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

Report to Congress

Prepared for

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EVALUATION OF THE CANCER PREVENTION AND TREATMENT DEMONSTRATION
FOR RACIAL AND ETHNIC MINORITIES

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EXECUTIVE SUMMARY

In Section 122 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, 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. When mandating this study, Congress posed three key evaluation questions:

1. Did the intervention (i.e., patient navigation) improve quality of services provided and reduce disparities for racial/ethnic minorities?
2. Did the intervention reduce Medicare costs for participants, or was it at least budget-neutral?
3. Were participants and providers satisfied with the intervention services?

A total of \$25 million was authorized for this demonstration and its evaluation. As a result of this legislation, the Centers for Medicare & Medicaid Services (CMS) launched a new demonstration in 2006 aimed at reducing racial/ethnic disparities in cancer screening and treatment among Medicare beneficiaries. Six sites were selected for this demonstration, named the Cancer Prevention and Treatment Demonstration for Racial and Ethnic Minorities (CPTD). Two of the sites focused on African Americans living in urban areas: Johns Hopkins University in Baltimore, Maryland and Josephine Ford Cancer Center (Henry Ford Health System) in Detroit, Michigan. Two sites targeted Hispanic beneficiaries: University of Texas M.D. Anderson Cancer Center and University of Medicine and Dentistry of New Jersey. Of the remaining two sites, the University of Utah Huntsman Cancer Institute targeted numerous American Indian tribes located in Utah and Montana, and Moloka'i General Hospital targeted Asian Pacific Islanders (A/PI), largely Native Hawaiians and Filipinos living in Hawaii.

Each demonstration site is recruiting Medicare beneficiaries into two arms: a screening arm and a treatment arm. Within each arm, beneficiaries are then randomized into either the intervention group or the control group. (Because the American Indian and Native Hawaiian communities are closely knit, the randomization protocol was modified for these two sites.) The patient navigation services that the intervention group receives include assistance with getting appropriate screening tests for breast, cervical, colorectal, and prostate cancer as well as timely diagnostic tests. Intervention group participants who are diagnosed with breast, cervical, colorectal, lung or prostate cancer receive assistance getting primary and secondary cancer treatments. Control group participants receive educational materials at the time of enrollment and “usual care” thereafter. Sites receive a monthly per member payment for all participants in the intervention group.

This report summarizes the experience of all six sites during their first year of implementation, based on in-person site visits and document review. This report also includes claims-based analyses of disparities in cancer screening across the six sites. The second Report to Congress, due to Congress two years after this first report, will address the research questions posed by Congress and include results from analysis of Medicare claims data, Cancer Status Assessment (CSA) surveys, demonstration cost data, and a second round of case studies. A final

Report will include results from analysis of the CSA surveys collected through the end of the demonstration as well as Medicare claims data.

The CSAs are administered by the sites and collect data on cancer screening history, health status, quality of life, and other participant information not available in claims data. All participants receive a baseline CSA at the time that they are enrolled in the demonstration, and again at the end of the demonstration (exit CSA). In addition, participants enrolled in the intervention group of the study receive an annual CSA during each year that they are enrolled in the demonstration; this survey collects information on the navigation services received during the prior year.

The timing requirements set forth in section 122(b)(2) of BIPA stipulated that the demonstration projects begin “not later than 2 years after the date of the enactment of [BIPA].” CMS did not solicit cooperative agreement proposals for the demonstration until December 23, 2004 and did not announce the demonstration sites until April 3, 2006. This delay occurred because the steps involved in designing the demonstration, starting with the evidence report through the demonstration’s approval, took longer than anticipated.

Five of the six sites (all but Josephine Ford Cancer Center) encountered difficulties with identifying eligible beneficiaries and enrolling them in the demonstration, resulting in substantially fewer participants than initially projected. (Moloka’i met its year 1 screening enrollment goals, but because of its alternative study design, all participants were in the intervention group.) 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. (The majority of treatment participants also are at Josephine Ford.)

Challenges 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 their 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, because of delays in institutional review board approval and staff recruitment.

Sites have taken advantage of lessons learned during the first 15 months of the demonstration, and adapted their enrollment strategies as a result. In addition, sites have benefited from learning about each other’s enrollment experiences through monthly teleconferences organized by CMS.

All sites received \$50,000 in start-up funding. They also receive a fixed payment for each baseline CSA they conduct of participants, for similar exit surveys at the end of the demonstration, as well as for annual follow-up surveys of those participants in the intervention groups. Finally, each site received a monthly capitation payment for intervention group

participants. This payment covers the costs of the intervention (patient navigation services). Both the capitation payments and the CSA payments were negotiated by each site with CMS.

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 due to slower than expected enrollments. In response to these mounting financial obligations, CMS re-negotiated with individual sites, making increases in capitation payments, CSA payments, and/or lump sum payments for debt relief. In some instances, total enrollment goals were also re-negotiated. Total CMS spending on the CPTD remains unchanged, however, i.e., not to exceed the \$25 million obligated by Congress.

By design, each site developed its own intervention tailored to the needs of its community. Three of the sites have adopted a nurse/lay navigation model in which nurses play a leadership and oversight role, supported by lay navigators from the community. The other three sites rely almost entirely on lay navigators (community health workers) who 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, have more thoroughly developed patient flow algorithms that may result in better monitoring of care over time. This model also includes more direct interaction with primary care providers in the community, thus allowing them greater influence over screening rates.

Reductions in screening disparities under the CPTD will 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/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. In order to put these local disparities in context, national screening rates were constructed for whites and all racial/ethnic minority groups included in the demonstration.

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

Similar disparities were observed within 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—Asian Pacific Islanders in Moloka'i and Hispanics in Newark—were found to have significantly higher screening rates than their white colleagues in the same geographic area for at least three of the four tests. Further research will examine determine the reasons for these differences. Possible reasons include differences in the ethnic mix or country of origin of minority groups in these two locations compared with Medicare beneficiaries nationally or differences in the minorities' socioeconomic status compared with white Medicare beneficiaries in those locations.

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SECTION 1 INTRODUCTION

Racial/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 [NCI], 2001). For those with a positive test result, racial/ethnic minorities are more likely to experience delays in receiving the diagnostic tests needed to confirm a cancer diagnosis (Ries et al., 2003; Battaglia, 2007). Similarly, differences in primary cancer treatment, as well as appropriate adjuvant therapy, have been shown to exist between white and minority populations (AHRQ, 2004). Although 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 Benefits Improvement and Protection Act of 2000).

Section 122 requires an evaluation report to Congress every two years from the date of the initial demonstration implementation, making this first report due in September 2008. The demonstration evaluation is required to describe the demonstration projects and evaluate demonstration cost-effectiveness, the quality of the health care services provided under the demonstration, and beneficiary and provider satisfaction under the demonstration. The report also is to include any other information regarding the demonstration as the Secretary 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 technically acceptable proposals, the Centers for Medicare & Medicaid Services (CMS) concluded that it could award either six projects for four years or nine projects for three years. Given the startup 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 two full years of demonstration data. This longer period will permit CMS to determine whether the projects should be extended before they are terminated since CMS will no longer have a mandated appropriation for their continued operation.

The statute also dictates that the Secretary shall continue the existing demonstration projects and may expand the number of demonstration projects “if the initial report under subsection (c) contains an evaluation that demonstration projects [either] (A) reduce expenditures under the Medicare program under Title XVIII of the Social Security Act; or (B) do not increase expenditures under the Medicare program and reduce racial and ethnic health disparities in the quality of health care services provided to target individuals and increase satisfaction of beneficiaries and health care providers.” Unfortunately, this initial Report to Congress is not able to address these issues because sufficient Medicare claims data are not available to determine findings at this point in the demonstration experience. Therefore, this Report addresses the implementation experience and baseline screening rates, but does not include an analysis of

claims data on the costs to the Medicare program. Findings on these topics are expected to be included in the subsequent reports once all available data have been analyzed.

The Centers for Medicare & Medicaid Services (CMS) contracted with the Schneider Institute for Health Policy at Brandeis University, who, 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) who help steer Medicare beneficiaries through the health care system (Brandeis University, 2003). PNs have primarily been used 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 Racial and Ethnic Minorities. In particular, the announcement sought demonstration projects that targeted four legislatively mandated minority populations: American Indians, Asian Pacific Islanders (A/PI), African Americans, and Hispanics. By law, CMS was also required to include at least one rural site and one inner city site, as well as a site in the Pacific Islands, which CMS limited to the state of Hawaii. Applications were due March 23, 2005. While Congress had mandated a total of eight demonstration projects, the quality of applications was such that CMS could only identify six that met the requirements outlined in the announcement. Following review of all applications and negotiations with individual sites, CMS announced the selection of six CPTD sites on April 3, 2006. Enrollment of beneficiaries began October 1 of that year.

The six sites and their target populations were as follows:

1. University of Utah Huntsman Cancer Institute, Salt Lake City, UT: American Indians
2. Johns Hopkins University, Baltimore, MD: African Americans
3. Josephine Ford Cancer Center, Henry Ford Health System, Detroit, MI: African Americans
4. University of Texas M.D. Anderson Cancer Center, Houston, TX: Hispanics
5. University of Medicine and Dentistry of New Jersey (UMDNJ), Newark, NJ: Hispanics
6. Moloka'i General Hospital, Moloka'i, HI: Asian Pacific Islanders (largely Native Hawaiians and Filipinos)

This report describes each of the demonstration projects, their implementation experience, and their enrollment to date. The next section of this report describes the evaluation methodology and eligibility criteria in detail.

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

Each site has two study arms: a screening arm and a treatment arm. Both study arms have one intervention group and one control group. As participants are recruited into the study, they complete a face-to-face baseline survey that includes questions on cancer risk factors, utilization of screening tests, and cancer history. This Cancer Status Assessment (CSA) survey serves several purposes: (1) it 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 they administer. 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.

2.3 Randomization Method

Participants within each arm are randomized to either the intervention (i.e., patient navigation) 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 nature of the close-knit community on the small island of Moloka'i, CMS granted permission to assign all residents of the island to the intervention and then assign people living in similar communities on the nearby island of Oahu to the control group.

Huntsman is targeting American Indians spread across numerous remote reservations in two states, Utah and Montana. As 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, such 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; however, adaptations to the evaluation design have been made to try and alleviate this problem.

2.4 Interventions

The screening intervention group receives 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), as well as clinical practice guidelines. The treatment intervention group receives navigation services to ensure completion of all primary and secondary cancer treatments and all necessary followup and monitoring.

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 in order to ensure that the intervention is culturally sensitive to the needs of each minority community. The patient navigation models adopted by each site are described in detail in Section 3.4 below. The variation in both PN models and target populations across the sites will 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

There are three sources of funding for each demonstration project: (1) start-up payments, (2) payment for administration of CMS-mandated participant surveys, and (3) capitated payments for navigation services.

The first 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 will 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. This will be discussed below in Section 3.3.

Third, sites receive a capitated monthly payment for all intervention group participants. This payment covers the cost of navigation services and varies across sites. The sites proposed payment rates, based on 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.

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 so 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.

As will be discussed in Section 3.3 below, five of the six sites encountered significant financial difficulties, and CMS made significant increases in payments to these sites.

2.6 Evaluation Overview

When mandating this study, Congress posed three key evaluation questions:

1. Did the intervention (i.e., patient navigation) improve quality of services provided and reduce disparities for racial/ethnic minorities?
2. Did the intervention reduce Medicare costs for participants, or was it at least budget-neutral?
3. Were participants and providers satisfied with the intervention services?

CSAs, Medicare claims data, and case studies will be used to answer these three questions and other secondary questions, and findings will be provided in our second Report to Congress. Key to interpreting evaluation results will be a thorough understanding of each site's patient navigation model. The programs were deliberately not standardized across the sites so that each site could adapt its program to the needs of the population it plans to serve. Therefore, case studies of these sites are a particularly important component of the evaluation. This initial Report to Congress is based on information collected through the first set of case studies, including visits to all six sites, and enrollment and other data reported to CMS.

2.7 Case Study Methods

Case studies of each site included an in-person visit, telephone followup, and review of documents, including sites' initial applications, quarterly progress reports, Institutional Review Board (IRB) protocols, and any other written materials. Prior to each site visit, semistructured telephone interviews with CMS project officers and principal investigators (PIs) were conducted to determine the barriers and challenges to initial start-up and to plan for the site visit. A criterion was set such that sites were not visited until participants had been enrolled into each arm of the study to ensure that the sites could speak to the lessons learned for each study arm. As a result, the site visits took place over a much longer period of time than is typical for an evaluation of

this sort. The first site visit took place at Josephine Ford in December 2006, and the last site visit was at M.D. Anderson in August 2007.

