COMMENTS REGARDING PROPOSED POLICY TE-4
Submitted by Duke University Health System, Inc.

Contact: Catharine W. Cummer
Regulatory Counsel, Strategic Planning
Duke University Health System, Inc.
catharine.cummer@duke.edu

Duke University Health System, Inc. hereby submits these comments regarding the proposed Policy TE-4 regarding linear accelerators. Radiation oncology services provided on linear accelerators are a complex treatment with serious health implications in their delivery, and further analysis is warranted before any change of this magnitude is implemented.

Standard of Care

The proposal refers to radiation oncology as reflecting the "standard of care" for cancer treatment, analogizing this proposal to existing Policy TE-3 which provides an avenue for hospitals with a 24-hour emergency department to develop an MRI consistent with the standard of care for emergency services.

In evaluating exceptions to the standard need methodology and determinations, it is important to consider the context in which a specific service may be standard of care. All of the regulated services governed by the State Medical Facilities Plan reflect standard of care for various conditions, including open-heart surgery, cardiac catheterization, and even inpatient acute care beds. However, it is not necessarily the standard of care for every provider to offer those services regardless of capacity that otherwise exists.

In the case of Policy TE-3, patients presenting to a hospital with an emergency department may need immediate imaging procedures for diagnosis and treatment planning and/or may need imaging in connection with an inpatient admission; requiring those patients to be transferred to another facility for imaging is not always feasible. Therefore, MRI access is part of the standard of care within a dedicated emergency department. Similarly, the SHCC's recent modification of the acute care bed methodology to allow for development of neonatal beds without a need determination reflected that the standard of care for a hospital providing labor and delivery services includes being able to provide Level II neonatal services immediately. In both instances, the need for the regulated service may arise urgently and without advance warning, and having the resource immediately available onsite may be warranted regardless of capacity elsewhere in the service area.

Here, while radiation oncology may be a standard treatment for appropriate patients, these services are most commonly provided on a scheduled, outpatient basis. Such patients can typically be referred to providers in the area with existing capacity consistent with the standard of care.

Radiation Oncology Health and Safety Considerations

Radiation oncology is also a complex treatment modality with significant implications for patient health and safety. As set forth below, this modality raises specific implications for quality of care and the risks of improper utilization.

Correlation of volume and quality

The proposed Policy would effectively eliminate utilization considerations for new providers. First, the Policy would extend eligibility to any provider who "proposes" to fit one of certain designated program categories. This does not reflect any requirement when such designation would occur, if ever. Moreover, as set forth below, the program categories do not themselves reflect any particular patient volume. The Policy would also expressly eliminate any volume expectations or performance thresholds for applicants for linear accelerators.

The referenced American College of Surgeons Commission on Cancer categories include community and other programs that do not correlate to significant patient volumes, including the following:

- **Community Cancer Program (CCP):** The facility accessions more than 100 but fewer than 500 newly diagnosed cancer cases each year.
- **Free Standing Cancer Center Program (FCCP):** The facility is a nonhospital-based program and offers at least one cancer-related treatment modality. The full range of diagnostic and treatment services is available by referral. Referral to CoC-accredited cancer program(s) is preferred. There is no minimum caseload requirement for this category.
- **Hospital Associate Cancer Program (HACP):** The facility accessions 100 or fewer newly diagnosed cancer cases each year and has a limited range of diagnostic and treatment services available on-site. Other services are available by referral. Clinical research is not required.

These categories include providers whose volumes of eligible patients would not be enough to support a linear accelerator. For reference, the current CON performance thresholds require providers to project serving 250 radiation oncology patients per year, or a commensurate number of procedures. Only a portion of cancer diagnoses lead to radiation oncology treatment, as many patients may undergo surgery, chemotherapy, and/or other interventions or monitoring without radiation oncology.

Radiation oncology facility volumes correlate strongly to patient outcomes. In the November 1, 2021 issue of the journal Cancer, study authors concluded that "By uniformly analyzing multiple disease sites grouped according to appropriate indications for radiation delivery, we show that for most cancer patients, receipt of radiation treatment at high-volume facilities impacts survival, independent of surgery." See Tchelebi, Leila T. et al, "Impact of Radiation Therapy Facility Volume on Survival in Patients with Cancer," Cancer, November 1, 2021, 4081 at 4088 (emphasis added) (see Attachments). That is, patients at high-volume facilities had greater survival rates than patients at lower-volume facilities. Encouraging the proliferation

of centers that may be low-volume – and may lower volumes at other existing providers with sufficient capacity to meet patient need – may lower quality of care. This is in addition to the other effects of unnecessary duplication of services with which the certificate of need law is concerned.

Risks of overutilization

While having facilities with low volumes can affect quality of care, there is also the risk that the development of additional linear accelerators can lead to over-referral of patients who may not need this service.

A comprehensive study reported in 2013 found that urologists who acquired linear accelerators increased their referrals to radiation oncology services substantially more than other providers who did not own their own equipment. See Mitchell, Jean, "Urologists' use of intensity-modulated radiation therapy for prostate cancer," New England Journal of Medicine, 2013 Oct 24;369(17):1629-37 (see Attachments).

This increased use also correlated to increased costs. Medicare: Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny, GAO-13-525, Published: Jul 19, 2013. Publicly Released: Aug 01, 2013 (see Attachment). This report found:

- IMRT utilization among self-referring groups increased by 456 percent, while decreasing among non-self-referrers by five percent.
- IMRT spending by self-referral groups increased by approximately $138 million, compared to a $91 million decrease in the non-self-referral group.

To the extent that the proposed Policy TE-4 would allow providers to develop linear accelerators with the potential for self-referral, especially without any utilization standards to document the unmet patient need for the equipment, it could exacerbate the problem identified in this report.

Safety Risks

In addition to increased costs and quality outcomes, the provision of unnecessary services can have a direct effect on patient health and safety. Unlike diagnostic imaging, which may have relatively few health side effects, radiation oncology is a therapeutic intervention with significant risks to the patient that have to be carefully managed. Even when provided appropriately, side effects can be both short term, including skin problems and low blood count, and longer term, including heart complications. (See, e.g., https://www.cancer.org/cancer/managing-cancer/treatment-types/radiation/effects-on-different-parts-of-body.html). In addition, treatment or equipment errors can lead to devastating damage to patients. (See, e.g., https://www.nytimes.com/2010/01/24/health/24radiation.html). The comprehensive quality and safety oversight needed to provide safe radiation oncology services may not be feasible for a low-volume center.

Alternatives to the Proposed Policy

As the proposal notes, there have been 4 need determinations generated by petitions for adjustments within the past 6 plan years. This reflects that the summer petition process is effective

in addressing local needs, for example where there is not available capacity to which patients can be referred or a provider can demonstrate the need for immediate or emergency access to services. To the extent that there is interest in examining the need methodology, a work group could be formed to allow for more comprehensive input by stakeholders.

Attachments

A Tchelebi, Leila T. et al, "Impact of Radiation Therapy Facility Volume on Survival in Patients with Cancer," Cancer, November 1, 2021, 4081

B Mitchell, Jean, "Urologists' use of intensity-modulated radiation therapy for prostate cancer," New England Journal of Medicine, 2013 Oct 24;369(17):1629-37

C Medicare: Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny, **GAO-13-525,** Published: Jul 19, 2013. Publicly Released: Aug 01, 2013

Original Article

Impact of Radiation Therapy Facility Volume on Survival in Patients With Cancer

Leila T. Tchelebi, MD [1]; Biyi Shen, MS[2]; Ming Wang, PhD [2]; Niraj J. Gusani, MD, MS [2,3]; Vonn Walter, PhD[2,4]; Ross Abrams, MD[5]; Vivek Verma, MD [6]; and Nicholas G. Zaorsky, MD, MS [1,2]

BACKGROUND: This study examined whether radiation therapy facility volumes correlate with survival after curative intent treatment of solid tumors. **METHODS:** The National Cancer Database was queried for patients with solid tumors treated with curative-intent radiation therapy from 2004-2013. Facilities were stratified into 4 volume categories: low, intermediate, high, and very high. Primary cancer sites were divided into neoadjuvant, adjuvant, or definitive radiation subgroups. Kaplan-Meier curves of 5-year postradiation survival probability, stratified by facility volume, were generated with log-rank tests for group comparisons. Cox proportional hazard models were used to evaluate the effect of facility volume on survival, adjusted for multiple covariates. **RESULTS:** There were 253,422 patients treated at 1289 facilities: 6231 received neoadjuvant radiation, 147,980 received adjuvant radiation, and 99,211 received definitive radiation without surgery. Among patients receiving neoadjuvant radiation, survival correlated with facility volume for patients with rectal cancer (hazard ratio [HR], 0.75; 95% CI, 0.6-0.94; $P = .01$). For cancers of the breast and uterus, patients receiving adjuvant radiation at very high-volume facilities (vs low volume) had improved survival (HR, 0.83; 95% CI, 0.77-0.90; $P < .001$ and HR, 0.77, 95% CI, 0.62-0.97; $P = .03$, respectively). For patients receiving definitive radiation for prostate, non–small cell lung, pancreas, and head and neck cancer, there was an improvement in survival for patients treated at very high-volume centers ($P < .05$). **CONCLUSIONS:** For select cancer patients, treatment with curative radiation at higher volume facilities is associated with improved survival. In particular, patients receiving radiation therapy in the definitive setting without surgery may benefit most from treatment at high-volume centers. ***Cancer* 2021;127:4081-4090**. © *2021 American Cancer Society*.

KEYWORDS: facility volume, quality, radiation therapy, solid tumors, survival.

INTRODUCTION

Since the 1980s, there has been a growing body of research investigating the association between facility volume and patient outcomes for a number of procedures and medical conditions.[1] Most of the literature supports the conclusion that patients treated at high-volume facilities have improved outcomes. As a result, practice guidelines recommend that patients with particular diseases receive treatment at high-volume centers. For cancer patients, most of the existing literature focuses only on surgical facility volume.[2-14] However, of the 14 million patients diagnosed with cancer each year, approximately 1 quarter receive radiation therapy as part of the curative intent management of their disease.[15,16] Although existing studies show a survival benefit to receiving radiation therapy at high-volume versus low-volume centers, they only focus on a few disease sites, without accounting for receipt of surgery, and with variable definitions of facility volume.[17-24]

The National Comprehensive Cancer Network (NCCN) recommends that patients with certain malignancies receive surgery at high-volume centers.[25] For example, the NCCN recommends that patients with lung or prostate cancer receive treatment at high-volume surgical centers, and it strongly recommends that patients with esophageal cancer do the same. The guidelines do not make similar recommendations for radiation therapy, despite radiation therapy being a standard part of the curative treatment paradigm for patients with these and other malignancies. Like surgery, radiation therapy can be complex and nuanced. Radiotherapy variables of concern include target-volume delineation, dose coverage, organ-at-risk sparing, and dosimetric parameters used to evaluate treatment plan quality.

The purpose of the current work is to uniformly evaluate the impact of radiation therapy facility volume on survival in patients with cancer. Our goal was to confirm and expand upon the findings of previous works showing that radiation therapy facility volume impacts survival across a variety of disease sites, while also controlling for receipt of surgery,

Corresponding Author: Nicholas Zaorsky, MD MS, Department of Radiation Oncology, Penn State Cancer Institute, 500 University Drive, Hershey, PA 17033 (nicholaszaorsky@gmail.com; nzaorsky@pennstatehealth.psu.edu).

