%)	M.D. Anderson (%)	UMDNJ (%)	Moloka'i (%)
Pap test	6.0	27.6	43.4	36.4	35.5	26.6
Mammogram	25.6	53.6	67.6	56.0	57.2	37.3
Flexible sigmoidoscopy/colonoscopy	58.4	50.8	60.2	52.4	50.6	68.0
FOBT	61.4	37.4	47.5	49.1	49.5	50.3
PSA	36.6	37.5	58.9	52.2	47.5	42.9

NOTE:

* A response was considered validated if the participant had the screening test according to the CSA, and a claim was found within the time frame reported on the CSA; or the participant did not have the screening test according to the CSA, and a claim was not found.

SOURCES: Analysis of baseline CSAs through December 31, 2007, and Medicare claims and denominator file data for 2002–2007.

usually lowest for participants at Huntsman. American Indians can receive services from Indian Health Service facilities, and claims for these services are not always submitted to Medicare. The absence of claims for participants at the Huntsman site may therefore reflect the use of services through the Indian Health Service rather than less reliable self-reporting of cancer screening tests.

The results of these analyses substantiate CPTD sites' concerns about the accuracy of self-reported screening tests in the CSA and the validity of using the CSA data to guide PN. Although the results of these analyses are generally consistent with the low validation rates reported in previous studies (Armstrong, Long, and Shea, 2004; Baier et al., 2000; Caplan, Mandelson, and Anderson, 2003; Champion et al., 1998; Fiscella et al., 2006; Jordan et al., 1999; Mandelson et al., 1999; May and Trontell, 1998; McGovern et al., 1998; McPhee et al., 2002), the percentage of self-reported screening tests in the CSA confirmed by claims data is lower than the percentages found in previous studies. Several factors may contribute to this lower validation rate, including the longer recall period used in this analysis (up to 5 years vs. 1–2 years in most previous studies) and use of claims (vs. medical or laboratory records in many previous studies) to validate results. Most importantly, CPTD includes only racial and ethnic minorities and only elderly, both of which represent only small parts of the population in most other studies. Several studies have found lower validation rates for self-reported use of cancer screening among minorities (Champion et al, 1998; Fiscella et al., 2006; McPhee et al., 2002). These findings suggest that comparisons of screening rates among racial and ethnic groups, based on self-reporting, may be biased and possibly understate disparities. This will not affect

the evaluation, as claims data will be used to assess the demonstration's impact on screening rates.

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SECTION 5
OVERVIEW OF FINAL REPORT TO CONGRESS

The third and final Report to Congress will include results from analysis of Medicare claims data, CSAs, and demonstration cost data and will answer the questions posed by Congress in the authorizing legislation. These questions will be answered for the screening arm of the demonstration only. All analyses will be conducted for each site separately. The small number of participants enrolled in the treatment arm will not provide sufficient power to test the impact of PN for participants already diagnosed with cancer. Below we summarize the methods and data sources that will be used to answer Congress' questions.

Did the intervention (i.e., patient navigation) improve quality of services provided and reduce disparities for racial and ethnic minorities?

Medicare Parts A and B claims will be used to estimate the impact of PN on screening rates for participants, comparing rates in the intervention vs. control group. Baseline and exit survey results will be used to estimate the impact of the intervention on beneficiary outcomes, such as quality of life.

Did the intervention reduce Medicare costs for participants, or was it at least budget-neutral?

Medicare Parts A and B claims will also be used to determine whether PN had spillover effects on Medicare use and expenditures. Because analysis of claims data alone might suggest increased costs associated with PN, we will also analyze health-related quality of life data (from the baseline and exit CSAs). Data from both claims and CSAs will be combined to determine the cost-effectiveness and cost-utility of PN and to assess whether any higher costs are offset by improved quality of life. Actual cost data from each site will also be used to assess both start-up costs and annual implementation costs of the demonstration. These data will be used to calculate the program costs of PN (as opposed to the costs from Medicare's perspective).

Were participants satisfied with the intervention services?

Annual CSA surveys of intervention group participants will be used to assess their satisfaction with navigation services. Baseline and exit CSAs will be used to compare the use of facilitation services more generally between the intervention and control groups.

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