During the site visit, face-to-face interviews were conducted with people who had been involved in setting up the program and establishing patient enrollment and recruitment activities, including key program staff, senior management within the organization for each program, and community partners. Two evaluators attended each site visit, with one serving as lead interviewer for all of the site visits, and the second serving as notetaker. The notetaker typed each interview and used digital recording to refine the notes upon return from the visit. Thorough review of the gathered information was conducted so that a detailed report could be created for each site. Before being submitted to CMS, this report was shared with the sites in order to ensure accuracy of information reported.

SECTION 3 CPTD—THE FIRST 15 MONTHS

3.1 Overview of Demonstration Sites

Table 1 provides an overview of the six sites. Four of the six sites are based in academic medical centers that house major cancer treatment centers. The fifth (Josephine Ford) 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 site (Moloka'i) is based in a small general hospital.

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. Huntsman is targeting American Indian reservations in remote and mountainous sections of Montana and Utah. The remaining four sites are all located in the inner city of major metropolitan areas.

Two of the sites gave their CPTD programs a distinctive name. In the case of Moloka'i, *Kukui Ahi* means "to light or guide the way." For M.D. Anderson's demonstration, the acronym FAROS means lighthouse in Spanish. The remaining four sites simply use their organizational name in describing their programs.

Table 1 also shows the diversity of sources sites used to recruit participants into their programs. All of the sites sent letters and/or made telephone calls to potential participants. They all initially relied on lists of Medicare beneficiaries generated by CMS. As will be discussed later, these lists proved to be problematic. Often, potential participants had enrolled in managed care plans by the time they were contacted by the sites (and hence were ineligible for the demonstration). Three of the sites developed lists of Medicare beneficiaries who had visited their own health care systems based on their electronic medical records (EMRs). This list of beneficiaries has proven to be particularly valuable for Josephine Ford, because there are many primary care and specialty clinics within the site's vertically integrated delivery system.

All sites expected to recruit demonstration participants from community partners or at community events. We describe their different approaches in more detail below. Four of the sites used "in-reach" to find potential participants for the treatment arm (i.e., they recruited cancer patients from their own clinics), and two of these sites also used "in-reach" to identify potential participants in the screening arm. Other recruitment sources were used less frequently, such as local physician referral and local media.

3.2 Enrollment into the Demonstration

At the start of the demonstration, sites had projected their expected enrollment into both arms of the study. Table 2 displays projected and actual enrollment for the screening and treatment arms for each site. The first pair of columns in Table 2 display projected enrollment for the total duration of the demonstration, and the next pair of columns show projected enrollment by the end of Year 1 (September 30, 2007). Enrollment goals varied across sites; the much lower numbers for Moloka'i reflect 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. Most

Table 1
Description of demonstration sites

Site	Location	Lead organizational unit	Priority population	Rural/urban	Name of program (if applicable)	Recruitment sources						
						List provided by C.M.S.	Health system enrollees (list site developed from EMR)	Phone call/letter from program	Community partners/ events	Referrals from local physicians	Media/newspaper	Clinics within site (in reach) (•) bullet=screening arm (†) dagger=treatment arm
Moloka'i General Hospital	Moloka'i (island), Hawaii (Maui County)	Moloka'i General Hospital	Asian, Pacific Islander, Native Hawaiian	Rural	<i>Kukui Ahi</i> Cancer Program	•		•	•	•		
Huntsman Cancer Institute	Intermountain West, Utah, and Montana	Huntsman Cancer Institute in Utah, Sletten Cancer Institute, Montana (sub to HCI)	American Indian	Rural	None given	•			•			
Josephine Ford Cancer Center—Henry Ford Health System	Detroit, Michigan (Wayne County)	Josephine Ford Cancer Center-Henry Ford Health System	African Americans	Urban	None given	•	•	•	•		•	• †
The University of Medicine and Dentistry of New Jersey	Newark, New Jersey	New Jersey Medical School	Latino	Urban	None given	•	•	•	•			• †
The University of Texas, M.D. Anderson Cancer Center	Houston, Texas (Harris County)	Center for Research on Minority Health	Hispanic/Mexican Americans	Urban	FAROS (Facilitated Assistance Research and Outreach Services)	•	•	•	•	•	•	†
Johns Hopkins University	Baltimore City, Maryland	Bloomberg School of Public Health	African Americans	Urban	None given	•		•	•			†

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

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

Site	Location	Original total projected enrollment		Projected Year 1 enrollment		Actual Year 1 enrollment (as of January 15, 2008)		Revised total enrollment goals (as of January 15, 2008)	
		Screening	Treatment	Screening	Treatment	Screening	Treatment	Screening	Treatment
Moloka'i General Hospital	Moloka'i (island), Hawaii (Maui County)	528	50	176	16	173	13	528	50
Huntsman Cancer Institute	Intermountain West, Utah and Montana	1,800	140	1,800	140	486	1	1,635	140
Josephine Ford Cancer Center--Henry Ford Health System	Detroit, Michigan (Wayne County)	1,900	1,150	1,600	850	2,405	179	2,876	274
The University of Medicine and Dentistry of New Jersey	Newark, New Jersey	1,284	100	670	50	446	44	1,259	100
The University of Texas, M.D. Anderson Cancer Center	Houston, Texas (Harris County)	3,240	360	1,280	160	156	59	1,887	900
Johns Hopkins University	Baltimore City, Maryland	2,874	200	958	60	472	4	2,000	200
Total		11,626	2,000	6,484	1,276	4,138	300	10,185	1,664

SOURCE: Centers for Medicare & Medicaid Services, 2008.

of the sites also expected to enroll participants throughout the duration of the demonstration. However, two sites expected to enroll either all (Huntsman) or almost all (Josephine Ford) of their participants in the first year.

The third pair of columns in Table 2 show the actual number of participants enrolled into each arm after 15 months, or approximately January 15, 2008. With the exception of Josephine Ford and Moloka'i, the sites fell well short of their Year 1 screening enrollment goals. Josephine Ford's vertically integrated delivery and EMR systems were key to its early success. This site was able to draw upon an initial list of every African American Medicare beneficiary who had received services anywhere within its health care system. Moloka'i was able to take advantage of its small size and close-knit community to enroll participants; however, it should be noted that all enrollments are in the intervention group. This site has not yet begun enrollment of control group participants on the nearby island of Oahu.

Enrollment shortfalls in the other four sites were due, in part, to delays in program startup, staff recruitment, or IRB approvals. However, the primary obstacle was that recruitment of potential participants proved to be far more difficult than many sites had anticipated. This difficulty is described in more detail later in this report. As a result, one site (M.D. Anderson) greatly reduced the number of participants projected for the screening arm (see the last pair of columns in Table 2). The MD Anderson site shifted its enrollment targets to increase the number of people they would recruit with cancer and to decrease the number of people they would recruit without cancer because they believed that they would be more successful in recruiting people with cancer than people without cancer. This reduction was offset partially by increasing the number projected for the treatment arm, because M.D. Anderson believes it can take advantage of its status as an NCI-designated cancer center. Nonetheless, the revised total enrollment projections for this site are still below those originally estimated.

Originally, sites projected a total of 11,626 participants in the screening arm and 2,000 in the treatment arm, for a total of 13,626. Those numbers have now been changed to 10,160 and 1,664, respectively, for a total of 11,824. Of course, to reach these revised enrollment numbers, sites will need to dramatically boost recruitment in subsequent years relative to their current rates. Because the target populations and patient navigation 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 in order to have sufficient power to detect meaningful differences between intervention and control groups. Thus, even if all sites meet their revised enrollment goals, there only will be sufficient power to test the treatment arm at one of the six sites (M.D. Anderson).

3.3 CPTD Site Payments

As noted earlier, each of the sites received \$50,000 in upfront funding from CMS to help plan and implement the demonstration. The operational costs of running the demonstration were expected to be covered by the CSA and capitation payments. These payments were negotiated individually by each site with CMS, and vary as much as fivefold. Variation in capitations rates reflect differences in estimated navigation costs across the six sites. In the first year of the demonstration, payments for administering each baseline CSA to new participants varied from a low of \$18.43 in Moloka'i to a high of \$173.00 in Newark (see the first column in Table 3).

Table 3
Site payments, in dollars, by year (original and revised)

Site	Location	Original CSA fee (\$)				Revised CSA fee (\$)			Original capitation rate (\$)				Revised capitation rates (\$)		
		Year 1	Year 2	Year 3	Year 4	Year 2	Year 3	Year 4	Year 1	Year 2	Year 3	Year 4	Year 2	Year 3	Year 4
Moloka'i General Hospital	Moloka'i (island), Hawaii (Maui County)	18.43	18.43	18.43	18.43	18.43 ¹	18.43 ¹	18.43 ¹	324.62	99.40	60.24	42.63	99.40 ¹	60.24 ¹	42.63 ¹
Huntsman Cancer Institute	Intermountain West, Utah, and Montana	160.00	80.00	80.00	80.00	80.00 ¹	80.00 ¹	80.00 ¹	80.00	80.00	80.00	80.00	80.00 ¹	80.00 ¹	80.00 ¹
Josephine Ford Cancer Center—Henry Ford Health System	Detroit, Michigan (Wayne County)	38.54	38.54	38.54	38.54	38.54 ¹	38.54 ¹	38.54 ¹	71.82	71.82	71.82	71.82	71.82 ¹	71.82 ¹	71.82 ¹
The University of Medicine and Dentistry of New Jersey	Newark, New Jersey	173.00	75.00	75.00	75.00	101.00	101.00	101.00	217.32	92.49	76.43	77.32	215.00 ²	85.90	69.00 ²
The University of Texas, M.D. Anderson Cancer Center	Houston, Texas (Harris County)	40.00	40.00	40.00	40.00	40.00 ¹	40.00 ¹	40.00 ¹	83.65	83.65	83.65	83.65	83.65 ¹	83.65 ¹	83.65 ¹
Johns Hopkins University	Baltimore City, Maryland	117.00	86.00	77.00	69.00	117.00	77.00 ¹	69.00 ¹	137.00	104.00	90.00	98.00	184.55	90.00 ¹	98.00 ¹

¹No change.

²Amount represents maximum, but amount varies depending on date.

SOURCE: Centers for Medicare & Medicaid Services, 2008.

Year 1 capitation payments for participants enrolled in the intervention groups ranged from \$71.82 per participant per month in Detroit to \$324.62 in Moloka'i. All of the sites receive the same magnitude of payments for those enrolled in the treatment intervention group, as they do for those in the screening intervention group, even though the latter group presumably is less navigator intensive.

Three of the sites proposed that their CSA payments be reduced in subsequent years of the demonstration (Huntsman, Newark, and Johns Hopkins). Newark and Johns Hopkins also proposed that their capitation payments fall in later years, as did Moloka'i. These sites had all assumed that higher payments would be needed in the first year in order to cover their fixed costs, but that these payments could be lowered as enrollment grew over time.

Instead, because enrollments were lower than expected in Year 1, five of the six sites (all but Moloka'i) experienced considerable financial difficulties and applied to CMS for relief. This relief came in two forms: (1) increased CSA or capitation payments and/or (2) additional financing. Increases in CSA and capitation payments were intended to help improve cash flow. Two sites received increases in both of these payments: Newark for the duration of the demonstration and Johns Hopkins just for Year 2.

All five sites received relief for debts incurred during the first year of the demonstration; these debts ranged from a low of \$188,000 at UMDNJ to a high of \$699,454 at Josephine Ford. Josephine Ford had one-half of their Year 1 debt reimbursed, while the remaining four sites received funding for the full amount of their debt (Table 4). Furthermore, Johns Hopkins, M.D. Anderson and Huntsman will receive additional payments in each remaining year of the demonstration (Years 2–4). These funds will support the sites' fixed costs.

Table 4
Additional financing by site

Site	Location	Year 1 debt (\$)	Additional financing (\$)		
		(% reimbursed)	Year 2	Year 3	Year 4
Moloka'i General Hospital	Moloka'i (island), Hawaii (Maui County)	0 (0%)	0	0	0
Huntsman Cancer Institute	Intermountain West, Utah, and Montana	181,335 (100%)	433,500	247,944	160,596
Josephine Ford Cancer Center—Henry Ford Health System	Detroit, Michigan (Wayne County)	699,454 (50%)	0	0	0
The University of Medicine and Dentistry of New Jersey	Newark, New Jersey	188,000 (100%)	0	0	0
The University of Texas, M.D. Anderson Cancer Center	Houston, Texas (Harris County)	624,717 (100%)	608,520	608,520	608,520
Johns Hopkins University	Baltimore City, Maryland	409,021 (100%)	400,000	400,000	400,000

SOURCE: Centers for Medicare & Medicaid Services, 2008.