[1]Department of Radiation Oncology, Penn State Cancer Institute, Hershey, Pennsylvania; [2]Department of Public Health Sciences, Penn State College of Medicine, Hershey, Pennsylvania; [3]Department of Surgery, Penn State College of Medicine, Hershey, Pennsylvania; [4]Department of Biochemistry and Molecular Biology, Penn State College of Medicine, Hershey, Pennsylvania; [5]Department of Radiation Oncology, Sharett Cancer Institute, Hadassah Medical Center, Ein Kerem Jerusalem, Israel; [6]Department of Radiation Oncology, University of Texas M.D. Anderson Cancer Center, Houston, Texas

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which is known to be intimately linked to survival outcomes. Multiple cancer sites treated with radiation in 3 specific settings with respect to surgery (neoadjuvant, adjuvant, or definitive without surgery) were considered in this analysis. We hypothesized that patients receiving radiation therapy at very high-volume facilities would have improved survival versus those treated at low-volume facilities.

MATERIALS AND METHODS

Data Extraction and Synthesis

The National Cancer Database (NCDB) is a hospital-based cancer registry that collects data from American College of Surgeons-Commission on Cancer–accredited facilities. The database is sponsored by the American College of Surgeons and the American Cancer Society; it is recognized as the largest cancer registry worldwide. It includes 70% of all malignant cancers diagnosed in the United States.[26] The NCDB records patient demographics, comorbidities, tumor characteristics, and overall survival, as well as information regarding therapies delivered during the first course of treatment, including surgery, radiation therapy, immunotherapy, and chemotherapy.[27] Approximately 34 million cancer cases are included in the NCDB.

Patients

The NCDB was queried for patients with solid tumors commonly treated with radiation therapy for curative intent from 2004-2013. Patients with cancer of the breast, non–small cell lung, small cell lung, prostate, uterus, rectum, brain, esophagus, cervix, soft tissue sarcoma, head and neck (which includes larynx, tongue, tonsil, salivary gland, floor of mouth, hypopharynx, lip, oropharynx, and nasopharynx), and anus were included. Additionally, patients must have received radiation, either external beam or brachytherapy, and had valid survival information available during the study period. All treatment, including radiation, surgery, and systemic therapy, had to be delivered at the same facility. It should be noted that this inclusion criterion (ie, that all treatment rendered at the reporting facility) substantially reduced the number of patients included in this analysis. Patients were excluded if they had metastatic disease or only received palliative radiation (ie, 30 Gy in 10 fractions, 20 Gy in 5 fractions, or 8 Gy in 1 fraction). We excluded patients with solid malignancies for which radiation is not routinely administered as part of the definitive treatment of the disease or for which there were too few patients in the database to allow for meaningful statistical analysis (such as patients with cancers of the kidney, stomach, ovary, colon, hepatobiliary system, and melanoma).

Primary cancer sites were grouped and analyzed according to the setting in which radiation was delivered: neoadjuvant, adjuvant, and definitive. Primary sites were only included within a certain subgroup if radiation in that setting was considered a standard part of the treatment course during the study period. For example, although some patients with rectal cancer may receive radiation in the adjuvant or definitive setting, radiation is most commonly delivered in the neoadjuvant setting for this disease site. Thus it was included only within the neoadjuvant group. For certain cancers, radiation may be recommended in more than 1 setting. For example, radiation for head and neck cancer is commonly delivered both in the definitive setting and as adjuvant therapy for patients with high- risk features. Thus, head and neck cancer was analyzed both in the definitive and the adjuvant groups. Neoadjuvant radiation sites included the rectum, soft tissue sarcoma, and the esophagus. Adjuvant sites included the breast, uterus, brain, head and neck, soft tissue sarcoma, pancreas, and prostate. Definitive sites included non–small cell lung, small cell lung, head and neck, prostate, cervix, esophagus, pancreas, brain, and anus. The inclusion and exclusion criteria are shown in the flow diagram in Figure 1 for patients overall and in Supplementary Figures 1-3 for each radiation setting (neoadjuvant, adjuvant, definitive).

Statistical Analysis

The NCDB reports the facility where the patient received care using a unique facility code. This facility code, available for all patients included in our analyses, was used to determine facility volume. For patients overall and also for each cancer site, facilities were stratified into quartiles of patients categorized as low-, intermediate-, high-, and very high-volume facilities. This was accomplished by first ordering all treatment facilities from those treating the smallest number of patients with a particular cancer to those treating the largest number. The quartile cut points among these ordered facilities were then identified. Each quartile contained 25% of patients of a particular cancer type starting from the lowest volume to the highest (Supplementary Fig. 4). The number of unique facilities in each quartile ranges from 98 to 294. Only facilities that were open and treating patients during the entire study period were included in the analysis. Methodology was similar to prior work analyzing surgical facility volume and outcomes.[32]

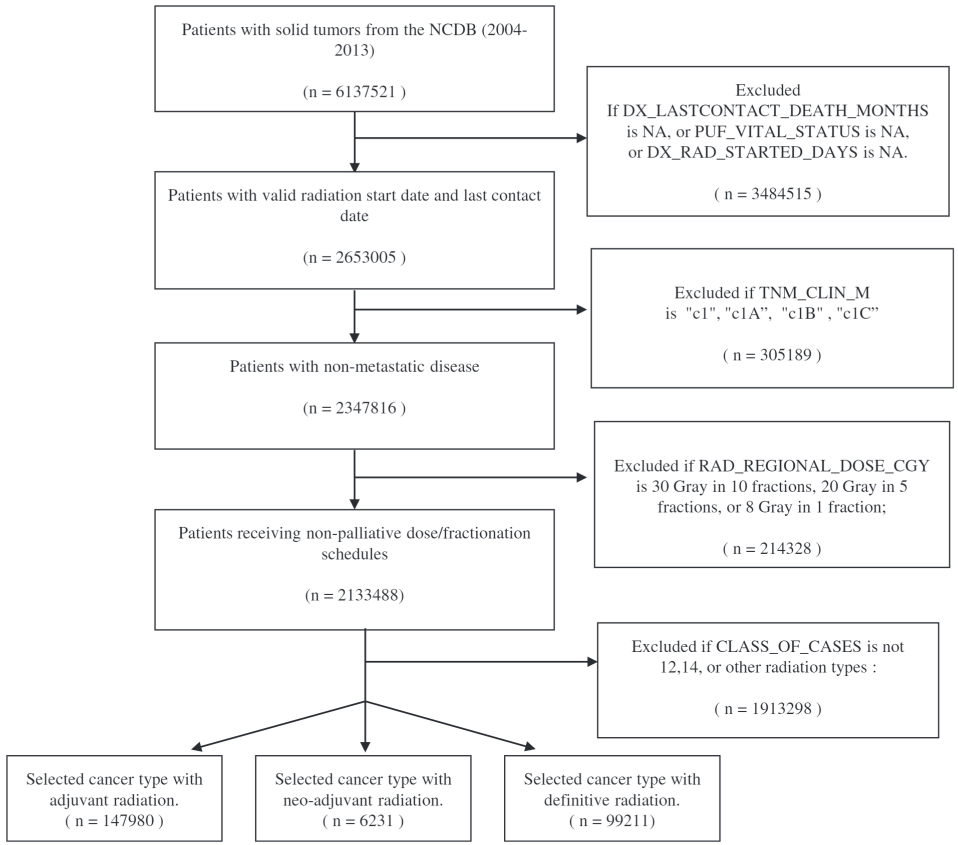

Figure 1. Flow diagram depicting exclusion criteria. Patients with select cancers treated by radiation therapy were extracted from the National Cancer Database (NCDB). Patients were then excluded if they: 1) had incomplete radiation or survival status data, 2) had metastatic disease, 3) sequence of radiation with respect to surgery was unknown, 4) were treated with palliative radiation regimens, and 5) did not receive all treatments (surgery, radiation, chemotherapy) at the same facility. DX, Diagnosis; NA, not applicable; PUF, participant user file; TNM, tumor, nodes, and metastases.

The primary outcome was survival, where the time-to-event outcome was defined as days before the first radiation treatment until death or 60 months, whichever was earlier. We defined survival as time since start of radiation, rather than time since diagnosis, to eliminate immortal time bias. We wanted to specifically assess survival outcomes following receipt of radiation therapy, not accounting for other therapies rendered. Kaplan-Meier curves stratified by volume were plotted for postradiation-survival probability by cancer type, with log-rank tests for stratified group comparison of survival curves (Figure 2).

A Cox proportional hazards regression analysis was conducted to determine if radiation therapy facility volume influenced 5-year postradiation survival. We performed a multivariable analysis by cancer site, adjusting for a number of covariates. Frequencies and percentages (%) are presented for categorical variables. The covariates included: 4 age-group levels based on quartiles, sex (male, female), race (White, Black, other), insurance status (none, private, Medicaid, Medicare, other), clinical disease stage (0, 1, 2, 3, unknown), geographical area (metro, urban, rural), annual household income (<$38,000,

$38,000-$47,999, $48,000-$62,999, ≥$63,000), Charlson-Deyo comorbidity score levels (0, 1, 2, 3), facility type (community cancer program, comprehensive community cancer program, academic/research program, integrated network cancer program), surgery performed (no, yes, unknown), chemotherapy treatment (no, yes, unknown), immunotherapy treatment (no, yes, unknown), and distance traveled to facility. The reference group for all analyses was patients treated at low-volume facilities. Hazard ratio (HR) estimates with 95% CIs were obtained, and *P* values were calculated based on Wald tests. All hypothesis tests were 2-sided with the statistical significance level of .05, and all statistical analyses were performed in R, version 3.5.1.

RESULTS

A total of 253,422 patients met our inclusion criteria and were included in this analysis. There were 6231 patients who received neoadjuvant radiation, 147,980 received adjuvant radiation, and 99,211 received definitive radiation without surgery. The average age among patients receiving neoadjuvant radiation was 60 years; for adjuvant radiation, it was 61 years; and for definitive radiation it was 67 years. Patients were treated at 1289 facilities: 851 for neoadjuvant radiation, 1265 for adjuvant, and 1230 for definitive. Among patients receiving neoadjuvant therapy, 4549 had rectal cancer, 745 had soft tissue sarcoma, and 937 had esophageal cancer. Among patients receiving adjuvant radiation, 115,597 had breast cancer, 8574 had uterine cancer, 7801 had brain cancer, 6922 had head and neck cancer, 3753 had prostate cancer, 1933 had soft tissue sarcoma, and 1579 had pancreas cancer. Among those receiving definitive radiation, 38,296 had prostate cancer, 28,180 had non–small cell lung cancer, 16,375 had head and neck cancer, 4325 had small cell lung cancer, 2788 had cervical cancer, 2709 had esophagus cancer, 2236 had anus cancer, 2062 had brain cancer, and 2075 had pancreas cancer. Additional patient characteristics are summarized in Table 1. The majority of patients were treated with ≥50 Gy (64%), followed by 30 to 50 Gy (32%). Fewer than 5% of patients received a dose of radiation ≤30 Gy (these patients were not excluded given that 25 Gy is an acceptable neoadjuvant regimen for rectal cancer).

