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

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

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

The main sources of data for this study were surveys administered by the sites to study participants and Medicare claims data from 2002 through 2010. The CSAs were administered by site personnel at baseline, when a study participant enrolled, and at exit, or when a study participant left the study. Sites also administered an annual survey to study participants, though most focused on the intervention group. The baseline CSA was required for someone to be considered a study participant, and the exit CSA was important for measuring program-related change on elements measured in the surveys. Survey data were sent from each site to Thomson Reuters and then on to RTI for analysis. The response rates for the exit CSAs were not ideal and differed by study site and participant status (intervention or control). The CSA data were therefore most useful for answering questions related to satisfaction with the intervention for the intervention group and for providing identifiers that allowed matching to the claims data. Using the identifying information from the baseline CSA, we matched each study participant to Medicare claims data, which allowed us to address outcomes for all study participants (not just the ones who had responded to the exit CSA). The Medicare claims data were the basis for analysis of changes in screening rates and spending in response to patient navigation interventions. The claims data from 2002 through 2010 allowed us to examine utilization and spending patterns before, during, and even after study enrollment. Because each site implemented its own patient navigation intervention, and because the target populations in each site were so different, all analysis was site specific.

Several other data sources were used for this report. RTI collected data from the sites. Annually, sites submitted to RTI a Cost Assessment Tool (CAT); quarterly, sites submitted PN

activity surveys. (More information is provided on these in section ES.12.) CMS provided RTI with enrollment and payment data. In addition, RTI conducted two rounds of site visits with each of the demonstration sites and delivered to CMS a site visit report for each site and each round. The evaluation team did not have access to sites' quarterly progress reports.

Demonstration Enrollment

Participation in the demonstration was voluntary, and beneficiaries could drop out at any time. Participants were automatically dropped if they became ineligible. For example, beneficiaries in managed care plans were not eligible for this demonstration, and those who later enrolled in a managed care plan also lost eligibility for the CPTD. Additionally, beneficiaries who were institutionalized or who had elected hospice were ineligible for the demonstration. All participants in the CPTD must be enrolled in Medicare Parts A and B throughout their enrollment in the demonstration. At the start of the demonstration, sites had projected their expected enrollment into the screening and treatment arms of the study. Enrollment goals varied across sites. All of the sites expected to enroll more participants into the screening arm of the study than into the treatment arm. Screening enrollment came much closer to meeting site goals, even exceeding it in certain sites.

Randomization Method

Participants within each arm were randomized by a third party to either the intervention (i.e., Patient Navigation) or the control group. Four of the sites randomized at the individual level so that patients were randomly assigned to either group. The remaining sites implemented variations on the randomized design. The fact that each site focused on Medicare beneficiaries from a single racial or ethnic minority group greatly strengthened the experimental design because intervention and control participants shared the same racial or ethnic background and were drawn from the same communities. However, in each site, this limited our ability to examine changes in screening rate disparities between groups. We were able to document changes in screening rates for the target group in each site.

Patient Navigation Interventions

The screening intervention group participants received navigation services to help ensure that they were administered the appropriate screenings for breast, cervical, colorectal, and prostate cancer in accordance with Medicare coverage policy for preventive services (CMS, 2011) and clinical practice guidelines. Guidelines were consistent through the demonstration period from 2006-2011. Sites varied in the specific screening guidelines they adopted, resulting in some variation in participant eligibility. Screening intervention group participants who had positive test results also received navigation services to help them obtain any necessary follow-up diagnostic tests. Sites varied in whether participants were contacted by phone or in person. Phone contact was more common. The intervention group in the treatment arm consisted of participants who had already been diagnosed with cancer. These participants received navigation services to ensure completion of all primary and secondary cancer treatments and all necessary follow-up and monitoring. Control groups in each arm received relevant educational materials. The materials varied across sites, but typically described cancer risk factors, the importance of screening, and the importance of adhering to treatment protocols. CMS reviewed and approved all educational materials in advance.

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

The Screening Arm

In each site, the bulk of the participants were in the screening arm. Meeting enrollment goals proved more time-consuming than sites had anticipated for both study arms but was far more difficult in the treatment arm relative to the screening arm. The screening arm was also always intended to be bigger. In addition to difficulties reaching and enrolling participants in the demonstration, once participants had enrolled, many became ineligible for the demonstration because of their enrollment in managed care. As a percentage of the overall enrollment across all sites, about 15.1 percent voluntarily disenrolled from the demonstration and was in managed care the next month. Because of this, recruitment and enrollment were ongoing site concerns.

All six sites relied primarily on participants telling the PN what their screening results were and whether follow-up care was needed. If participants seemed confused or uncertain about what they should do, PNs would try to help patients understand their results and follow-up plans when they could, but in general, each site had established procedures so that the PNs would help patients contact their health care providers to answer any questions. The primary reason for this procedure was that respondents expressed concerns about the lay PNs providing any type of medical advice or answering questions because they had no clinical training. Even at the one site that maintained a nurse/lay navigator model, a number of physicians had expressed concern about nurse navigators influencing what patients did for their treatment or follow-up care. Once participants were up to date with their screenings, all of the sites were to maintain ongoing contact with them.

Did Demonstration Activities Reduce Disparities for Racial and Ethnic Minorities?

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

The site-provided identifying information was used to create an analytic sample using Medicare claims data. Using procedure codes for each type of cancer screening, for each participant we created variables that reflected screening status before and after demonstration enrollment. Group means for screening rates are presented by site. Screening rates presented in Screening rate results compare the individual's entire period of enrollment in the demonstration, to that same length of time before demonstration enrollment. The average length of time that participants remained enrolled in the demonstration ranged from a low of 16 months to a high of 23 months; on average across all sites, it was 20.4 months. To determine whether any of the changes in screening rates between intervention and control group were statistically significant, we used logistic regression and controlled for pre-enrollment screening rates and demographic differences between intervention and control groups.