3.4 Overview of the Patient Navigation Models across Sites

Because the concept of patient navigation is relatively new to cancer care, many aspects of it have not been well established in the literature. Even finding an agreed upon definition of what patient navigation entails can be 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, p. 360). What these activities entail for navigators seems to vary quite dramatically across programs, with differences in their roles and responsibilities, the background and training required of the navigators, and the point during care that they are to provide their services. A number of programs, such as the one currently underway by NCI, focus on providing patient navigation from the point a person receives an abnormal cancer screening finding to the point of initiation of treatment (National Cancer Institute, 2007). The CMS program provides patient navigation for cancer screening, as well as for diagnostic and treatment services. In order to adapt the programs to the needs of each special population, the sites were provided the latitude to develop their own patient navigation models. Based on information obtained during the site visits, the models used by sites can be classified into two types: (1) a nurse/lay navigator model and (2) a lay-only navigator model (Table 5). Lay navigators are defined as people with no medical training or clinical experience, who may or may not have some college education, but are typically members of the community being reached and have an interest in care coordination.

The nurse/lay navigator model, used by three sites (Moloka’i, Josephine Ford, and M.D. Anderson), utilizes nurses in key leadership and oversight roles, supported by lay navigators from the community. For these three programs, the navigators are directly supervised by the nurses and the nurses provide daily oversight of their work, including review of the medical information obtained from patients. In this model, the nurses focus on assessing participants’ service needs and ensuring that care is received, while the lay navigator ensures that participants have access to those services.

The second model, used by the other three sites (Huntsman, UMDNJ, and Johns Hopkins), relies almost entirely on lay navigators who provide the bulk of services directly to participants. For these programs, there is limited clinical oversight, when compared with the nurse/lay navigator model. For all the programs, while clinical expertise was evident among key staff members, such as the PI or another lead program staff member, the lay-only navigator model provides less direct access to this expertise than the nurse/lay navigator model. In these three programs, those with clinical expertise do not provide day-to-day oversight of the work of the navigators; instead, the nurses are available to the navigators on an as-needed basis. The advantages to this model are that, by having only lay navigators, whose salary is significantly less than that of a nurse, the programs are able to afford more navigators in order to reach more participants.

In terms of recruitment of the PNs, each program went through their respective human resources departments to identify potential candidates. For the nurses hired in the nurse/lay navigator model, all of the nurses were hired from within their organization (i.e., people working in other parts of the organization transferred to this position). For all six programs, recruiting lay navigators was more challenging and required posting new job announcements and identifying and interviewing a number of potential candidates. Several programs (i.e., Moloka’i, Huntsman, M.D. Anderson, and Johns Hopkins) had had some success in recruiting and hiring lay navigators, but were still struggling with identifying all the lay navigators that they needed for their programs.

Table 5
Patient navigation model, by site

Site	Location	Dates of site visit	Number of patient navigators at time of site visit	Type of navigation model (nurse/lay or lay)
Moloka'i General Hospital	Moloka'i (island), Hawaii (Maui County)	April 2007	2 (+ 1 clerical assistant coordinating the treatment arm)	Nurse/lay
Huntsman Cancer Institute	Intermountain West, Utah, and Montana	June 2007	23	Lay
Josephine Ford Cancer Center—Henry Ford Health System	Detroit, Michigan (Wayne County)	December 2006	14 (7 pairs of nurses and advocates)	Nurse/lay
The University of Medicine and Dentistry of New Jersey	Newark, New Jersey	May 2007	3	Lay
The University of Texas, M.D. Anderson Cancer Center	Houston, Texas (Harris County)	August 2007	2 (+ 3 community health workers)	Nurse/lay
Johns Hopkins University	Baltimore City, Maryland	July 2007	1 (+ 4 field interviewers)	Lay

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

Once the lay navigators were hired, each site had a mechanism for training them on the basics of patient navigation. Two sites (M.D. Anderson and Moloka'i) had established formal relationships with local partners to provide the training. For these programs, the partners were already involved in training people to fill similar roles and worked with the CPTD sites to adapt their training to their lay navigators. All sites provided some type of basic training specific to the program that they required the nurses and/or lay navigators to attend and had staff accessible to the navigators for one-on-one mentoring as needed. Two sites (UMDNJ, M.D. Anderson) developed training on the basics of cancer care to provide to their lay navigators. In addition, UMDNJ had the lay navigators participate in ongoing training provided by CancerCare, a national nonprofit organization, and Johns Hopkins had ongoing training provided by the American Cancer Society (ACS). The differences in these roles for each model are described below for each aspect of a participant's progression through the care continuum.

3.4.1 Participant Outreach and Recruitment

Participant enrollment was set to begin in fall 2006, but not all sites were ready to begin recruitment at that time. Delays in navigator recruitment and IRB approval resulted in a staggered startup over 6 months. All six sites initially relied heavily on recruiting participants from lists provided by CMS of eligible Medicare beneficiaries residing in each geographic area. All sites signed CMS data use agreements protecting the privacy and confidentiality of the contact information.

Four of the sites began recruitment by sending letters to these beneficiaries to invite them to participate in the study. Five of the sites attempted to call the patients, while the sixth (Johns Hopkins) relied solely on home visits to the participants because of the large number of households without phones in its target area. (However, other sites conducted home visits as well.) Because the strategy of relying on the CMS list was expected to yield a small proportion of total participants, sites needed to develop other ways to quickly identify and recruit participants. Table 6 summarizes the other outreach strategies used by the sites to identify potential enrollees at the time of the site visits. Since then, sites have identified new venues for outreach, notably churches.

Table 6
Summary of screening arm outreach strategies used by CMS sites

Screening arm outreach strategy	Number of sites using strategy during start-up ¹
Home visits to patients on list (unless refusal to participate was received prior to visit)	5
Sites conducting some community outreach during site visit	6
Attend events at the following locations to introduce study and invite people to participate:	
■ Senior centers	3
■ Senior housing projects	1
■ Community centers	2
■ Adult day care	1
Formal education workshop provided at local facilities where elders are in attendance	2
Attend local health fairs or other community events	4
Mass media campaign	2

¹ Start-up is defined as the point of award to the time of the site visit (i.e., for most sites this was within 1 month of enrollment of patients into both arms of the study).

Although sites intended for the lay navigators to be solely responsible for conducting community outreach, both nurse and lay navigators ended up working to identify eligible beneficiaries in order to increase the number of participants enrolled in the program as quickly as possible. Of the three sites with nurse/lay navigator models, none expected the nurses to continue conducting outreach efforts once the enrollment numbers were increased. Barriers to outreach reported by sites included participants' reluctance to accept home visits, particularly in crime-ridden areas, and difficulty gaining access to people at community facilities because of resistance of the facility's management to involve their clients in another study. Site staff also consistently noted challenges related to geographic distance, even in urban areas, because of traffic and travel time for home visits.

In addition to outreach efforts, four sites developed strategies for in-reach (all but Moloka'i and Huntsman), or the recruitment of participants already in the base medical setting, into the treatment arm. Two sites (UMDNJ, Josephine Ford) also used this approach to identify potential participants for the screening arm.

Barriers to in-reach were primarily related to the inability of facilities' information technology (IT) systems to link information on participants. In one case (UMDNJ), participants who were hospitalized could not be identified through the IT system for recruitment into the study. In two other sites (Johns Hopkins, UMDNJ), the outpatient clinic IT systems could not be accessed by the navigators at the time of the site visits, making it difficult to identify potentially eligible participants. This problem was being addressed at the time of the site visit, but had been challenging to resolve because of the lack of personnel to work on IT-related barriers.

Overall, a major barrier faced by all sites in achieving their targeted enrollment numbers has been the aggressive marketing of Medicare managed care plans to enroll beneficiaries into both their medical and Part D (prescription drug) plans. A number of Medicare Advantage plans have offered Part D coverage to enrollees at low or zero premiums. As a result, higher than expected numbers of beneficiaries have enrolled in managed care, making them ineligible for the demonstration. In addition, there have been substantial enrollments of dually eligible beneficiaries into Special Needs Plans (SNPs). Because minority populations are more likely to be dually eligible, these SNPs have siphoned off potential CPTD participants.

3.4.2 Participants in the Screening Arm

All sites received 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 CSA, access beneficiaries' medical records, and contact their primary care providers, if applicable.

Once participants complete the baseline survey and are assigned to the screening arm, they are randomized to either the control or the intervention group. Participants in the control group are sent letters with related educational materials. For participants in the intervention (or navigation) group, their responses on the baseline survey are used to determine which screening tests they are due to receive. Medicare coverage rules are used to determine the appropriate periodicity for each test. The three sites with a nurse/lay navigator model begin to schedule appointments for screenings based on survey responses, while also requesting medical records

from primary care providers, as available. The other three sites with the lay-only navigator model also request medical records and/or refer participants to their primary care provider to confirm the self-reports. If the participant does not wish to see his or her primary care provider, or the provider fails to send medical records, all sites must rely on the survey self-reports to determine when screenings are to be done. In both types of models, the lay navigators then work to address participant barriers to attending appointments. Interestingly, navigators at all six sites reported similar barriers among their participants, including fears of being diagnosed with cancer and lack of transportation. A general lack of understanding regarding cancer screening and a distrust of the health care system were reported by four of the sites.

As the navigators schedule appointments, three of the sites (Johns Hopkins, Josephine Ford, M.D. Anderson) maintain an electronic tracking system to follow participants and record information for each service encounter. One site (Moloka'i) has a formal, hardcopy medical charting system for navigators to complete for each participant encounter, and two sites (UMDNJ, Huntsman) keep logs of participant contacts.

All six sites rely primarily on participants telling the navigator what their screening results are and whether follow-up care is needed. If participants seem confused or uncertain about what they should do, the three nurse/lay navigator sites reported that they would call the physician directly to obtain the results and schedule followup according to recommendations. The other three sites typically encourage participants to call the physician to obtain better instructions; the navigator then schedules any necessary procedures. Once participants are up to date with their screenings, only UMDNJ has a protocol in place for ongoing, monthly navigator contact with intervention group participants; the other sites wait until it is time for participants' annual screenings to contact them again.

3.4.3 Participants in the Treatment Arm

As with the screening arm, participants (i.e., patients) assigned to the treatment arm of the study are randomized to the control or intervention group. All sites send letters with educational materials (e.g., information on resources, nutritional education) to control group patients. Patients assigned to either group of the treatment arm can be people who are not currently receiving treatment but have had treatment within the past 5 years. Therefore, the needs of patients in the intervention group of the treatment arm can vary greatly. All the sites work to ensure that patients in the treatment arm are up to date with cancer screenings. Other services that navigators provide to intervention patients include helping schedule appointments, ensuring that patients understand and follow treatment plans, and identifying resources when possible (e.g., wigs for women in chemotherapy, financial assistance for medications). Navigators at all of the sites reported that patients seem to have a lack of understanding of their treatment needs and the importance of following up with their cancer specialists on a regular basis.

In general, the screening arms of all six programs were much more fully developed than the treatment arms. This was largely due to the fact that sites initiated recruitment in the screening arm first, because this was the arm with the largest enrollment targets. As a result, less attention had been devoted to planning the treatment arm. In some sites, it was unclear what the roles and responsibilities of the navigators working with cancer patients would be once the program increased patient enrollment in this arm.

3.5 Early Successes

Early successes identified across the sites include varying levels of support from their existing organizational infrastructure, the staff selected or recruited to work on the program, and the support from local community partners. Each of these areas of early success, as well as examples from selected sites, is provided below.

3.5.1 Organizational Infrastructure and Support

Three aspects of organizational infrastructure seemed to result in accomplishment of early successes across sites: (1) institutional knowledge and expertise for conducting a demonstration; (2) access of program staff to resources such as development of IT systems to support their program; and (3) support among organizational leaders for the ongoing implementation of the program, even when their budgets are in deficit. Some sites have been better able to wield the infrastructure for the benefit of the program, while others have more difficulty gaining organizational support.

All but one (Moloka'i) of the sites had previously conducted clinical trials that required similar types of recruitment processes as that of this program. While two of these five sites (M.D. Anderson, Huntsman) had not conducted clinical trials with their target populations for this program, the institutional knowledge from these experiences is clearly benefiting the sites in terms of knowing how to best staff the project, create educational materials to provide to patients, and develop recruitment strategies. Staff at Josephine Ford, for example, met with key staff who led similar studies at the center in order to gain their advice on initiation of the CMS program. This advice proved to be valuable in helping the site avoid potential pitfalls in program implementation.

Because the PIs at each site are well established within their organization, all were able to access important resources for benefit of the program. Office space, supplies, and resources such as expertise from IT support have proved important to having the program start and operate smoothly. The IT support at three sites (M.D. Anderson, Josephine Ford, Johns Hopkins) resulted in relatively sophisticated tracking systems for the program to monitor their contacts with participants. Other sites without this IT support are relying on paper medical records for patient tracking and are experiencing challenges with adequately recording encounters. It is important to note that, as the budget deficit increased for some programs, one site in particular (M.D. Anderson) experienced increasing challenges in accessing support (e.g., limits were placed on use of postage and mailing supplies).