Table 2 shows the HRs for survival in patients following receipt of radiation therapy in the neoadjuvant (Table 2, Panel A) adjuvant (Table 2, Panel B), and definitive (Table 2, Panel C) setting. Corresponding Kaplan-Meier plots showing the survival probability for patients receiving neoadjuvant (Fig. 2A), adjuvant (Fig. 2B), and

TABLE 1. Demographic and Clinical Characteristics of Patients

Characteristic	Neoadjuvant	Adjuvant	Definitive
Age, y			
<55	1975 (31.7)	44,625 (30.2)	12,731 (12.8)
55-64	1976 (31.7)	45,331 (30.6)	26,650 (26.9)
65-73	1345 (21.6)	35,503 (24.0)	32,385 (32.6)
≥74	935 (15.0)	22,521 (15.2)	27,445 (27.7)
Sex			
Male	4005 (64.3)	16,605 (11.2)	72,766 (73.3)
Female	2226 (35.7)	131,375 (88.8)	26,445 (26.7)
Race			
White	5215 (84.0)	121,989 (83.0)	80,413 (81.7)
Black	712 (11.5)	19,275 (13.1)	15,545 (15.7)
Other	282 (4.5)	5708 (3.9)	2492 (2.5)
Insurance status			
Not insured	490 (8.0)	4474 (3.1)	3893 (4.0)
Private insurance	2860 (46.6)	76,999 (52.7)	30,002 (30.7)
Medicaid	539 (8.8)	10157 (7.0)	7145 (7.3)
Medicare	2189 (35.7)	53,144 (36.4)	55,543 (56.9)
Other government	60 (1.0)	1238 (0.8)	1023 (1.1)
Stage			
0	8 (0.1)	23,234 (18.4)	371 (0.4)
1	570 (9.9)	60,624 (48.1)	27,355 (28.9)
2	2239 (39.1)	29,253 (23.2)	34,094 (36.0)
3	2908 (50.8)	9960 (7.9)	24,256 (25.6)
4	4 (0.1)	2907 (2.3)	8642 (9.1)
Unknown	0 (0.0)	0 (0.0)	0 (0.0)
Urban/rural			
Metro counties	5196 (85.4)	127,106 (88.0)	80,753 (83.3)
Urban counties	776 (12.8)	15,432 (10.7)	14,244 (14.7)
Rural counties	114 (1.9)	1900 (1.3)	1902 (2.0)
Income			
<$38,000	1170 (18.8)	22,943 (15.5)	20,439 (20.7)
$38,000-$47,999	1460 (23.5)	31,586 (21.4)	24,498 (24.8)
$48,000-$62,999	1676 (26.9)	39,593 (26.8)	26,336 (26.7)
≥$63,000	1913 (30.8)	53,499 (36.2)	27,450 (27.8)
Charlson-Deyo comorbidity score			
0	4816 (77.3)	120,605 (81.5)	71,204 (71.8)
1	1138 (18.3)	22,194 (15.0)	19,792 (19.9)
2	185 (3.0)	4060 (2.7)	5822 (5.9)
3	92 (1.5)	1121 (0.8)	2393 (2.4)
Facility type			
Community cancer program	392 (6.6)	11,695 (8.2)	8331 (8.5)
Comprehensive community cancer program	2467 (41.7)	66,395 (46.6)	45,314 (46.2)
Academic/research program	2461 (41.6)	51,313 (36.1)	33,629 (34.3)
Integrated network cancer program	591 (10.0)	12,910 (9.1)	10,873 (11.1)
Surgery			
No	5 (0.1)	272 (0.2)	99,211 (100.0)
Yes	6226 (99.9)	147,708 (99.8)	0 (0.0)
Unknown	0 (0.0)	0 (0.0)	0 (0.0)
Chemotherapy			
No	634 (16.8)	89,942 (61.6)	59,092 (60.3)
Yes	5579 (83.2)	56,071 (38.4)	38,907 (39.7)
Unknown	0 (0.0)	0 (0.0)	0 (0.0)
Immunotherapy (including IL-2 and BCG)			
No	6200 (99.7)	144,820 (98.0)	98,346 (99.5)
Yes	19 (0.3)	2926 (2.0)	447 (0.5)
Unknown	0 (0.0)	0 (0.0)	0 (0.0)

The numbers outside parenthesis are the number of patients and the numbers inside parenthesis are the % of patients.
Neoadjuvant, adjuvant, and definitive groups are based on NCDB coding. In rare cases (<0.5%), patients in neoadjuvant or adjuvant groups did not receive surgery.

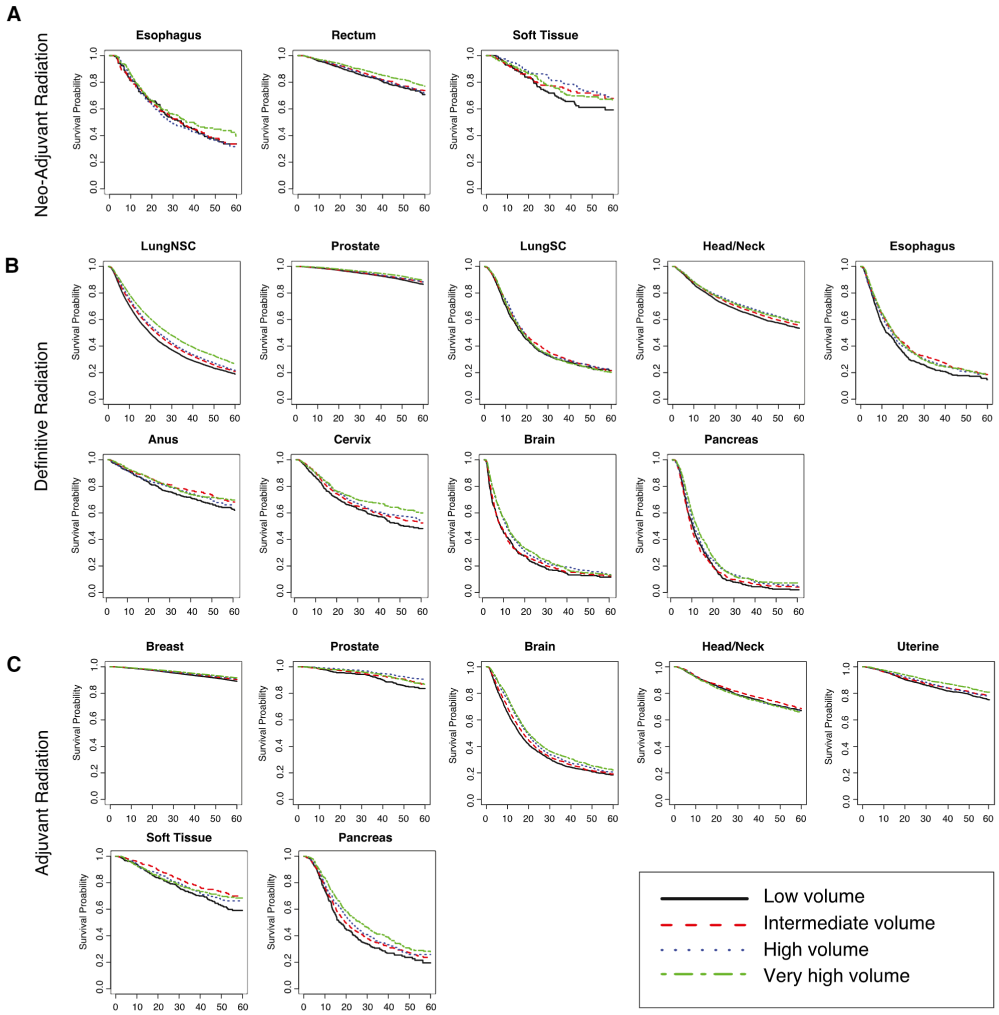

Figure 2. Kaplan-Meier survival curves for 5-year postradiation therapy survival probability. The x-axis shows the survival time in months up to 5 years. The y-axis shows the probability of survival from 0.2 to 1.0. A survival curve is provided for each of the cancer sites included in the analysis grouped by radiation sequence with respect to surgery: neoadjuvant (A), adjuvant (B), and definitive (C). Facility volume is designated using the following colors: black = low, red = intermediate, blue = high, and green = very high. LungSC, small cell lung cancer; LungNSC, non-small cell lung cancer; Soft tissue, soft tissue sarcoma.

definitive (Fig. 2C) radiation for each disease site are shown in Figure 2. For patients receiving radiation in the neoadjuvant setting, there was no difference in survival among patients overall according to facility volume (HR, 0.90; 95% CI, 0.77-1.05; $P = .18$). For patients with rectal cancer receiving neoadjuvant radiation, treatment at very high-volume facilities (vs low volume) had improved survival (HR, 0.75; 95% CI, 0.6-0.94; $P = .01$). However, for patients with soft tissue sarcoma or esophageal cancer receiving neoadjuvant radiation, facility

TABLE 2. Hazard Ratios With 95% CIs From Multiple Cox Regressions, Grouped by Radiation Setting, Cancer Site, and Facility Volume