Another important aspect of organizational support is through the linkages four of the programs had made with internal clinics or units that provided them with specific expertise. Three of the sites (Johns Hopkins, Josephine Ford, M.D. Anderson) had collaborated with their oncology clinics in order to determine ways to access and recruit patients into the treatment arm who had been diagnosed with cancer and/or were undergoing treatment. Four sites had identified other clinics within their systems for access to patients who may be eligible for the screening arm, such as ambulatory care or primary care clinics, and are actively working on strategies for identifying and recruiting program participants from these clinics into the study. The remaining

two sites either lack the organizational structure to do so (Huntsman) or have not determined effective strategies for promoting the existing linkages (Moloka'i).

Finally, as noted earlier, CMS provided each site with \$50,000 in start-up funds, with each site then relying on their capitation and CSA reimbursements to underwrite the ongoing costs of serving their participants. Because all the sites experienced delays in recruiting the numbers of patients they had planned for in the first 6 months of the demonstration, five of the six were running a deficit by the summer of 2007. These deficits were causing increasing problems for the project PIs, who had to justify the ongoing implementation of a program that was clearly losing money. Three sites (M.D. Anderson, UMDNJ, and Johns Hopkins) were under particular pressure to increase their numbers of enrolled patients quickly or face termination of the program. In each case, however, leaders within the organizations remained in support of continuing the program and were actively working with the PIs to develop strategies to address budget issues. This organizational support among key leaders is considered to be an important aspect of their ongoing program development at all of the sites.

3.5.2 Staffing

At the time of the site visits, program staff at all sites were clearly committed to the success of the patient navigation program. Staff expressed enthusiasm over the importance of the program and their commitment to helping achieve its goals. Most of the staff at each site, particularly those who were PNs or community health workers, were representatives from the local population and had obtained training on how to carry out their responsibilities. Sites with potential participants speaking languages other than English were able to recruit PNs who are bilingual in Spanish, related American Indian, and other languages.

In addition to these staff, most programs noted the importance of having clinical expertise readily available to their PNs in order to answer questions and monitor patient encounters. Three of the programs used the model described as nurse/lay navigator, and each described the importance of this clinical oversight. The remaining sites either had physicians who were serving as the PI (UMDNJ, Huntsman) and could provide that oversight themselves, or had identified an oncology nurse to work closely with the PN for participants in the treatment arm (Johns Hopkins).

3.5.3 Community Support

All of the sites recognized the need to spend more time identifying and working with community partners in order to obtain better access to their target population, but few had accomplished this outreach by the time of the evaluation site visits. Because of the need to focus on setting up each program and starting enrollment, most sites worked the hardest at these tasks during the start-up period and had little time to devote to partnership development. Three sites (Huntsman, Moloka'i, Johns Hopkins) had made a concerted effort to reach out to local partners (or tribes, in the case of Huntsman) to create linkages to benefit the CPTD and were showing early signs of success. Huntsman staff had visited with a number of tribal leaders in both Utah and Montana to facilitate development of the program on local reservations. Moloka'i staff were actively working with local providers and community organizations to develop outreach strategies to increase patient recruitment. Johns Hopkins' staff established a community advisory

committee (CAC) that included members from local cancer advocacy agencies, African American churches, and local community leaders. The CAC had been active in advising the program on recruitment strategies and was setting up contacts with local ministers of churches for the PI to meet with in order to garner their support for the program. This type of support seemed to be increasing the community's awareness of the program, thereby informing potential participants of their viability. The sites generally had a limited history of working with their priority population, and two sites (M.D. Anderson, UMDNJ) that had not worked as actively with local partners reported that they had plans to increase their efforts in this area during the next few months because it was hurting their ability to identify eligible patients. The sixth site, Josephine Ford, was visited very early in the program implementation phase (December 2006) and was having tremendous success identifying eligible patients through its EMR system. Josephine Ford did, however, discuss plans for reaching out to local partners and had recently met with partners throughout the region to identify effective collaborations.

3.6 Implementation Challenges

All of the programs had experienced numerous challenges during initiation. None of the six sites had enrolled the number of participants that they had planned for during the first 6 months of the study, and all were working to develop strategies for increasing these numbers. The one site that came closest to reaching its planned enrollment numbers (Josephine Ford) was enabled by its health system's EMR system, such that the site could identify thousands of patients within the system and contact them for participation in the program. The challenges noted across the sites with regard to program initiation and program implementation are described as follows.

3.6.1 Program Initiation

The program initiation phase is the period of time from award to enrollment of the first patient into each arm of the study. The program initiation phase presented challenges to sites in being able to quickly staff their programs. The sites often relied on infrastructure within their organization that may or may not have had the capacity to support the CPTD, while simultaneously readying their programs for patient recruitment and enrollment. Specific challenges within each of these areas are described below.

Staffing—Sites were having difficulty recruiting PNs who were able to work flexible schedules for the salaries provided. Two programs were having particular difficulty with recruitment because of the geographic distances covered by their programs and the unwillingness of PNs to travel these distances. One of these sites (Moloka'i) did not provide mileage reimbursement to PNs and, in hindsight, noted that it hoped to revise the budgets in order to cover the increasing costs of gas. The other site, Huntsman, was operating the program differently in the two states of Utah and Montana. In Utah, funds had not been allocated to pay for mileage reimbursement of PNs traveling across reservations to enroll patients into the program and take them to appointments, because it had not been considered as a need at the time, while in Montana, funding had been allocated for this cost. PNs who were interviewed noted the importance of having this cost reimbursed, particularly because the cost per gallon of gas had increased so much and the distances they had to travel were so great. Even programs in urban areas were having difficulty recruiting and identifying staff who were both willing to travel to

potential participants' homes and willing to work flexible hours to meet the needs of recruited patients. Four of the sites (M.D. Anderson, Johns Hopkins, Josephine Ford, Moloka'i) were experiencing challenges in recruiting and retaining lay navigators who were sensitive to and represented the local disparate populations being targeted by their programs.

Infrastructure—With any new initiative, it is often difficult to integrate the structures and staff for the new program into an existing organization. Infrastructure challenges were quite evident for all six of the sites, from the lack of adequate office space for the newly hired program staff (Josephine Ford, Huntsman) to the inability to link existing IT systems so that staff could easily identify potential participants and/or access information (UMDNJ, Johns Hopkins). In addition to the difficulties in linking existing IT systems, because of the required data elements and patient tracking, IT system development proved to be a barrier for UMDNJ, causing delays in the site's ability to set up tracking systems for its patients.

Participant recruitment and enrollment—The most significant challenge faced across all six sites was in enrolling eligible participants. Because of the recent enactment of Medicare Part D and the establishment of SNPs targeting dually eligible beneficiaries, there was a much larger than expected proportion of the population that had enrolled in a managed care plan. As a result, it was difficult for sites to identify participants who met all the eligibility requirements for CPTD (i.e., Medicare A and B, but not managed care, and so forth.). As a rule, sites had underestimated the penetration of Medicare managed care in their communities. In addition, sites reported problems with the lists provided by CMS. All six sites noted that the lists they received included a lower number of potential enrollees than they had expected. These lists were derived from all Medicare A and B enrollees residing in the geographic location of the site. Most of the lists included far fewer potential enrollees than the sites believed was accurate. In addition, as the sites began to contact those people on their lists, they found that many were ineligible because they had enrolled in a managed care plan since the list was generated by CMS. Also, all of the sites had encountered reluctance among potential enrollees to share their Medicare information during the enrollment process or to consider participation out of fear that the program may be illegitimate or that their benefits may be negatively affected. Sites noted a general lack of understanding among Medicare beneficiaries about the benefits that they are entitled to use.

Other recruitment challenges came from a general lack of existing partnerships with community agencies that serve their targeted populations. All sites reported spending more time than expected establishing these partnerships and identifying ways to access the eligible populations to inform them about the program. At the time of the site visits, all sites reported that they were starting to make progress in working with partners in order to recruit participants into their programs, but this was turning out to be a slow and laborious process for most sites.

The majority of efforts for participant recruitment and enrollment had focused on the screening arm of the program, because that was intended to serve the majority of patients. None of the sites had thoroughly developed the treatment arm of their studies, determined how services would be assured to these patients, and what the PNs' role was to be throughout the course of care for patients in this arm. In addition, the number of patients to be enrolled in this arm was not adequately projected by the sites, such that two (Johns Hopkins, M.D. Anderson) had planned to rely only on incident or new cases of cancer for enrollment into the treatment arm, instead of cases that were prevalent or existing cases of cancer. By the time of the site visits, the programs

had learned that incident cases would not provide them with sufficient numbers of enrolled patients in the treatment arm, and they were adjusting their strategies to include all eligible cancer cases as possible enrollees.

3.6.2 Program Implementation

Sites were relatively new at program implementation at the time of the site visits, but had experienced challenges in the areas of providing patient services, establishing important community relationships, and operating under a financially challenging structure.

Patient-related challenges—PNs were encountering patient-related challenges to ensuring that intervention participants received screenings in a timely manner, according to national screening guidelines. Most of the PNs were working to improve access to screening as someone outside the system of care for the patient’s primary providers. Five sites (all except Josephine Ford, which was recruiting people primarily from within its health system) were basically trying to influence patients to receive screening care through providers with whom they had little or no contact as of the site visits. For these sites, enrollees completed the CSA, which provided information on the last screenings they had obtained for each of the study cancers (i.e., breast, cervical, prostate, and colorectal). Based on their CSA responses, the PNs would either inform the patients that they needed to see their primary care provider to assess their screening needs (UMDNJ, Johns Hopkins, Huntsman) or begin to schedule screening tests (Moloka’i, M.D. Anderson). (For Huntsman participants, appointments were scheduled at the Indian Health Service). If participants indicated that they did not want to go to their primary provider, all sites would perform this function instead.

Those sites that rely mainly on the primary care provider to refer patients to screening tests are dependent on that provider following the guidelines. Ultimately, this challenge may mean that some patients at these sites do not receive screening tests as recommended because of their physician’s practice patterns. In addition, PNs had quickly encountered the problem of patients not following through with screenings when they learned the amounts of their copayments. Copayments for procedures are major barriers for patients. Two sites (UMDNJ, Johns Hopkins) noted that patients had requested that the program pay for a living expense (like heating) so that the patient could afford the screening test. While sites, of course, did not pay such expenses, it highlighted for them the numerous needs among the elderly population in their areas and why cancer screening may not be among the highest priority for spending in their target populations. This was particularly evident for the tests with higher copays, like colonoscopies.

Community-related challenges—As noted, all of the sites experienced challenges in establishing partnerships with local community agencies that could provide them access to the eligible populations. In addition, sites experienced community-related challenges among potential enrollees. Two of the sites (Johns Hopkins in Baltimore, UMDNJ in Newark), located in relatively high-crime areas, were conducting home visits and experienced difficulties in having participants even open the door to listen to them for fear that they were con artists or insincere. The local crime rate was compounded by a history in the Johns Hopkins, UMDNJ, and Josephine Ford (Detroit) communities of the participating institutions’ research with the target populations. In some cases, the history of the community was that research had been conducted

inappropriately among minority populations (Josephine Ford) or too many studies had been done such that the community was saturated (M.D. Anderson in the Houston area, Johns Hopkins in Baltimore). In addition to the reluctance among potential enrollees, two sites (Moloka'i, UMDNJ) were also encountering physicians who were unwilling to refer their patients to the program for fear that the institution would “steal” the patients from their practice and therefore diminish their business.

Financially related challenges—Financial challenges were encountered at all the sites in at least one of two forms: (1) the higher than expected managed care enrollment, in part due to the concurrent roll-out of Part D; or (2) overruns in the program budget. As previously noted, all of the sites experienced challenges because of the timing of roll-out of Medicare D and of SNPs, which resulted in higher than expected enrollment in Medicare managed care plans. Finally, as discussed, five of the six sites had run over their initial budget of \$50,000 from CMS as of the site visits, primarily because of slower enrollment than anticipated. Some of these sites had put staff on the payroll well before IRB approval was granted, and thus they incurred debt even before they were “open for business.” By the time of the site visits, three sites (M.D. Anderson, UMDNJ, and Johns Hopkins) were under extreme pressure to increase enrollment or potentially have their programs shut down because of the budget deficits.

3.7 Lessons Learned

During the site visits, all respondents were asked to share their lessons learned for program initiation. Across the sites, these lessons learned centered around better planning at both the program and participant levels.

3.7.1 Program Level

Programs with the nurse/lay navigator model, in particular, noted the importance of having clinical oversight of the PNs as their role was established and better defined. Because the PN model was new to the sites, during the time of the site visits, the role of the PNs did seem to be evolving. The three programs with nurse or clinical oversight felt that the importance of this knowledge in establishing program structure (i.e., medical charting system in Moloka'i, direct physician-to-program contact in all three programs) to support the delivery of patient care over time was essential.