Cancer Site	Facility Volume Classification	No. of Patients	No. of Facilities	Max Facility Size in Group	Patients Treated/y/ Facility	Hazard Ratio (95% CI)	*P*
Panel A: Neo-Adjuvant Radiation Therapy: Patients Receiving Radiation Before Surgery							
Pooled sites	Low	1751	597	7	≤0.7	1.00	—
	Intermediate	1397	134	14	>0.7 and ≤1.4	0.84 (0.72-0.98)	.03
	High	1387	79	25	>1.4 and ≤2.5	0.95 (0.82-1.11)	.51
	Very high	1696	41	98	>2.5	0.90 (0.77-1.05)	.18
Rectum	Low	1019	540	5	<0.5	1.00	—
	Intermediate	1187	157	10	≥0.5 and <1	0.86 (0.7-1.05)	.14
	High	1195	84	18	≥1 and <1.8	0.94 (0.76-1.16)	.58
	Very high	1148	37	44	≥1.8	0.75 (0.6-0.94)	.01
Soft tissue sarcoma	Low	159	137	3	≤0.3	1.00	—
	Intermediate	176	32	8	>0.3 and ≤0.8	0.84 (0.51-1.39)	.50
	High	200	15	14	>0.8 and ≤1.4	0.77 (0.45-1.33)	.35
	Very high	210	8	38	>1.4	1.04 (0.62-1.75)	.87
Esophagus	Low	158	226	2	<0.2	1.00	—
	Intermediate	244	64	4	≥0.2 and <0.4	0.98 (0.73-1.32)	.89
	High	260	40	7	≥0.4 and <0.7	1.14 (0.85-1.53)	.37
	Very high	275	16	30	>=0.7	0.85 (0.63-1.15)	.29
Panel B: Adjuvant Radiation Therapy: Patients Receiving Radiation After Surgery							
Pooled sites	Low	37,180	887	130	≤13.0	1.00	—
	Intermediate	37,248	206	246	≥13.0 and <24.6	0.88 (0.83-0.93)	<.001
	High	35,759	115	410	≥24.6 and <41.0	0.80 (0.75-0.85)	<.001
	Very high	37,793	59	1304	≥41.0	0.80 (0.75-0.85)	<.001
Breast	Low	28,769	866	102	<10.2	1.00	—
	Intermediate	28,789	203	195	≥10.2 and <19.5	0.88 (0.82-0.94)	<.001
	High	29,045	117	332	≥9.5 and <33.2	0.88 (0.82-0.95)	<.001
	Very high	28,994	58	1059	≥33.2	0.83 (0.77-0.9)	<.001
Uterine	Low	2097	600	12	<1.2	1.00	—
	Intermediate	2184	118	26	≥1.2 and <2.6	0.9 (0.73-1.1)	.3
	High	2117	62	42	≥2.6 and <4.2	0.91 (0.74-1.14)	.42
	Very high	2176	33	136	≥4.2	0.77 (0.62-0.97)	.03
Brain	Low	1786	521	10	<1	1.00	—
	Intermediate	2108	120	25	≥1 and <2.5	0.97 (0.89-1.05)	.43
	High	1866	53	50	≥2.5 and <5	0.91 (0.83-1.00)	.04
	Very high	2041	24	169	>=5	0.96 (0.87-1.06)	.47
Head/neck	Low	2133	600	12	≤1.2	1.00	—
	Intermediate	2202	118	26	>1.2 and ≤2.6	0.86 (0.75-0.98)	.03
	High	2187	62	42	>2.6 and ≤4.2	0.92 (0.79-1.06)	.25
	Very high	2221	33	136	>4.2	0.88 (0.76-1.02)	.11
Prostate	Low	787	505	4	<0.4	1.00	—
	Intermediate	1032	157	9	≥0.4 and <0.9	0.83 (0.59-1.16)	.28
	High	986	70	15	≥0.9 and <1.5	0.67 (0.46-0.98)	.04
	Very high	948	34	108	≥1.5	0.88 (0.63-1.25)	.49
Soft tissue sarcoma	Low	469	432	3	≤0.3	1.00	—
	Intermediate	442	106	6	>0.3 and ≤0.6	0.71 (0.51-0.99)	.04
	High	517	58	11	>0.6 and ≤1.1	0.96 (0.68-1.34)	.80
	Very high	505	26	37	>1.1	0.73 (0.51-1.04)	.08
Pancreas	Low	262	245	3	≤0.3	1.00	—
	Intermediate	525	88	8	>0.3 and ≤0.8	0.90 (0.72-1.13)	.36
	High	384	26	15	>0.8 and ≤1.5	0.89 (0.69-1.14)	.35
	Very high	408	17	55	>1.5	1.00 (0.77-1.31)	.98
Panel C: Definitive Radiation Therapy: Patients Receiving Radiation Only Without Surgery							
Pooled sites	Low	25,034	844	85	≤8.5	1.00	—
	Intermediate	24,856	206	171	>8.5 and ≤17.1	0.95 (0.92-0.98)	<.001
	High	24,252	117	268	>17.1 and ≤26.8	0.94 (0.91-0.97)	<.001
	Very high	25,069	68	659	>26.8	0.87 (0.84-0.90)	<.001
Prostate	Low	9333	735	39	<3.9	1.00	—
	Intermediate	9609	178	72	≥3.9 and <7.2	0.97 (0.87-1.07)	.51
	High	9724	101	130	≥7.2 and <13	0.91 (0.82-1.01)	.08
	Very high	9630	48	428	≥13	0.82 (0.74-0.91)	<.001
Non-small cell lung	Low	6813	753	27	<2.7	1.00	—
	Intermediate	7002	181	55	≥2.7 and <5.5	0.98 (0.93-1.02)	.31
	High	7240	105	85	≥5.5 and <8.5	0.95 (0.9-0.99)	.02
	Very high	7125	58	239	≥8.5	0.89 (0.84-0.93)	<.001

(*Continued*)

TABLE 2. *Continued*

Cancer Site	Facility Volume Classification	No. of Patients	No. of Facilities	Max Facility Size in Group	Patients Treated/y/ Facility	Hazard Ratio (95% CI)	*P*
Head/neck	Low	3720	688	15	≤1.5	1.00	—
	Intermediate	4447	188	30	>1.5 and ≤3	0.86 (0.82-0.96)	<.001
	High	4169	106	56	>3 and ≤5.6	0.83 (0.76-0.90)	<.001
	Very high	4204	50	148	>5.6	0.82 (0.75-0.90)	<.001
Small cell lung	Low	967	562	5	<0.5	1.00	—
	Intermediate	1181	134	9	≥0.5 and <0.9	0.96 (0.86-1.07)	.47
	High	978	83	14	≥0.9 and <1.4	0.98 (0.87-1.1)	.73
	Very high	1199	53	50	≥1.4	1.01 (0.9-1.13)	.93
Cervix	Low	544	378	4	<0.4	1.00	-
	Intermediate	800	126	9	≥0.4 and <0.9	0.95 (0.79-1.15)	.62
	High	740	55	15	≥0.9 and <1.5	0.92 (0.74-1.14)	.43
	Very high	704	23	67	≥1.5	0.85 (0.68-1.07)	.17
Esophagus	Low	520	480	3	<0.3	1.00	—
	Intermediate	663	120	5	≥0.3 and <0.5	0.89 (0.77-1.04)	.14
	High	826	99	10	≥0.5 and <1	0.94 (0.81-1.09)	.39
	Very high	700	45	28	≥1	0.88 (0.75-1.03)	.12
Anus	Low	487	447	3	<0.3	1.00	—
	Intermediate	463	100	5	≥0.3 and <0.5	0.83 (0.64-1.08)	.17
	High	626	74	8	≥0.5 and <0.8	1.07 (0.83-1.37)	.6
	Very high	660	48	20	≥0.8	0.98 (0.76-1.27)	.91
Brain	Low	422	365	3	≤0.3	1.00	—
	Intermediate	550	95	7	>0.3 and ≤0.7	0.93 (0.80-1.09)	.39
	High	524	52	12	>0.7 and ≤1.2	0.96 (0.80-1.14)	.6
	Very high	566	27	41	>1.2	0.98 (0.82-1.17)	.82
Pancreas	Low	430	379	3	≤0.3	1.00	—
	Intermediate	503	93	7	>0.3 and ≤0.7	1.05 (0.90-1.22)	.56
	High	576	49	14	>0.7 and ≤1.4	0.87 (0.75-1.02)	.09
	Very high	566	21	62	>1.4	0.84 (0.71-0.98)	.0

Disease sites are ordered by decreasing number of patients. Max Facility Size in Group refers to the maximum number of patients treated at a largest volume facility within the size subgroup. For example, for patients with prostate cancer treated in the definitive setting, the maximum number of patients treated at a facility within the low-volume subgroup over the 10-year study period was 39 patients. Patients treated per year, per facility, divides the "Max Facility Size in Group" by the study period (ie, 10) to give the average number of patients treated per year at that facility. For example, for patients with prostate cancer treated in the definitive setting, the largest treatment facility within the low-volume subgroup treated fewer than 4 patients per year.

volume had no impact on survival. For patients receiving adjuvant radiation, very high-volume facilities had significantly improved survival compared with low-volume facilities (HR, 0.80; 95% CI, 0.75-0.85; $P < .001$), and there was an incremental improvement in relative risk of death as the facility volume increased (ie, risk of death was highest for patients at low-volume facilities, followed by intermediate-volume, then high-volume, and very high-volume facilities, respectively). For cancers of the breast and uterus, patients receiving adjuvant radiation at very high-volume facilities had improved survival compared with treatment at low-volume facilities (HR, 0.83; 95% CI, 0.77-0.90; $P < .01$ and HR, 0.77; 95% CI, 0.62-0.97; $P = .03$, respectively). The magnitude of benefit was small for patients with breast cancer relative to patients with uterine cancer as shown in Figure 2B. For all patients receiving definitive radiation, there was an improvement in survival among patients receiving radiation at very high-volume facilities versus low-volume facilities (HR, 0.87; 95% CI, 0.84-0.90; $P < .001$), and there was an incremental improvement in relative risk of death as the facility volume increased. For patients receiving definitive treatment for prostate cancer, non–small cell lung cancer, head and neck cancer, and pancreas cancer there was an improvement in survival by receiving radiation at very high-volume versus low-volume facilities. The magnitude of benefit was greatest for patients with non–small cell lung and head and neck cancers (Fig. 2C). For the remaining cancers included in the definitive group (small cell lung, cervix, esophagus, anus, and brain) survival was not impacted by facility-volume size.

DISCUSSION

This is the first study to examine the impact of radiation therapy facility volume on survival among multiple cancer sites while adjusting for multiple covariates, with a consistent definition for radiation therapy facility volume, treatment inclusion and exclusion criteria, and survival outcomes. We found that facility volume had a statistically significant impact on the survival of patients receiving radiation for the most common cancers, specifically cancers of the breast, prostate, head and neck, rectum,

and non–small cell lung, in addition to pancreas cancer. For patients receiving radiation in either the adjuvant or the definitive setting, there is a decreased risk of death at 5-years postradiation among patients treated at very high-volume facilities versus low-volume facilities (HR, 0.80; 95% CI, 0.75-0.85; $P < .001$ for adjuvant and HR, 0.87; 95% CI, 0.84-0.90; $P < .001$ for definitive).These benefits were driven by patients with breast cancer in the case of adjuvant radiation, and prostate cancer and non–small cell lung cancer in the case of definitive radiation, which made up the plurality of patients included. Importantly for these patients, there was an incremental benefit in survival with increasing facility volume.

The magniture of benefit in overall survival was disease-site specific. The magnitude of benefit was small for breast and prostate cancer patients, as shown in the Kaplan-Meier curves, given the high-survival probability of patients with these malignancies. In contrast, the magnitude of benefit was substantial for patients with non–small cell lung cancer, who are at much higher risk of dying of their cancer at 5 years. For patients receiving neoadjuvant radiation, there was a survival advantage among rectal cancer patients treated at very high-volume versus low-volume facilities (HR, 0.75; 95% CI, 0.60-0.94; $P = .01$). There was a concomitant separation in the survival curves for these patients who are at risk of dying of their cancer at 5 years.

Radiation therapy facility volume is likely to be collinear with surgical volume and surgical volume has been shown to be associated with survival outcomes.[2,10,11,12,15] We thus not only controlled for surgery as a covariate in our analysis, but we grouped patients according to the setting in which they received radiation with respect to surgery. For most cancer patients receiving definitive radiation without surgery, survival was impacted by facility volume; there was an incremental improvement in survival probability with increasing facility volume.

The results of previous database studies consistently show an improvement in survival for patients receiving treatment at high-volume versus low-volume facilities.[17,18,20] However, they do not distinguish between the setting in which radiation was delivered, nor account for receipt of surgery, making it difficult to draw conclusions specifically regarding the effect of radiation therapy facility volume on survival. Moreover, previous studies use variable definitions of radiation therapy facility size and have only focused on a few disease sites. There are a limited number of studies that specifically analyze the impact of radiation facility volume on cancers being treated definitively with radiation without surgery. Two are NCDB analyses of patients with anal cancer. One grouped patients by facility volume according to tertiles,[24] and the other studied it as a continuous variable.[21] Both showed improved survival among patients treated at higher volume centers, in contrast to our study which did not show improved survival by facility volume for this disease site, indicating that the way in which facility size is defined can impact the study outcomes. Thus, a uniform definition is needed to draw meaningful conclusions regarding facility volume and impact on survival. Another trial analyzed patients treated definitively with chemotherapy and radiation for non–small cell lung cancer and found that treatment at a high-volume center was associated with improved survival (HR, 0.91; 95% CI, 0.84-0.99; $P = .04$).[28] The authors defined high-volume facilities as those in the 90th percentile of annual volume or centers treating more than 12 cases per year, whereas our definition of very high-volume facilities was facilities treating more than 8 patients per year. Another study that analyzed patients treated definitively for nasopharyngeal cancer found a 7% improvement in 5-year overall survival for patients treated at high-volume centers.[23] In this study, high volume was defined as the 80th percentile of patients because the top 20% of facilities treat nearly half of patients.

By uniformly analyzing multiple disease sites grouped according to appropriate indications for radiation delivery, we show that for most cancer patients, receipt of radiation treatment at high-volume facilities impacts survival, independent of surgery. The magnitude of benefit is cancer-specific, given the variable baseline survival probabilities among different solid malignancies. Although referral to high-volume centers for receipt of surgery is feasible, the same cannot be said of radiation therapy, which often requires several weeks of daily therapy in most cases, thus posing a challenge for patients living far from high-volume treatment facilities. This work thus serves to inform health policy by indicating that quality metrics should be implemented to equalize the quality of care across cancer facilities, such that centers treating a lower volume of patients are able to provide the same quality of care as larger centers treating a higher volume of patients. Further study into equalizing measures, such as centralized quality-assurance checks or integration of low-volume facilities into larger health networks with mandated peer review, is needed. This is of particular importance because the majority of patients receive their cancer care at community centers that treat a lower volume of patients.

There are several reasons why treatment at high-volume radiation therapy facilities may be associated with

improved survival outcomes. First, radiation oncologists treating a higher volume of patients with a particular disease may have more experience in terms of radiation therapy treatment planning and managing expected toxicities. It has been shown that adhering to radiation therapy protocol guidelines impacts patient outcomes,[29,30] and clinicians treating a larger number of patients may be more likely to comply with guidelines. Second, facility volume may be a surrogate for services provided by the entire facility, such as supportive care services or clincial trial accrual.[31,32] For instance, higher volume centers may be better equipped to manage side effects from treatment, resulting in improved patient outcomes, and better oncological services, in general, would result in more favorable outcomes for patients. Third, follow-up at higher volume centers with more resources may be more robust, so that recurrences and treatment failures are detected early, allowing for salvage therapies to be delivered. Fourth, patients treated at high-volume centers are more likely to be seen by a multidisciplinary group of providers: Multidisciplinary care has been shown to improve survival of cancer patients.[33-35]

This study has several limitations. As with all large cancer registries, the potential for misclassification caused by coding errors is one such limitation. In addition, incomplete patient information was another limitation we encountered that resulted in our having to exclude many patients from our analysis. Also, the NCDB does not collect certain demographic and treatment variables, including performance status, chemotherapy regimens used, or salvage therapies administered, which may bias survival outcomes. In addition, facility volume can vary by year, affecting facility designation. We attempted to control for this by only including centers treating patients throughout the entire study period, and we took an average of annual facility volume to determine facility designation. We considered performing sensitivity analyses using other methods of stratifying facility volume including as a continuous variable. However, we elected to use quartiles because this method most easily allows facilities to identify as being low, intermediate, high, or very high volume. Furthermore, it is most in line with the methods used in previous publications, allowing for a more robust comparison.

Another limitation was our inability to account for selection bias. Patients treated at high-volume centers may inherently be healthier or lower risk than those treated at lower volume centers. Patients with a higher income and education level, who are more likely to be healthy and lower risk, have access to more resources allowing them to travel long distances to preferentially seek care at higher volume centers. Conversely, patients with more-complicated clinical scenarios may be preferentially referred to high-volume centers given their increased expertise in managing such patients. There is also the concern of surgical bias. High-volume radiation centers are also likely to be high-volume surgical centers where surgical expertise impacted patient outcomes, which may have confounded our results among patients in the neoadjuvant and adjuvant subgroups. We attempted to control for this by including surgery as a covariate in our model. Moreover, we found that facility volume impacted survival for the largest number of patients in the definitive group (ie, those not receiving surgery). Finally, different malignancies and stages within a particular cancer are treated differently, thus combining multiple disease stages and sites together may cause specific intricacies of each cancer type to become lost in this type of analysis.

In conclusion, for patients with the most common solid malignancies, treatment at high-volume radiation therapy facilities results in improved survival for cancer patients, and the magnitude of benefit varies by cancer site. The reasons for which radiation therapy is associated with improved survival at higher volume centers requires further study so that metrics to ensure equal radiation therapy quality across all treatment centers can be implemented.

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AUTHOR CONTRIBUTIONS

Leila T. Tchelebi: Conceptualization, investigation, project administration, visualization, writing–original draft, writing–review and editing. **Biyi Shen:** Data curation, formal analysis, investigation, visualization, and writing–review and editing. **Ming Wang:** Data curation, formal analysis, investigation, methodology, visualization, and writing–review and editing. **Niraj J. Gusani:** Conceptualization and writing–review and editing. **Vonn Walter:** Data curation, formal analysis, methodology, and writing–review and editing. **Ross Abrams:** Writing–review and editing. **Vivek Verma:** Writing–review and editing. **Nicholas G. Zaorsky:** Conceptualization, data curation, investigation, methodology, project administration, resources, supervision, visualization, and writing–review and editing.

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SPECIAL ARTICLE

Urologists' Use of Intensity-Modulated Radiation Therapy for Prostate Cancer

Jean M. Mitchell, Ph.D.

ABSTRACT

BACKGROUND

Some urology groups have integrated intensity-modulated radiation therapy (IMRT), a radiation treatment with a high reimbursement rate, into their practice. This is permitted by the exception for in-office ancillary services in the federal prohibition against self-referral. I examined the association between ownership of IMRT services and use of IMRT to treat prostate cancer.

METHODS

Using Medicare claims from 2005 through 2010, I constructed two samples: one comprising 35 self-referring urology groups in private practice and a matched control group comprising 35 non–self-referring urology groups in private practice, and the other comprising non–self-referring urologists employed at 11 National Comprehensive Cancer Network centers matched with 11 self-referring urology groups in private practice. I compared the use of IMRT in the periods before and during ownership and used a difference-in-differences analysis to evaluate changes in IMRT use according to self-referral status.

RESULTS

The rate of IMRT use by self-referring urologists in private practice increased from 13.1 to 32.3%, an increase of 19.2 percentage points ($P<0.001$). Among non–self-referring urologists, the rate of IMRT use increased from 14.3 to 15.6%, an increase of 1.3 percentage points ($P=0.05$). The unadjusted difference-in-differences effect was 17.9 percentage points ($P<0.001$). The regression-adjusted increase in IMRT use associated with self-referral was 16.4 percentage points ($P<0.001$). The rate of IMRT use by urologists working at National Comprehensive Cancer Network centers remained stable at 8.0% but increased by 33.0 percentage points among the 11 matched self-referring urology groups. The regression-adjusted difference-in-differences effect was 29.3 percentage points ($P<0.001$).

CONCLUSIONS

Urologists who acquired ownership of IMRT services increased their use of IMRT substantially more than urologists who did not own such services. Allowing urologists to self-refer for IMRT may contribute to increased use of this expensive therapy. (Funded by the American Society for Radiation Oncology.)

From Georgetown University, Washington, DC. Address reprint requests to Dr. Mitchell at Georgetown University, Old North 314, 37th & O Sts. NW, Washington, DC 20057, or at mitchejm@georgetown.edu.

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In 2011, nearly 240,900 men in the United States received a new diagnosis of prostate cancer.[1] Approximately 90% of these men had clinically localized disease, which was indolent in most cases. The relative 10-year survival rate among all men with prostate cancer is 98%.[1,2] Primary definitive treatments include prostatectomy, external-beam radiation therapy, and brachytherapy. Alternatively, the patient may opt for a less aggressive (monitoring) approach that includes active surveillance or hormone therapy. Table 1 describes each treatment option.

Despite substantial variation in reimbursement, evidence suggests that for low-risk disease, the three primary definitive treatments are clinically equivalent when measured in terms of survival.[2,6] Moreover, clinical studies indicate that no single treatment approach is preferable with respect to the risk of adverse events and implications for quality of life.[7,8] When selecting a treatment option, the patient will consider the recommendations of his physicians, the tumor attributes, whether monitoring is preferable to definitive treatment, the costs of and time required for treatment, potential side effects (urinary, bowel, and sexual dysfunction), and individual characteristics (e.g., age, race or ethnic group, and highest educational level attained). Lacking clinical expertise, the patient must rely on his treating physician to act as his agent in the health care decision-making process. Given this asymmetrical information problem, the physician's recommendation has considerable influence on the patient's decision.[9,10]

Since 2005, an increasing number of urologists (physicians who diagnose and sometimes treat prostate cancer) have expanded their scope of practice to incorporate intensity-modulated radiation therapy (IMRT), a radiation treatment with a high rate of reimbursement.[11,12] Because urologists are not trained in radiation oncology, the group typically hires a radiation oncologist to develop and monitor IMRT for patients with prostate cancer who are treated by urologists in the group. IMRT revenues represent additional income for the urology group; therefore, each urologist has financial incentives to refer patients for IMRT. Such arrangements enable urologists to partially replace the income losses they incurred after Medicare substantially cut payments for androgen-deprivation therapies in the mid-2000s.[4,12]

The practice whereby a physician refers patients to facilities in which the physician has an investment interest is known as self-referral.[13,14] This practice is controversial because it poses a conflict of interest for referring physician–investors. Although self-referral is generally illegal, the federal prohibition has exceptions that permit physicians to self-refer under certain conditions. The most notable exception concerns in-office ancillary services; this provision enables individual physicians and physician groups to integrate designated health services, including radiation therapy, into their practices without violating the law.[13-15] Before the adoption of the self-referral model, urologists sent patients with prostate cancer to radiation oncologists who worked at either hospital-based or independent radiation centers.

Considerable research has shown that self-referral is linked to the increased use of services and escalating health care spending, with no clear benefit to patients.[15-22] Most prior studies have focused on advanced imaging techniques and specialty hospitals.[17-25] Little research during the past few years has examined the effects of self-referral on other services that fall under the umbrella of the exception for in-office ancillary services.[26,27] To address this knowledge gap, I compared the frequency of use of IMRT for patients with prostate cancer by self-referring urologists, before and after they acquired IMRT services, with the use rates among non–self-referring urologists, who referred their patients to either hospital-based or independent radiation centers.

METHODS

DATA SOURCES

The analysis relied on five data sources with information about Medicare fee-for-service beneficiaries: the carrier file, the hospital outpatient file, the beneficiary summary file, the Medicare Physician Identification and Eligibility Registry file, and the National Provider Identifier file. The carrier file contains claims submitted by physicians, laboratories, diagnostic centers, and radiation centers, and the hospital outpatient file contains information submitted by hospital outpatient departments. The Centers for Medicare and Medicaid Services (CMS) has developed algorithms to identify beneficiaries with chronic conditions (including prostate cancer) from Medicare claims data.

Relying on anecdotal information, I selected states in which at least one IMRT self-referral arrangement had been established and neighboring states in which such arrangements did not exist.