Sites had varying levels of interactions with community partners, and those that had established some key partnerships (Moloka'i, Huntsman) stressed the importance of taking the time to learn about the local partners and how to best work together to reach the eligible populations. All six sites recognized the need to better understand partners and initiate relationships prior to initiating a program like CPTD, so that plans can be made to effectively recruit their constituents in the program.

3.7.2 Participant Level

Sites reaching out to minority populations noted the need to address cultural barriers and believe in their planning (i.e., there is a notion in the Hispanic community that by talking about cancer you are “tempting fate” and will get it). Sites stressed the need to identify staff who are

culturally competent and are aware of the myths and barriers in the targeted communities so that they can anticipate and address them more effectively.

Sites also pointed out that they should carefully consider incentives given to patients and even ask for their input in terms of what would be important for them to receive. For example, M.D. Anderson purchased \$10 cell phone cards, only to discover that the cards could not be used to make international calls (e.g., to Mexico), and most of the population already had phones with free long distance.

3.8 Conclusions

The sites had all experienced great challenges in initiating their programs and enrolling the patients they had projected. Nevertheless, they had each learned from their first 6 to 9 months of program implementation and were implementing solutions. Besides learning from their own early experiences, sites also benefitted from hearing the experiences of their colleagues at other demonstration sites. CMS held regular monthly conference calls with all sites, during which sites shared their enrollment strategies with each other. In addition, CMS holds annual meetings in Baltimore attended by staff from all six sites.

Sites had understandably focused their attention during start-up on establishing their patient services and navigation processes. Limited time was available to focus on community partnership development. It seemed clear that sites had greatly underestimated how well they could access potential enrollees on their own, and some lacked specific knowledge of how to work effectively to quickly recruit participants. Because of the special needs of the populations they hope to reach, sites will need to spend more time in the coming months reaching out to key partners in order to gain trust in their communities and among their providers.

Three of the sites are relying on local primary providers to refer patients for screening services appropriately (Johns Hopkins, UMDNJ, Huntsman). Because provider education is not being delivered, this reliance on each individual's practice patterns is likely to affect the sites' ability to increase screening rates. In terms of patient care, three sites (Moloka'i, Josephine Ford, M.D. Anderson) had thoroughly developed their patient flow in the screening arm to have protocols in place for providing monitoring of patients with abnormal screening results. The remaining sites had not experienced that situation and were unclear how they would ensure that patients are tracked through diagnostic procedures, other than through patients reporting to the PNs. In addition, as the sites move forward, more attention will need to be given by the sites on how the treatment arm will be navigated over time in order to best affect their access to care. Ultimately, because of the difficulties encountered during start-up, all of the sites are significantly behind in enrolling the anticipated number of patients—some more so than others. To show effect over time, the enrollment process at all sites will need to improve quickly.

SECTION 4

BASELINE DISPARITIES IN CANCER SCREENING RATES

Reductions in screening disparities under the CPTD will 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 population (racial/ethnic minority). As a result, the magnitude of preexisting (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/ethnic minority groups included in the demonstration.

4.1 Methods

For the baseline screening analyses, the outpatient Standard Analytic File (SAF), Medicare Provider Analysis and Review (MEDPAR), and National Claims History (NCH) Part B data were analyzed for the two calendar years immediately preceding the demonstration: 2004–2005. These claims were linked to the denominator file to obtain beneficiary characteristics and to identify deaths and periods of managed care enrollment. The 5 percent file was used for the analysis of national screening rates, while 100 percent data were used for the site-specific rates. All cases were weighted based on the number of months a beneficiary was alive in each year, in fee-for-service, and enrolled in Parts A and B.

For screening recommendations, Medicare coverage policies and guidelines from the ACS and the U.S. Preventive Services Task Force (USPSTF) were reviewed. The CPT, HCPCS, and ICD-9 codes were identified for each screening test. Algorithms were created based on age and screening codes to determine whether the beneficiary had had the specific screen on the appropriate time table.

Screening rates were created for 2004, 2005, and for the 2 years combined. Because rate comparisons can be affected by age-related differences between groups, we computed age-adjusted rates by weighting minority group data by the age-gender composition of the white reference population. The demonstration areas were defined using zip codes that were confirmed by each site. There were essentially no differences in rates between 2004 and 2005. Two-year screening rates were higher for all groups, as expected, but relative differences between whites and minorities were unchanged. Therefore, data for the more recent year (2005) are presented, because 1-year rates are more consistent with those calculated from other sources, such as the National Health Interview Survey.

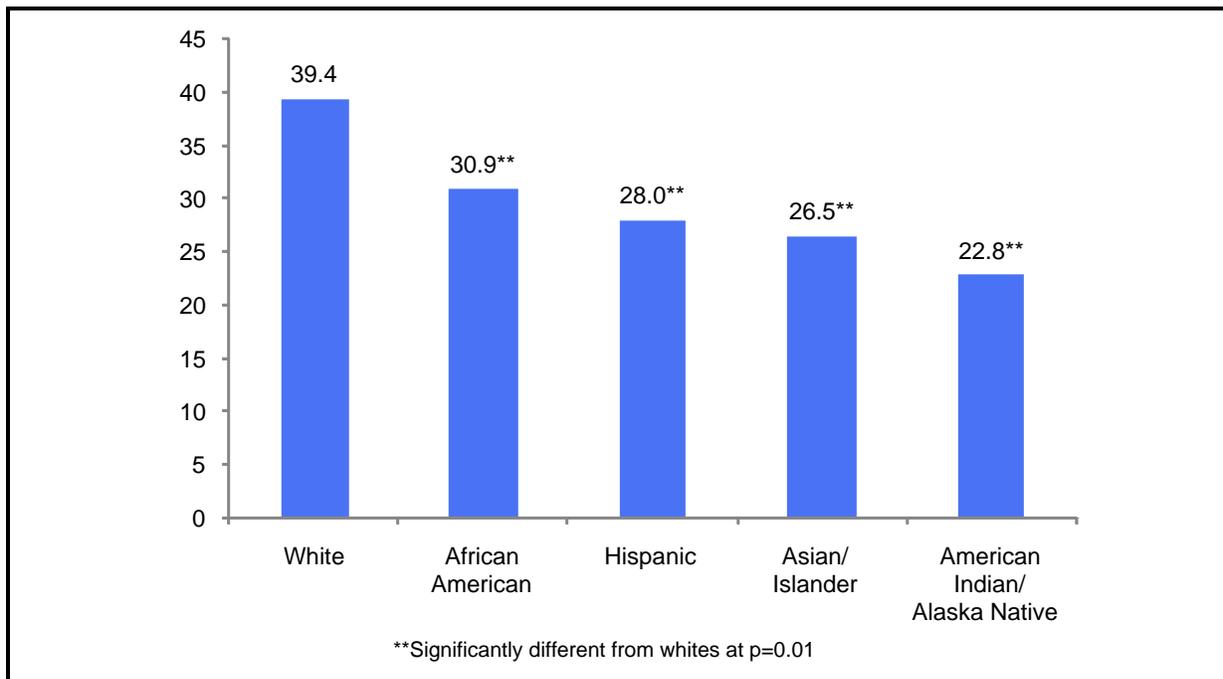
4.2 Results

4.2.1 National Rates for Cancer Screening Tests

Note that all screening rates for white Medicare beneficiaries are significantly higher than for the various minority beneficiaries. In a few instances, the differences are quite small and not clinically meaningful. The rates attained significance because of the very large sample sizes, even in the 5 percent sample.

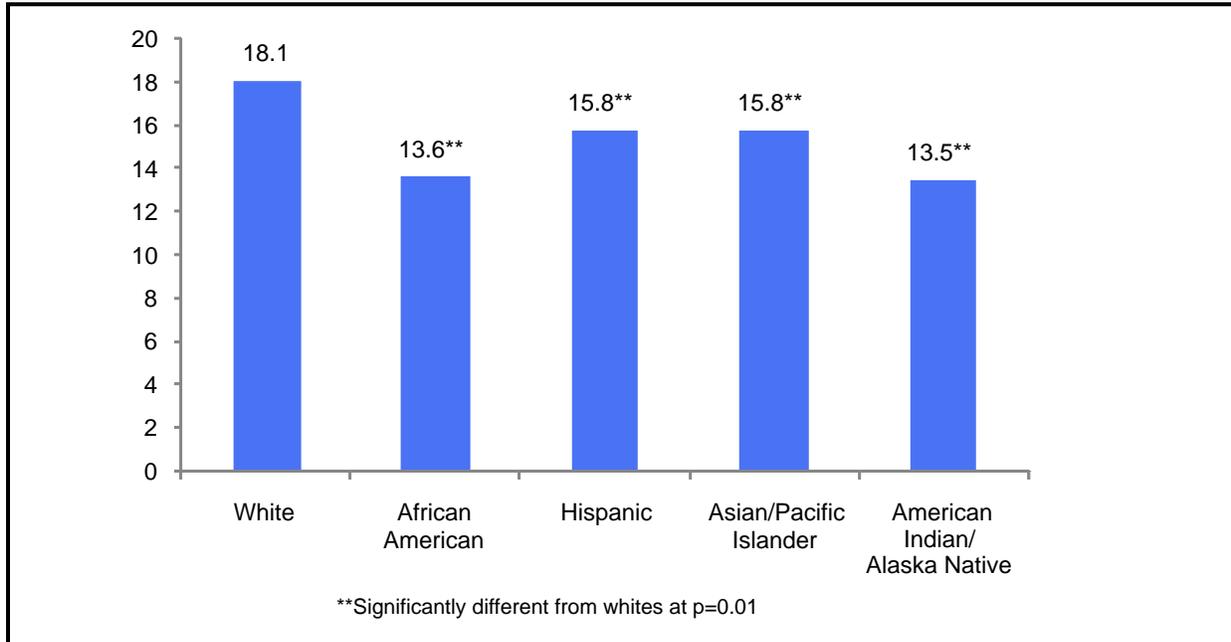
Mammograms are covered by Medicare each year for women 40 years and older, and one baseline mammogram is also covered for women between age 35 and 40. Both ACS and USPSTF guidelines recommend annual mammograms for women 50 years or older, and every 1 to 2 years for women 40 years or older, depending on evidence of risk factors associated with breast cancer incidence (Agency for Healthcare Research and Quality, 2007). Nationally in 2005, white Medicare beneficiaries had the highest rates of mammograms at 39.4 percent (Figure 1). African Americans, Hispanics, and A/PIs had rates of between 26.5 percent and 30.9 percent, while American Indians/Alaska Natives had the lowest rates at 22.8 percent.

Figure 1
U.S. Medicare mammogram rates, by race and ethnicity



Medicare coverage for Papanicolaou (Pap) tests varies depending on age. For women of childbearing age who have had an abnormal Pap test within 36 months or other women who have been determined to be at “high risk” for cervical cancer by the local Medicare contractor, Medicare covers Pap tests annually. Otherwise, Medicare covers Pap tests every 24 months, with no upper age limit. ACS and USPSTF guidelines recommend having a Pap test every 1 to 3 years, depending on type of Pap test, risk factors to developing cervical cancer (e.g., multiple sexual partners, history of human papillomavirus), and number of consecutive tests that were normal. In addition, if a woman has had a history of normal Pap tests, ACS and USPSTF recommend discontinuing the test by age 70. In light of these coverage guidelines and recommendations, nationally, the rates of Pap tests for Medicare beneficiaries in 2005 ranged from roughly 14 percent to 18 percent (Figure 2). American Indians/Alaska Natives and African Americans had rates of 13.5 and 13.6, respectively, while whites had a rate of 18.1 percent.

Figure 2
U.S. Medicare Pap test rates, by race and ethnicity



For beneficiaries at normal risk for colorectal cancer, Medicare covers colonoscopies once every 10 years starting at the age of 50. This is also the recommendation of ACS and USPSTF. Nationally in 2005, the rates of colonoscopy were less than 10.0 percent for any racial or ethnic group, and ranged from 6.9 percent for American Indians/Alaska Natives to 9.9 percent for whites (Figure 3).

Medicare covers prostate specific antigen (PSA) tests annually for men over the age of 50. While this is also recommended by ACS, USPSTF concluded that the evidence was insufficient to recommend either for or against use of the PSA test (Agency for Healthcare Research and Quality, 2007). The rates of PSA tests ranged nationally in 2005 from 21.4 percent for American Indians/Alaska Natives to 43.2 percent for whites (Figure 4). African Americans, Hispanics, and APIs had rates between 35.7 percent and 38.1 percent.

Figure 3
U.S. Medicare colonoscopy rates, by race and ethnicity

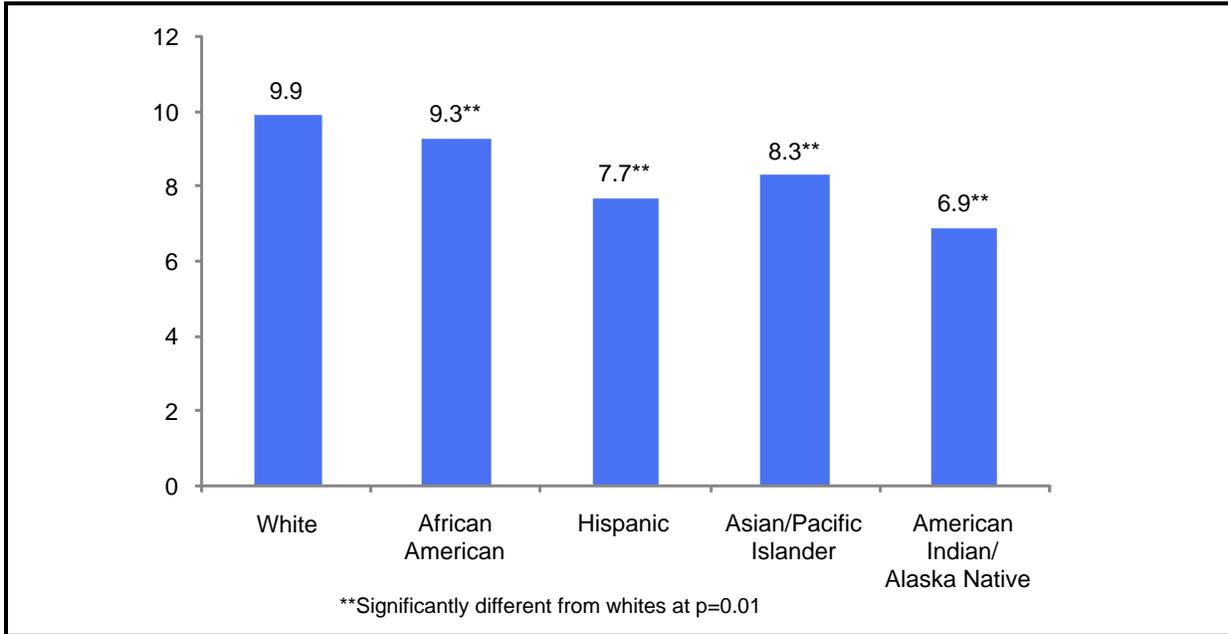
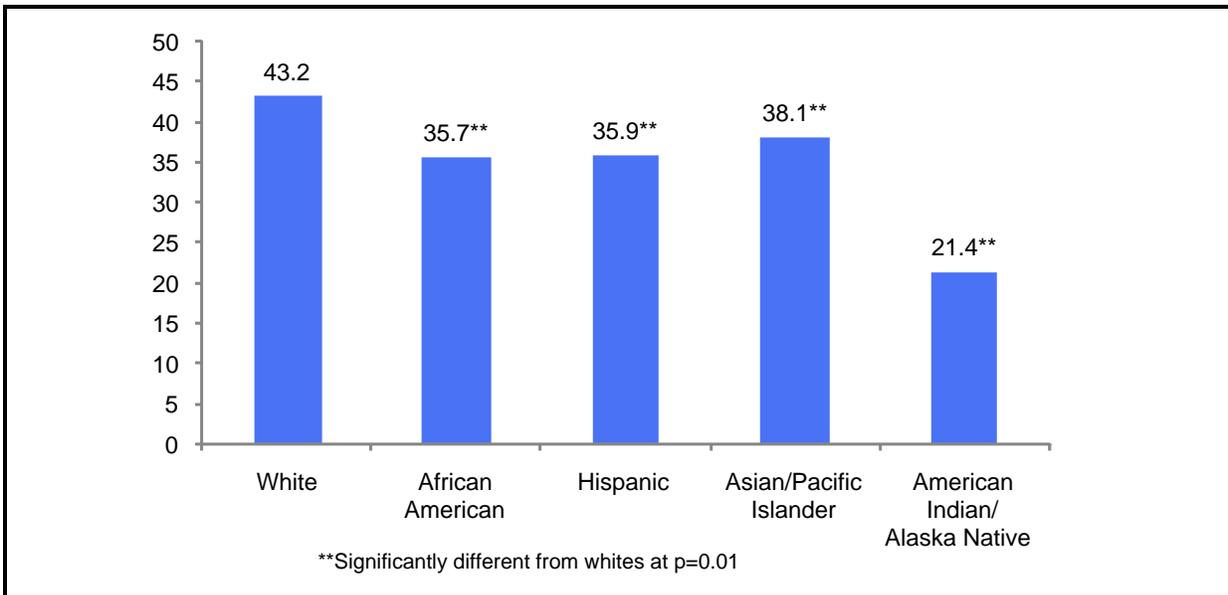


Figure 4
U.S. Medicare PSA rates, by race and ethnicity



4.2.2 Cancer Screening Rates by Demonstration Site

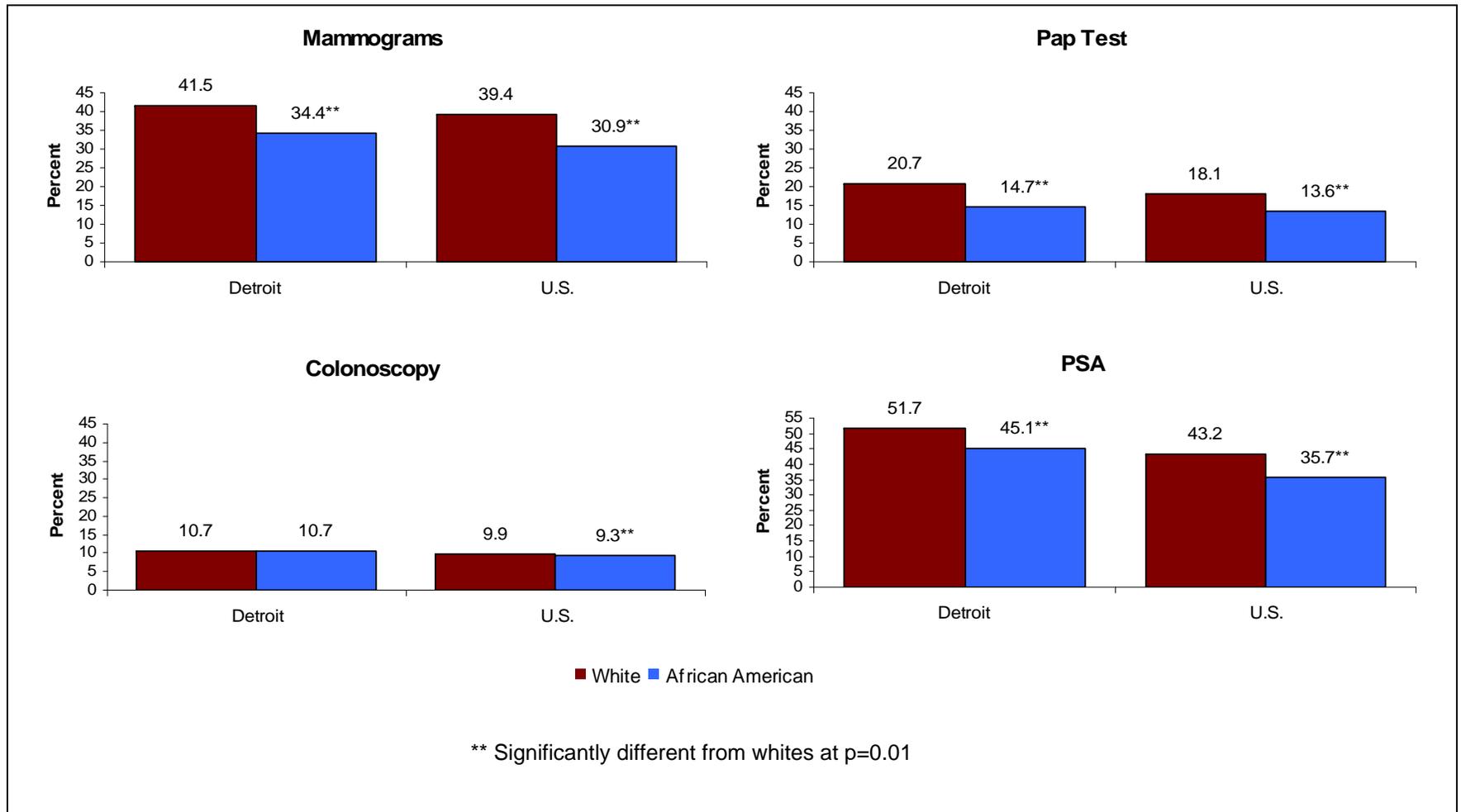
Detroit, Michigan

For this demonstration site, the geographic area includes the Detroit metropolitan area and encompasses the city of Detroit and the surrounding counties of Wayne, Oakland, and Macomb. This site focuses on African Americans.

For African American and white Medicare beneficiaries, the rates for all of the cancer screening tests in the Detroit demonstration area were higher than the rates for African American and white Medicare beneficiaries nationally (Figure 5). Presumably, this is due to better access to health care services in a large metropolitan area like Detroit. Nevertheless, the rates for all tests, with the exception of colonoscopies, were still significantly lower for African Americans in Detroit than they were for whites living in the same city. Specifically,

- 34.4 percent of African American women compared with 41.5 percent of white women had mammograms,
- 14.7 percent of African American women compared with nearly 21 percent of white women had Pap tests,
- 10.7 percent of African Americans and 10.7 percent of whites had colonoscopies, and
- 45.1 percent of African American men compared with 51.7 percent of white men had PSAs.

Figure 5
U.S. Medicare cancer screening rates for whites and African Americans: Detroit and the U.S.



Baltimore, Maryland

The Baltimore City, Maryland, demonstration site focused on African Americans. Compared with national Medicare rates for African Americans, the Baltimore demonstration area had higher Medicare rates for mammograms, Pap tests, and colonoscopies (Figure 6). Again, it is assumed that this reflects the enhanced access to services in a large metropolitan area relative to the nation at large. In Baltimore, however, African American Medicare beneficiaries had lower rates than white Medicare beneficiaries for all screening tests. Specifically,

- 36.4 percent of African American women compared with 40.6 percent of white women had mammograms,
- 16.0 percent of African American women compared with 20.0 percent of white women had Pap tests,
- 9.7 percent African Americans compared with 10.4 percent of whites had colonoscopies, and
- 31.0 of African American men compared with 40.2 percent of white men had PSAs.

Moloka'i, Hawaii

This demonstration area encompasses Moloka'i, an island in Maui County of Hawaii, as well as a small region of Oahu, near the town of Wai'anae. The target population is A/PI, primarily Filipinos and Native Hawaiians. We note that the Medicare race designation is A/PI, which consists of more races and ethnicities than just Filipino and Native Hawaiians, which may affect results.

For this demonstration area, with the exception of colonoscopies, A/PI Medicare beneficiaries had higher rates for all screening tests than A/PI Medicare beneficiaries nationally (Figure 7). Furthermore, A/PI Medicare beneficiaries in the demonstration area had higher rates of screening tests compared with white Medicare beneficiaries. Specifically, in this demonstration area

- 32.7 percent of A/PI women compared with 30.9 of white women had mammograms,
- 22.2 percent of A/PI women compared with 18.0 percent of white women had Pap tests,
- 7.6 percent of A/PI compared with 7.2 percent of whites had colonoscopies (although the difference was not significant), and
- 38.9 percent of A/PI men compared with 35.1 percent of white men had PSAs.

Figure 6
U.S. Medicare cancer screening rates for whites and African Americans: Baltimore and the U.S.