Table 1. Treatment Options for Clinically Localized Prostate Cancer.*

Treatment	Description	Claim Code†	Mean Cost Estimate‡
Radical prostatectomy§	Complete removal of the prostate gland is performed with the use of one of three surgical approaches: radical retropubic prostatectomy, laparoscopic radical prostatectomy, or robot-assisted prostatectomy; the latter two are less invasive.	55801, 55810, 55812, 55815, 55821, 55831, 55840, 55842, 55845, 55866, and 55899	$16,762¶
Brachytherapy§	Brachytherapy with the use of low-dose-rate isotopes involves permanent implantation of seeds that emit a low dose of radiation over a period of several months. Some patients also receive a boost of external-beam radiation therapy or androgen-deprivation therapy.	55875, 55862, 55865, 77778, 77784, and 77787	$17,076¶
IMRT	This advanced form of three-dimensional radiation therapy involves the use of a computer-driven machine that revolves around the patient as it delivers radiation. Radiation beams are aimed at the prostate from multiple angles. Intensity can be adjusted to maximize the dose targeted at the cancerous tissue and minimize the dose to surrounding healthy tissue.	77418	$31,574¶
Androgen-deprivation therapy	This hormone treatment reduces the effects of testosterone, thereby slowing the growth of prostate cancer. Medications are administered orally or injected to reduce or block circulating androgens.	54520, J1950, J9217, J9218, J9219, and J9202	$2,112‖
Active surveillance	This active plan to postpone intervention typically involves monitoring with office visits every 6 months, prostate-specific antigen testing, digital rectal examination, and prostate biopsy.	NA	$4,228**
Less common procedures			
Cryosurgery	Liquid nitrogen or liquid carbon dioxide is used to freeze tissue in order to destroy abnormal cells.	55873	—
Stereotactic body radiation therapy	This type of external-beam radiation therapy involves the use of special equipment to position a patient and precisely deliver radiation to tumors in the body (except the brain). The total dose of radiation is divided into smaller doses given over a period of several days. This type of radiation therapy helps spare normal tissue.	G0339 and G0340 during 2005–2006 and 77435 during 2007–2010	—
External-beam radiation therapy as a three-dimensional conformal treatment	Also called three-dimensional radiation therapy and three-dimensional conformal radiation therapy, this procedure uses a computer to create a three-dimensional picture of the tumor, allowing doctors to give the highest possible dose of radiation to the tumor, while sparing as much of the normal tissue as possible.	77401–77404, 77406–77409, 77411–77413, and 77416	$20,588¶

* IMRT denotes intensity-modulated radiation therapy, and NA not applicable.
† The codes used to identify alternative treatment options are based on the Healthcare Common Procedure Coding System.
‡ The mean cost for each treatment is provided in 2005 dollars. Reliable cost-estimate data are not available for cryosurgery and stereotactic body radiation therapy because these procedures are much less common than the other procedures listed.
§ Some patients who undergo brachytherapy or prostatectomy also receive radiation (external-beam radiation therapy or IMRT) as adjuvant therapy but not as the primary treatment.
¶ Cost-estimate data are from Nguyen et al.[3]
‖ Cost-estimate data are from Shahinian et al.[4]
** Cost-estimate data are from the Institute for Clinical and Economic Review.[5]

I obtained hospital-outpatient and carrier claims for services received by men with prostate cancer according to the CMS algorithm during the period from January 1, 2005, through December 31, 2010. The beneficiaries were continuously enrolled in the Medicare fee-for-service program and resided in 26 geographically dispersed states (see the Supplementary Appendix, available with the full text of this article at NEJM.org).

With clinical guidance from a urologist in private practice who specializes in treating prostate cancer, I developed an algorithm to identify men with newly diagnosed, nonmetastatic prostate cancer from the initial data extract (see the Supplementary Appendix). The inclusion criteria stipulated that a beneficiary had to have undergone a biopsy performed by a member of a participating urology group because of possible

prostate cancer (Healthcare Common Procedure Coding System code 55700), without a diagnosis of prostate cancer on the biopsy claim, followed by a diagnosis of prostate cancer within 30 days after the biopsy.

The urologist–consultant recommended a 6-month observation period after the date of the initial diagnosis of prostate cancer. I assessed the treatments received by each beneficiary during this period. After 6 months, the beneficiary was no longer considered to have a new diagnosis, so any treatment received after this time window was excluded. Patients who received a diagnosis within 6 months before the end of either the period before IMRT services were acquired (the preownership period) or the period of IMRT ownership were excluded from the analysis. The rationale for their exclusion was that these patients did not have the full 6 months of follow-up during the period in which they received the diagnosis.

CONSTRUCTION OF THE SAMPLE

I identified 50 urology practices that established a self-referral arrangement involving IMRT for the treatment of prostate cancer between January 1, 2005, and January 15, 2010. The initial list included 37 groups identified by the *Wall Street Journal* as acquiring ownership of IMRT services.[12] During the search for control groups to match these 37 groups, I identified an additional 13 self-referring groups. The initial data request to CMS was for data from the 17 states that had 1 or more of the self-referring urology groups identified by the *Wall Street Journal*. I also requested data for 9 states in which there were no known self-referring groups.

A total of 8 of the 50 practices were located in states not included in the data request to CMS. A total of 7 of the remaining 42 self-referring groups were excluded from the primary sample for one of the following reasons: the group had fewer than 20 cases during the preownership period (3 groups), the group had fewer than 20 cases during the ownership period (1), or the group could not be matched with a suitable control in a nearby market area (3). The third situation was the consequence of several smaller groups in one metropolitan area merging to form 3 large self-referring practices. Thus, the analysis focused on 35 of the original 50 self-referring urology practices that had been identified. Considerable literature has documented the existence of substantial geographic variation in physician practice patterns, use of services, and health care spending.[28,29] To account for such geographic variation in practice patterns, each self-referring urology group was matched with a non–self-referring group in private practice that was located in the same or a nearby market area.

A second control group comprised men treated by non–self-referring urologists who were employed by National Comprehensive Cancer Network (NCCN) centers. Physicians working at these centers are likely to practice on the basis of clinical evidence and are unlikely to derive financial benefits from recommending specific services. There are 21 NCCN centers in the United States. Of these centers, 4 were excluded because they were located in Ohio, Missouri, Nebraska, or North Carolina — states that were not included in the data request to CMS. It was also necessary to exclude 5 centers because they could not be matched to a self-referring urology practice in a nearby market area. Another center was excluded because it had a financial relationship with a self-referring urology practice. Thus, the analysis focused on urologists working at 11 cancer centers and 11 matched self-referring private practices within close proximity.

Using information reported on the website of each self-referring and non–self-referring practice, I identified the names of the urologists. Next, I searched the Medicare Physician Identification and Eligibility Registry and the National Provider Identifier files to match each physician's name with his or her unique identification number. Using the physician identification numbers, I searched the claims to identify the tax identification numbers associated with each urologist. Finally, I extracted all claims for cases of prostate cancer with the earmarked physician and tax identification numbers and then sequentially ordered the claims to create a medical profile of services received by each beneficiary.

Relying on clinical guidance from a urologist and a radiation oncologist, I constructed variables to earmark the receipt of the alternative cancer treatments, using Healthcare Common Procedure Coding System codes (Table 1). Because the self-referring urology practices began billing Medicare for IMRT at different points in time, it was critical to assign the same preownership and ownership periods to each matched pair. I determined the preownership and ownership periods for each matched pair on the basis of the date on which each self-referring practice began bill-

ing Medicare for IMRT. The individually matched treatment and control groups were then concatenated (linked) to construct a sample of men with newly diagnosed, nonmetastatic prostate cancer. The primary sample comprised 35 self-referring and 35 matched non–self-referring urology practices located in eight of the nine regions of the United States as defined by the Census Bureau. The study was approved by the institutional review board at Georgetown University.

STATISTICAL ANALYSIS

Changes over time in IMRT use according to self-referral status were evaluated with the use of a difference-in-differences analysis. This approach controls for initial differences in practice patterns during the preownership period and secular trends that affect the use of IMRT and are unrelated to ownership status. The empirical specification, shown below, was estimated by means of a linear probability model and logistic regression. If the difference-in-differences estimator is positive, this implies that the frequency of use of IMRT increased more (or decreased less) among self-referring urologists than among their non–self-referring counterparts. The regression models included controls for patient age, status with respect to coexisting conditions, year of diagnosis, and indicator variables identifying the urology group that treated each beneficiary.[30] The rationale for the inclusion of each of these variables is provided in the Supplementary Appendix.

The model was specified as follows:

$$\begin{aligned}\text{IMRT}_{ijt} = {} & \beta_0 + \beta_1\ \text{Selfref}_{ijt} + \\ & \delta_j\ \text{Urology Group}_j + \alpha_t\ \text{Cancer Year}_t + \\ & \beta_2\ \text{Age}_{ijt} + \beta_3\ \text{Coexisting Condition}_{ijt} + u_{ijt},\end{aligned}$$

where i is the beneficiary, j the urology group, t the time period, and u_{ijt} the error term.

IMRT_{ijt} was equal to 1 if one of the following applied: the beneficiary was seen by a non–self-referring urologist during either the preownership or ownership period and received IMRT, the beneficiary was seen by a self-referring urologist during the preownership period and received IMRT, or the beneficiary was seen by a self-referring urologist during the ownership period and received IMRT that was performed and billed by the self-referring urology group. The dependent variable equals 0 for all other observations, including beneficiaries seen by a self-referring urologist during the ownership period who underwent IMRT that was performed and billed by a non–self-referring provider. Although these beneficiaries received IMRT, assigning a value of 1 to these observations would bias upward the coefficient for the self-referral variable. Selfref_{ijt} was equal to 1 if the beneficiary was treated by a self-referring urologist after the physician's practice began billing Medicare for IMRT. I also evaluated the time from the date of the cancer diagnosis to the initiation of definitive treatment in order to assess whether the time to the initiation of treatment was shorter among patients treated by integrated urology–radiation oncology practices.

RESULTS

USE OF IMRT AND OTHER TREATMENTS

Table 2 shows the rates of IMRT use by urologists in private practice, with adjustment for self-referral status and ownership period. Among beneficiaries treated by self-referring urologists in private practice, the rate of IMRT referral increased from 13.1 to 32.3%, an increase of 19.2 percentage points (P<0.001). Approximately 6.0% of the men treated by self-referring urologists underwent IMRT performed by non–self-referring providers. Rates of brachytherapy and hormone use fell by 13.0 and 8.1 percentage points, respectively (P<0.001). Changes in use rates for prostatectomy and active surveillance were inconsequential. By contrast, the rate of IMRT referral among patients treated by non–self-referring urologists was virtually unchanged between the preownership and ownership periods, from 14.3 to 15.6%, which was an increase of 1.3 percentage points (P=0.05). Use rates for the remaining treatment options by non–self-referring urologists remained stable.

The unadjusted difference-in-differences analysis comparing the frequency of use of IMRT among men treated by urologists in private practice is shown in Figure 1A. Self-referral was associated with an unadjusted increase in IMRT use of 17.9 percentage points (P<0.001). Results stratified according to age were similar (Fig. S1 and S2 in the Supplementary Appendix).