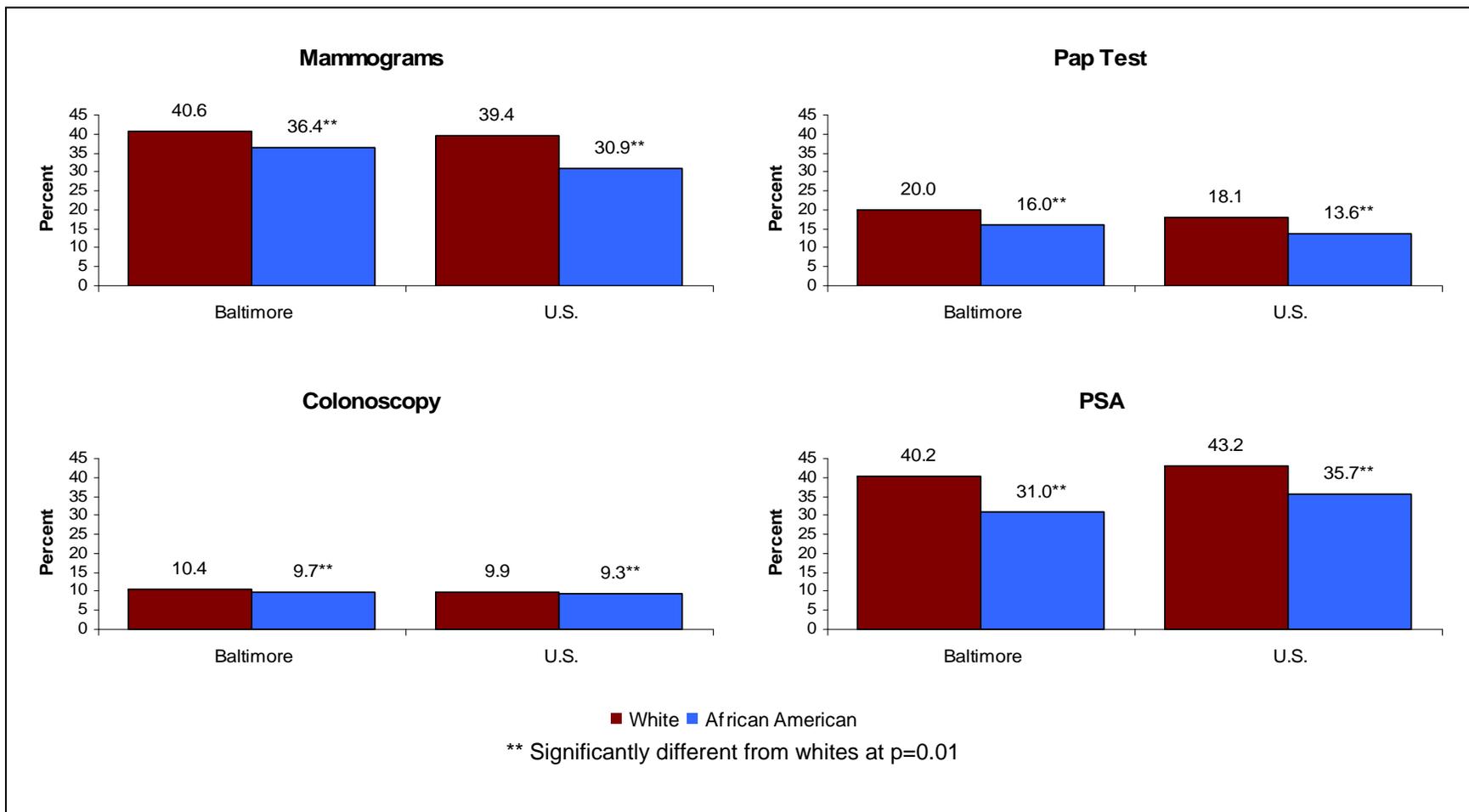
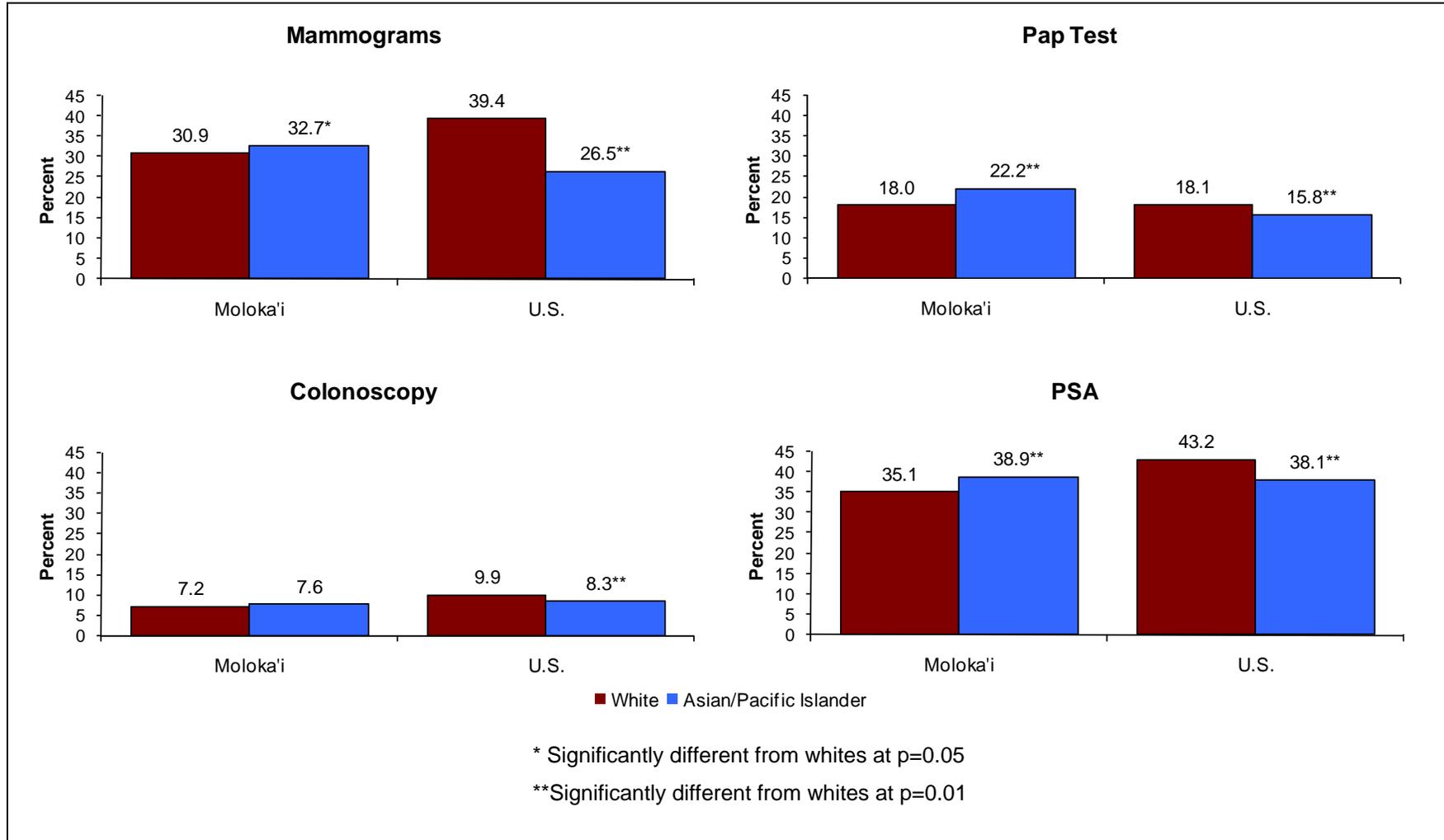


Figure 7
Medicare cancer screening rates for whites and Asian Pacific Islanders: Moloka'i and the U.S.



Intermountain West—Utah and Montana

The demonstration site for Huntsman Cancer Institute consist of various American Indian reservations in Utah and Montana, with the priority population being American Indians representing several tribes. We note that nationally there is no single Medicare race designation for American Indians. The designation is combined with Alaska Natives, which may affect results. Furthermore, because American Indians receive care from the IHS, the rates using Medicare claims may be an underestimate.

American Indian Medicare beneficiaries in the demonstration area had lower rates of cancer screening tests when compared with American Indian Medicare beneficiaries nationally (Figure 8). American Indian Medicare beneficiaries in the demonstration area also had lower rates of cancer screening tests compared with white Medicare beneficiaries in the same area. Specifically, in the demonstration area

- 13.0 percent of American Indian women compared with 34.5 percent of white women had mammograms,
- 7.6 percent of American Indian women compared with 12.2 percent of white women had Pap tests,
- 5.6 percent of American Indians compared with 10.0 percent of whites had colonoscopies, and
- 12.5 percent of American Indian men compared with 39.2 percent of white men had PSAs.

Houston, Texas

The demonstration site for M.D. Anderson is the city of Houston, which comprises parts of Fort Bend, Harris, and Montgomery counties.¹ The focus of this demonstration is Hispanics.

Hispanic Medicare beneficiaries in Houston had lower rates of all screening tests compared with Hispanic Medicare beneficiaries nationally (Figure 9). The rates for colonoscopies were most similar, with 7.0 percent of Hispanics having colonoscopies at the demonstration site compared with 7.7 percent of Hispanics nationally. In Houston, Hispanic Medicare beneficiaries also had lower rates of all screening tests compared with white Medicare beneficiaries nationally. Specifically,

¹ We note that since this analysis, M.D. Anderson has expanded its demonstration site.

Figure 8
U.S. Medicare cancer screening rates for whites and American Indian/Alaska Natives: Huntsman and the U.S.

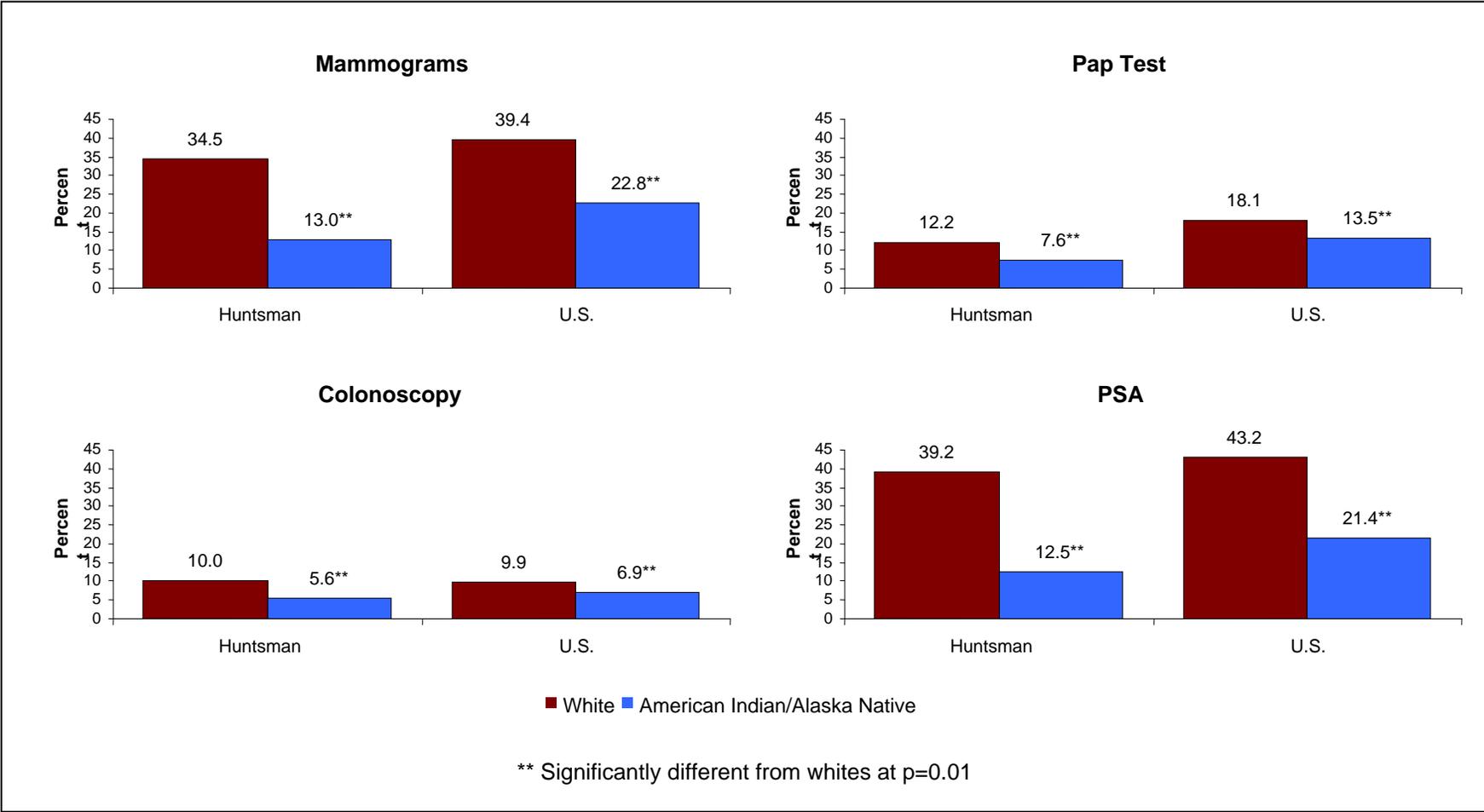
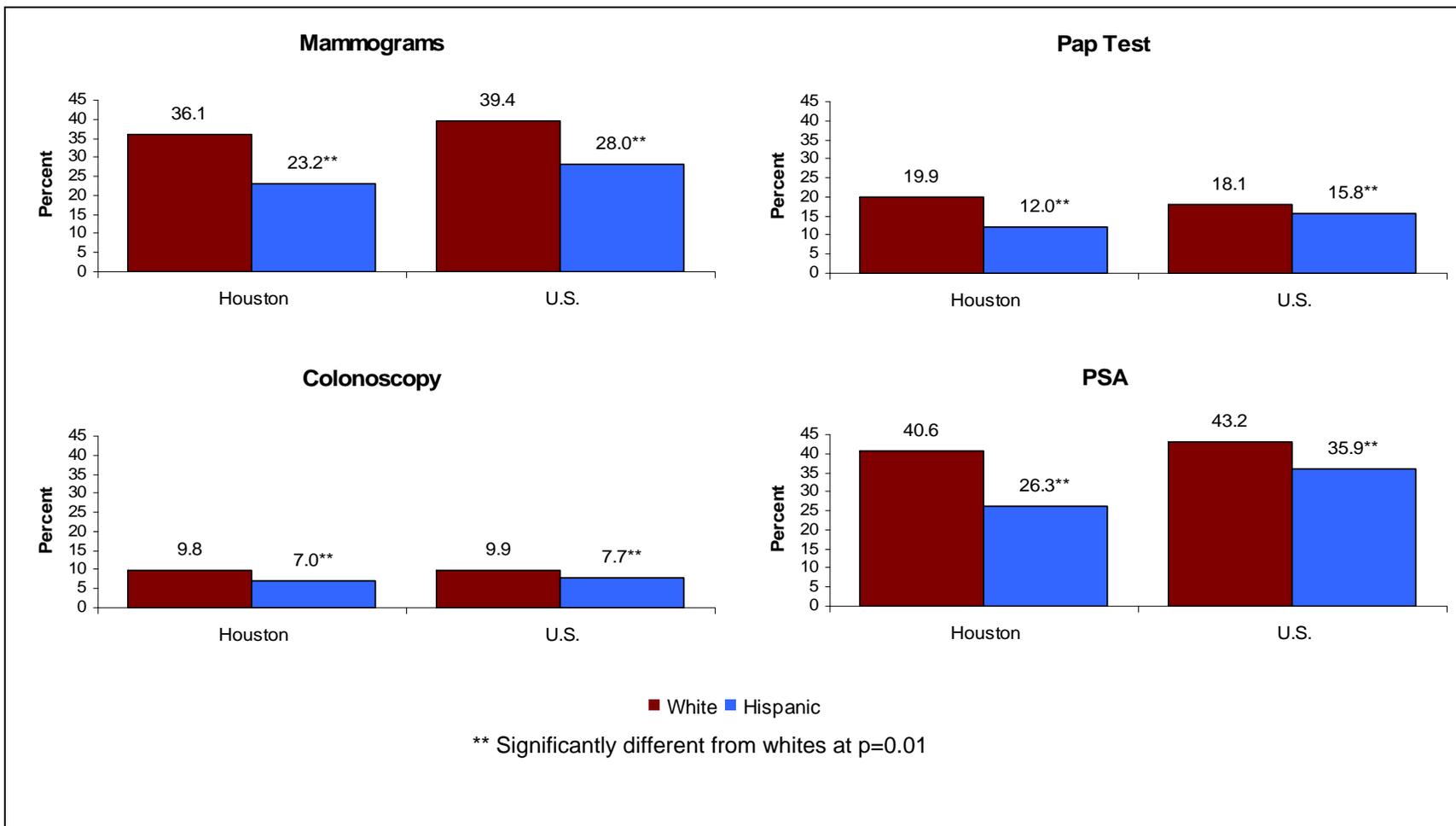