Table 3 shows the changes in use rates from the preownership period to the ownership period among men treated by urologists working at 11 NCCN centers and their counterparts at 11 matched self-referring urology practices. The

Table 2. Treatment Provided for Men with Newly Diagnosed, Nonmetastatic Prostate Cancer in the 35 Matched Groups of Self-Referring and Non–Self-Referring Urologists in Private Practice, According to Self-Referral Status and Ownership Period.*

Treatment	Self-Referring Urologists in Private Practice				Non–Self-Referring Urologists in Private Practice			
	Preownership Period (N=13,929)	Ownership Period (N=14,319)	Change	P Value	Preownership Period (N=5404)	Ownership Period (N=5113)	Change	P Value
IMRT delivery by self-referring group (%)	13.1	32.3	19.2	<0.001	—	—	—	—
IMRT delivery by other provider (%)	—	6.3	—	—	14.3	15.6	1.3	0.05
Brachytherapy (%)	18.6	5.6	–13.0	<0.001	18.9	17.9	–1.0	0.19
Prostatectomy (%)	17.7	16.6	–1.1	0.01	21.9	23.8	1.9	0.02
Androgen-deprivation therapy (%)	16.5	8.4	–8.1	<0.001	15.6	11.4	–4.2	<0.001
Active surveillance (%)	26.7	27.0	0.3	0.65	26.1	27.4	1.3	0.12
Other procedure (%)	7.3	3.9	–3.4	<0.001	3.2	3.9	0.7	0.05
Time from diagnosis to treatment (days)	79.8±37.9	76.0±32.6	–3.8	<0.001	78.8±38.1	78.0±36.2	–0.8	0.50

* Plus–minus values are means ±SD. For percentage data, change is shown in percentage points. Beneficiaries who underwent prostatectomy or brachytherapy may also have received adjuvant radiation therapy (external-beam radiation therapy or IMRT), but the definitive treatment was either brachytherapy or prostatectomy.

rate of IMRT use by self-referring urologists rose from 9.0 to 42.0%, an increase of 33.0 percentage points (P<0.001). Another 4.5% of men seen by self-referring urologists obtained IMRT from another provider. Rates of brachytherapy and hormone use fell by 14.9 percentage points and 10.0 percentage points, respectively (P<0.001 for both comparisons). The percentage of men monitored with active-surveillance protocols fell by 6.3 percentage points, and the use of prostatectomy and other procedures declined by less than 4.0 percentage points (P<0.001 for all comparisons). By contrast, there was virtually no change in the practice patterns of urologists employed by NCCN centers. During both periods, approximately 8.0% of the men seen by urologists at cancer centers underwent IMRT.

Figure 1B shows the unadjusted difference-in-differences results for men treated by urologists employed by NCCN centers and those treated by self-referring urologists in private practice. The unadjusted difference-in-differences estimator (self-referral effect) was 32.6 percentage points (P<0.001). Analyses stratified according to age yielded similar findings (Fig. S3 and S4 in the Supplementary Appendix).

Regression analyses that were adjusted for age, status with respect to coexisting conditions, year of cancer diagnosis, and urology-group fixed effects had similar results. The analysis that was based on urologists in private practice indicated that self-referral was associated with an increase in IMRT use of 16.4 percentage points (P<0.001) (Table 4, and Table S1 in the Supplementary Appendix). Results of regression analyses with urologists employed by cancer centers as matched controls were similar to the unadjusted findings; self-referral was associated with an increase in IMRT use of 29.3 percentage points (P<0.001) (Table S1 in the Supplementary Appendix). Sensitivity analyses that used alternative modeling approaches had similar results (Table S1 in the Supplementary Appendix).

TIME TO INITIATION OF TREATMENT

The unadjusted difference-in-differences analysis in which urologists in private practice were used as controls suggested that self-referral was associated with a 3.0-day decline in the time to the initiation of treatment (P<0.001). Similar unadjusted analyses in which urologists employed by cancer centers were used as controls suggested that self-referral was associated with a reduction of 6.4 days in the time to the initiation of treatment (P<0.001). These significant, although modest, reductions in the time to treatment initiation with self-referral became increases, albeit insignificant, in regression-adjusted analyses that

controlled for urology group, type of definitive treatment, age, year of cancer diagnosis, and status with respect to coexisting conditions. In analyses with urologists in private practice as controls, self-referral was associated with an increase in the time to the initiation of treatment of 1.3 days (P=0.12); in analyses with urologists employed at cancer centers as controls, the increase was 1.9 days (P=0.39) (Table S2 in the Supplementary Appendix).

DISCUSSION

The results of this study indicate that referral by urologists to IMRT services in which they have a financial interest is associated with large increases in the rate of IMRT use for Medicare beneficiaries who have newly diagnosed, nonmetastatic prostate cancer. There was increased use of IMRT among private-practice urology groups that acquired ownership of IMRT services both in analyses that used other urology groups in private practice as controls and in analyses that used urologists employed by NCCN centers as controls. In adjusted analyses, self-referral was not associated with a shorter time to receipt of definitive treatment. These findings are consistent with the results of other studies showing substantial increases in the frequency of use of advanced imaging techniques, clinical laboratory testing, and anatomical-pathology services by self-referring physicians,[17-22,26,27] and also corroborate the significant increases in the use of surgery that characterize physician–owners of specialty hospitals.[23-25]

Financial incentives may have contributed to the increased use of IMRT among self-referring urologists; financial pressures induced by substantial start-up costs may likewise have prompted physician–owners to recommend IMRT in lieu of alternative treatments.[11,12] To establish an IMRT center requires a capital investment of $2 million and the hiring of advanced support staff. However, explanations other than financial incentives and pressures must be considered. For example, urologists may integrate IMRT into their practice because they believe this treatment will reduce the risk of adverse events and improve quality of life. However, evidence from clinical studies indicates that each primary treatment for prostate cancer has pros and cons in terms of side effects and their implications for quality of life.[7,8]

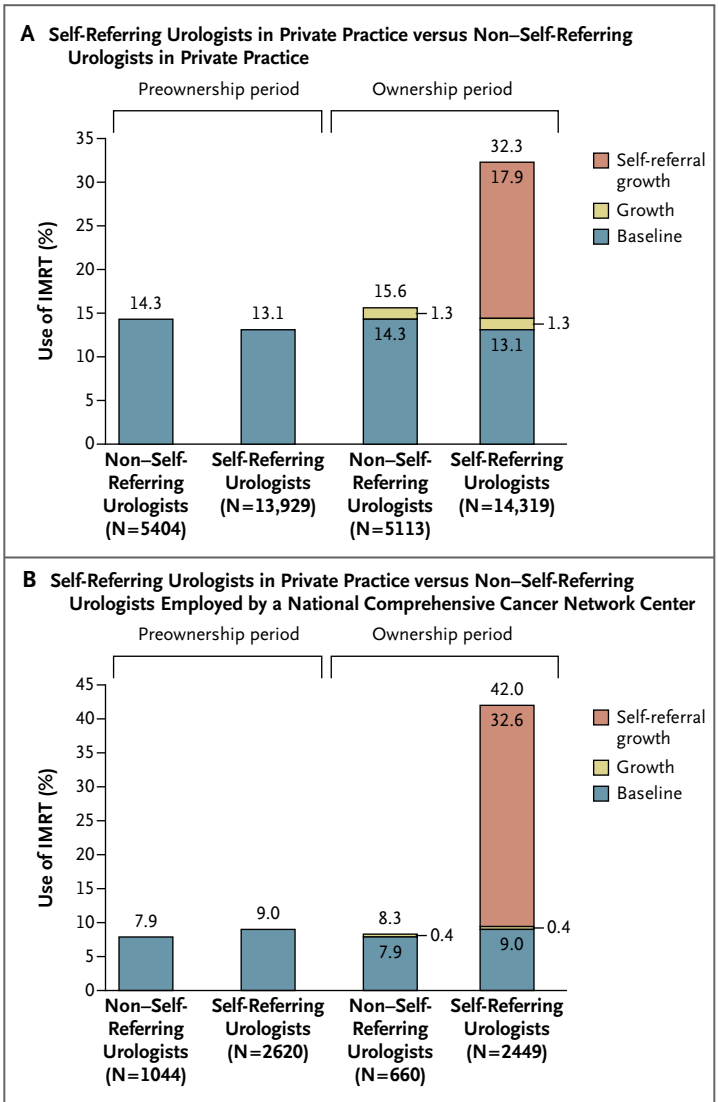

Figure 1. Use of Intensity-Modulated Radiation Therapy (IMRT) among Men 65 Years of Age or Older with Newly Diagnosed Prostate Cancer.

Panel A shows the results of the unadjusted difference-in-differences analysis comparing the frequency of use of IMRT among men treated by urologists in private practice. The difference in use between the period before acquiring IMRT services (the preownership period) and the ownership period for the self-referring urologists was 19.2 percentage points (P<0.001); the corresponding difference for non–self-referring urologists was 1.3 percentage points (P=0.05). Self-referral was associated with an unadjusted increase in IMRT use of 17.9 percentage points (P<0.001). Panel B shows the unadjusted difference-in-differences results for men treated by urologists employed by a National Comprehensive Cancer Network center and self-referring urologists in private practice. The difference in use between the preownership and ownership periods for the self-referring urologists was 33.0 percentage points (P<0.001); the corresponding difference for urologists employed at the cancer centers was 0.4 percentage points (P=0.78). The unadjusted difference-in-differences estimator (self-referral effect) was 32.6 percentage points (P<0.001).

Table 3. Treatment Provided in the 11 Matched Groups of Self-Referring Urologists in Private Practice and Non–Self-Referring Urologists Employed by a National Comprehensive Cancer Network Center, According to Self-Referral Status and Ownership Period.*

Treatment	Self-Referring Urologists in Private Practice				Non–Self-Referring Urologists Employed by the National Comprehensive Cancer Network			
	Preownership Period (N=2620)	Ownership Period (N=2449)	Change	P Value	Preownership Period (N=1044)	Ownership Period (N=600)	Change	P Value
IMRT delivery by self-referring group (%)	9.0	42.0	33.0	<0.001	—	—	—	—
IMRT delivery by other provider (%)	—	4.5	—	—	7.9	8.3	0.4	0.78
Brachytherapy (%)	17.6	2.7	−14.9	<0.001	6.3	8.5	2.2	0.09
Prostatectomy (%)	16.4	12.8	−3.6	<0.001	28.5	27.0	−1.5	0.50
Androgen-deprivation therapy (%)	17.4	7.4	−10.0	<0.001	12.0	9.7	−2.3	0.14
Active surveillance (%)	33.9	27.6	−6.3	<0.001	44.3	45.0	0.7	0.79
Other procedure (%)	5.7	3.0	−2.7	<0.001	1.0	1.5	0.5	0.30
Time from diagnosis to treatment (days)	80.0±35.9	71.2±31.1	−8.8	<0.001	84.4±38.9	82.0±36.7	−2.4	0.39

* Plus–minus values are means ±SD. For percentage data, change is shown in percentage points. Beneficiaries who underwent either prostatectomy or brachytherapy may also have received adjuvant radiation therapy (either external-beam radiation therapy or IMRT), but the definitive treatment was either brachytherapy or prostatectomy.

Table 4. Linear Probability and Logistic-Regression Difference-in-Differences Estimates Predicting Receipt of IMRT for the Comparison of Self-Referring Urologists in Private Practice with Non–Self-Referring Urologists in Private Practice.*

Estimate	Beneficiary Treated by Self-Referring Urologist during Ownership Period	P Value
Linear probability marginal effect	16.4 percentage points	<0.001
Logistic-regression marginal effect	16.9 percentage points	<0.001
Logistic-regression odds ratio (95% CI)	2.79 (2.53–3.08)	<0.001

* The sample of 38,765 patients included all beneficiaries treated by physicians in private practice from 35 self-referring urology groups that began billing Medicare for IMRT at some point during the period from January 1, 2005, through January 15, 2010, and those treated by physicians in private practice from 35 matched non–self-referring urology groups that did not bill Medicare for IMRT. All regression models included the age of the beneficiary at the time of the cancer diagnosis, indicator variables to distinguish year of diagnosis, indicator variables to identify the presence or absence of specific coexisting conditions, and indicator variables to control for the urology group that treated each beneficiary. CI denotes confidence interval.