Figure 9
U.S. Medicare cancer screening rates for whites and Hispanics: Houston and the U.S.



- 23.2 percent of Hispanic women compared with 36.1 percent of white women had mammograms,
- 12.0 percent of Hispanic women compared with 19.9 percent of white women had Pap tests,
- 7.0 percent of Hispanics compared with 9.8 percent of whites had colonoscopies, and
- 26.3 percent of Hispanic men compared with 40.6 percent of white men had PSAs.

Newark, New Jersey

The demonstration site for UMDNJ is the Newark metropolitan area. Hispanics are the priority population for this demonstration site.

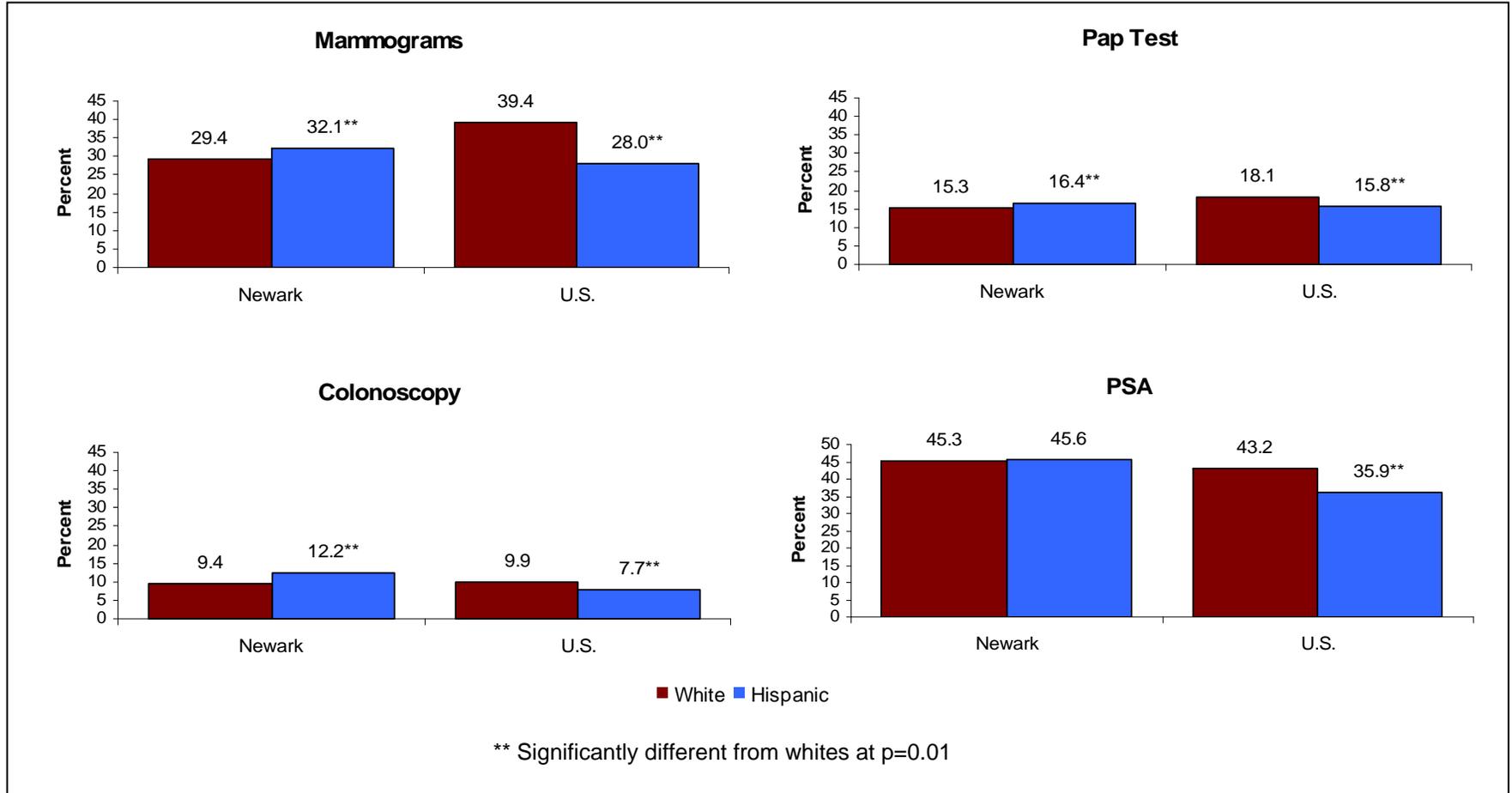
Across all cancer screenings without exception, Hispanic Medicare beneficiaries in Newark had higher screening rates than Hispanic Medicare beneficiaries nationally (Figure 10). We suspect that this may reflect cultural differences due to differences in country of origin for Hispanic Medicare beneficiaries residing in New Jersey compared with those nationally. New Jersey Hispanics are disproportionately from Puerto Rico, compared with Hispanics nationally who are more likely to have immigrated from Mexico. Hispanic Medicare beneficiaries in the demonstration area also had higher rates than white Medicare beneficiaries, except for PSA tests. Specifically, in the demonstration area

- 32.1 percent of Hispanic women compared with 29.4 percent of white women had mammograms,
- 16.4 percent of Hispanic women compared with 15.3 percent of white women had Pap tests,
- 12.2 percent of Hispanics compared with 9.4 percent of whites had colonoscopies, and
- 45.6 percent of Hispanic men and 45.3 percent of white men had PSAs (the difference was not statistically significant).

4.2.3 Summary

Both in Detroit and Baltimore, each of the screening rates for African Americans and for whites in the demonstration areas were higher than the screening rates nationally for African Americans and for whites, respectively, with the exception of the PSA screening rates in Baltimore. The reason for the higher screening rates in the demonstration areas may be due to the fact that both Detroit and Baltimore are large cities and residents may have better access to physicians, hospitals, and cancer centers compared with other areas of the country.

Figure 10
U.S. Medicare cancer screening rates for whites and Hispanics: Newark and the U.S.



In Moloka'i and a small region of Oahu, Hawaii, the screening rates for A/PI in the demonstration area were higher than the screening rates for whites on Moloka'i and for A/PI nationally, with the exception of colonoscopies.

In the Huntsman demonstration, the screening rates for American Indians were lower than for whites in the demonstration area and lower than for American Indians nationally. The difference in rates between American Indians in the demonstration area and American Indians nationally is likely due, in part, to the rural setting of the demonstration area and the difficulty residents there have accessing preventive cancer screenings. We note that the rates using Medicare claims may be underestimated as American Indians can seek care from IHS.

In Houston, the screening rates were lower for Hispanics compared with Hispanic rates nationally. On the other hand, in Newark, the screening rates for Hispanics were higher for each test in comparison to screening rates for whites in the demonstration area and in comparison to screenings rates for Hispanics nationally. The Behavioral Risk Factor Surveillance System, funded by the Centers for Disease Control and Prevention, found similar results for mammograms and Pap tests in New Jersey (2007{ XE "CDC, 2007" }). Differences may be driven by the Hispanic populations themselves, as New Jersey has a large Puerto Rican population, while Texas has a large Mexican population.

4.3 Conclusions

National screening rates for mammograms, Pap tests, colonoscopies, and PSA tests were calculated using 2005 Medicare claims and confirm the racial/ethnic disparities reported in the literature. African American, Hispanic, A/PI, and American Indian/Alaska Native Medicare beneficiaries were all significantly less likely to have received these tests during the year compared with white Medicare beneficiaries.

Similar disparities were observed within 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 (A/PI in Moloka'i and Hispanics in Newark) were found to have significantly higher screening rates than their white counterparts for at least three of the four tests. Further research is needed to determine the reasons for these differences. Possible reasons 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.

Administrative data, such as claims and enrollment records, do not include information on socioeconomic status. However, they do include information on whether an individual beneficiary is dually eligible for Medicaid, a good proxy for low income. Future work will recalculate national and site-specific screening rates, controlling for dual eligibility.

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SECTION 5 FUTURE EVALUATION PLANS

This first Report to Congress is based on information collected through the first set of case studies, including visits to all six sites and enrollment and other data reported to CMS. Subsequent Reports to Congress will include results from analysis of Medicare claims data, CSAs, demonstration cost data, and a second round of case studies. More detail is provided below.

Case Studies. A second round of case studies will be conducted at all 6 sites in 2009. These case studies will focus on progress made since the first case study, problems that were identified and how they were resolved, satisfaction of site providers (including navigators), etc. Common themes across sites will be identified, especially lessons learned that could help future patient navigation projects.

CSAs. Baseline and exit survey results will be used to estimate the impact of the intervention on beneficiary outcomes, such as quality of life. In addition, annual CSA surveys of intervention group participants will be used to assess their satisfaction with navigation services.

Medicare Claims. Medicare Part A and B claims will be used to estimate the impact of the intervention on screening rates for those participants in the screening arm, and on treatment completion rates for those in the treatment arm. Claims will also be used to determine whether the intervention has spill-over effects on Medicare use and expenditures.

Cost-Effectiveness, Cost-Utility, and Budget Impact. These analyses will combine data from both surveys and claims to determine the cost-effectiveness and cost-utility of the interventions. Analysis of claims data alone might suggest increased costs associated with patient navigation, for example, but the addition of health related quality of life data (from the CSAs) might show that these higher costs are offset by improved quality of life.

Demonstration Costs. Actual cost data will be obtained from each site to assess both start-up costs and annual implementation costs. These data will be used to calculate the program costs of patient navigation (as opposed to the costs from Medicare's perspective).

Together, these analyses will answer the questions posed by Congress:

1. Did the intervention (i.e., patient navigation) improve quality of services provided and reduce disparities for racial/ethnic minorities?
2. Did the intervention reduce Medicare costs for participants, or was it at least budget-neutral?
3. Were participants and providers satisfied with the intervention services?

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