In addition, the self-referring urologists in this study may have been early adopters of IMRT. However, the data do not support this explanation, because 60% of the self-referring practices established their IMRT center during the period from January 1, 2008, through January 15, 2010. Moreover, self-referring and non–self-referring urologists had similar rates of IMRT referral during the preownership period. Another possible explanation is patient preference. Some beneficiaries may prefer the latest technology even if the efficacy is speculative. Patients who were interested in IMRT may have sought care from integrated urology–radiation oncology practices.

The study has limitations that stem from deficiencies inherent in claims data. First, the analysis did not evaluate the appropriateness of IMRT use because information on tumor characteristics and radiation dose was unavailable. Second, claims data lack information on physician characteristics. Third, data on physicians' perceptions of profitability are not available. In particular, the costs of administering IMRT, including amortization and payments for radiation oncologists, are unknown. Nevertheless, Jacobs et al.[11] cited marketing materials from Urorad Healthcare, a company that sells complete packages of IMRT technology and services to urolo-

gists. The Urorad brochure claims that treating 1.5 new patients monthly with IMRT could generate more than $425,000 in additional revenue per urologist annually.

In conclusion, this study shows that men treated by self-referring urologists, as compared with men treated by non–self-referring urologists, are much more likely to undergo IMRT, a treatment with a high reimbursement rate, rather than less expensive options, despite evidence that all treatments yield similar outcomes.[2] The findings raise concerns regarding the appropriate use of IMRT, especially among older Medicare beneficiaries, for whom the risks of undergoing intensive irradiation probably exceed the benefits. Recent evidence suggests that the IMRT self-referral arrangement is becoming more common; by the end of 2011, approximately 19% of urology practices had incorporated IMRT services into their practice.[31] Permitting urologists to self-refer for IMRT may contribute to increased use of this expensive therapy.

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United States Government Accountability Office

Report to Congressional Requesters

July 2013

MEDICARE

Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny

GAO-13-525

July 2013

MEDICARE

Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny

GAO Highlights

Highlights of GAO-13-525, a report to congressional requesters

Why GAO Did This Study

Questions have been raised about self-referral's role in Medicare Part B expenditures' rapid growth. Self-referral occurs when a provider refers patients to entities in which the provider or the provider's family members have a financial interest. Services that can be self-referred under certain circumstances include IMRT, a common and costly treatment for prostate cancer. GAO was asked to examine Medicare self-referral trends among radiation oncology services. This report examines (1) trends in the number of and expenditures for prostate cancer-related IMRT services provided by self-referring and non-self-referring provider groups from 2006 through 2010 and (2) how the percentage of prostate cancer patients referred for IMRT may differ on the basis of whether providers self-refer. GAO analyzed Medicare Part B claims and developed a claims-based methodology to identify self-referring groups and providers. GAO also interviewed officials from the Centers for Medicare & Medicaid Services (CMS), which administers Medicare, and other stakeholders.

What GAO Recommends

Congress should consider directing the Secretary of Health and Human Services, whose agency oversees CMS, to require providers to disclose their financial interests in IMRT to their patients. GAO also recommends that CMS identify and monitor self-referral of IMRT services. HHS disagreed with GAO's recommendation. Given the magnitude of GAO's findings, GAO maintains CMS should identify and monitor self-referral of IMRT services.

View GAO-13-525. For more information, contact James C. Cosgrove at (202) 512-7114 or cosgrovej@gao.gov.

What GAO Found

The number of Medicare prostate cancer–related intensity-modulated radiation therapy (IMRT) services performed by self-referring groups increased rapidly, while declining for non-self-referring groups from 2006 to 2010. Over this period, the number of prostate cancer–related IMRT services performed by self-referring groups increased from about 80,000 to 366,000. Consistent with that growth, expenditures associated with these services and the number of self-referring groups also increased. The growth in services performed by self-referring groups was due entirely to limited-specialty groups—groups comprised of urologists and a small number of other specialties—rather than multispecialty groups.

Providers substantially increased the percentage of their prostate cancer patients they referred for IMRT after they began to self-refer. Providers that began self-referring in 2008 or 2009—referred to as switchers—referred 54 percent of their patients who were diagnosed with prostate cancer in 2009 for IMRT, compared to 37 percent of their patients diagnosed in 2007. In contrast, providers who did not begin to self-refer—that is, non-self-referrers and providers who self-referred the entire period—experienced much smaller changes over the same period. Among all providers who referred a Medicare beneficiary diagnosed with prostate cancer in 2009, those that self-referred were 53 percent more likely to refer their patients for IMRT and less likely to refer them for other treatments, especially a radical prostatectomy or brachytherapy. Compared to IMRT, those treatments are less costly and often considered equally appropriate but have different risks and side effects. Factors such as age, geographic location, and patient health did not explain the large differences between self-referring and non-self-referring providers. These analyses suggest that financial incentives for self-referring providers—specifically those in limited specialty groups—were likely a major factor driving the increase in the percentage of prostate cancer patients referred for IMRT. Medicare providers are generally not required to disclose that they self-refer IMRT services, and the Department of Health and Human Services (HHS) lacks the authority to establish such a requirement. Thus, beneficiaries may not be aware that their provider has a financial interest in recommending IMRT over alternative treatments that may be equally effective, have different risks and side effects, and are less expensive for Medicare and beneficiaries.

Change in the Percentage of Medicare Prostate Cancer Patients Providers Referred for IMRT after a Diagnosis of Prostate Cancer in 2007 or 2009

Type of provider	Percentage of providers' patients referred for IMRT among beneficiaries diagnosed in 2007	Percentage of providers' patients referred for IMRT among beneficiaries diagnosed in 2009	Percentage point change from 2007 to 2009	Percentage more or less likely providers were to refer patients for IMRT in 2009 compared to 2007
Switchers	37.0%	54.2%	17.2	46.6%
Non-self-referrers	31.4	33.1	1.7	5.5
Self-referrers	55.7	52.9	-2.8	-5.1

Source: GAO analysis of CMS data.

Note: Switchers did not self-refer in 2006 or 2007 but began to self-refer in either 2008 or 2009. The percentage by which providers were more or less likely to refer patients for IMRT in 2009 compared to 2007 is equivalent to the percentage point change from 2007 to 2009 divided by the percentage of providers' patients referred for IMRT among beneficiaries diagnosed in 2007.

Contents

Tables

Figures

Abbreviations

3D-CRT	three-dimensional conformal radiation therapy
ASTRO	American Society for Radiation Oncology
AUA	American Urological Association
CMS	Centers for Medicare & Medicaid Services
EBRT	external beam radiation therapy
FFS	fee-for-service
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
IMRT	intensity-modulated radiation therapy
IOAS	in-office ancillary services
LUGPA	Large Urology Group Practice Association
NPI	national provider identifier
PPACA	Patient Protection and Affordable Care Act
PSA	prostate-specific antigen
SEER	Surveillance Epidemiology and End Results
TIN	taxpayer identification number

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

July 19, 2013

Congressional Requesters

Expenditures for Medicare Part B services—which include physician and other outpatient services—have grown rapidly, increasing annually at 5.9 percent, on average, from 2007 through 2011. In comparison, the national economy grew by less than half that rate during the same period. Policymakers have questioned whether some of the growth in spending for Part B services may be attributed to self-referral, which occurs when providers refer their patients to entities—such as themselves or a group practice—in which they or a member of their families have a financial relationship.[1] While federal law generally prohibits self-referral under Medicare, there are exceptions for certain services and arrangements.[2] Among the Medicare diagnostic and therapeutic services that may be self-referred under one of these exceptions is intensity-modulated radiation therapy (IMRT), a form of external beam radiation therapy (EBRT) commonly used to treat prostate cancer. While there are multiple effective treatments for prostate cancer, IMRT is one of the most costly options. In 2010, expenditures for prostate cancer–related IMRT services accounted for about 55 percent of the $1.27 billion that Medicare paid for all IMRT services under Medicare Part B.

Questions have been raised about the effect of self-referral arrangements on the utilization of IMRT services reimbursed under Medicare Part B. Critics of such self-referral arrangements suggest that there may be a financial incentive to overutilize IMRT because diagnosing providers can earn more by self-referring IMRT services than if patients were referred

[1]Providers in our analysis that could self-refer could include physicians and other providers, such as nurse practitioners and physician assistants.

[2]Compliance with the physician self-referral law, commonly known as the Stark law, is outside the scope of this report. The Stark law prohibits physicians from making referrals for certain designated health services paid for by Medicare, to entities with which the physicians or immediate family members have a financial relationship, unless the arrangement complies with a specified exception, such as in-office ancillary services. 42 U.S.C. § 1395nn(b)(2). The requirements of the in-office ancillary services exception are found at 42 C.F.R. § 411.355(b) (2012).

for other treatments.[3] Other treatments for prostate cancer are often considered equally appropriate, as experts have not established a "gold standard" for the treatment of cancer that has not spread beyond the prostate (i.e., localized prostate cancer), which represents a large majority of newly diagnosed prostate cancers.[4] Proponents of self-referral arrangements contend that the self-referral of IMRT services does not affect clinical decision making and that patients benefit from self-referral through, for example, improved coordination among the providers who diagnose and treat patients.

You asked us to examine Medicare self-referral trends among radiation oncology services. In this report, we (1) compare trends in the number of and expenditures for prostate cancer–related IMRT services provided by self-referring and non-self-referring provider groups from 2006 through 2010 and (2) examine how the percentage of prostate cancer patients referred for IMRT may differ on the basis of whether providers self-refer.

To compare trends in the number of and expenditures for prostate cancer–related IMRT services provided by self-referring and non-self-referring groups in provider offices from 2006 through 2010, we analyzed IMRT delivery claims from the Medicare Part B Carrier file.[5] We identified

[3]For example, see Benjamin P. Falit, Cary P. Gross, and Kenneth B. Roberts, "Integrated Prostate Cancer Centers and Over-Utilization of IMRT: A Close Look at Fee-For-Service Medicine in Radiation Oncology," *International Journal of Radiation Oncology • Biology • Physics* 76, no. 5 (April 2010): 1285-88.

[4]For instance, for a subset of localized prostate cancers that are low risk, IMRT, brachytherapy, and a radical prostatectomy are all among the treatments considered appropriate. According to the National Cancer Institute, 81 percent of men who were diagnosed with prostate cancer from 2002 through 2008 in 18 geographic areas that provided cancer data to the National Cancer Institute were diagnosed with localized prostate cancer, while the rest were diagnosed at an unknown stage (3 percent) or after the cancer had spread regionally (12 percent) or distantly (4 percent). See http://seer.cancer.gov/statfacts/html/prost.html, accessed December 18, 2012.

[5]IMRT delivery codes represent individual treatment sessions during which patients receive radiation. In addition to receiving radiation, patients receive several different types of services during a course of IMRT. Our analysis of self-referred prostate cancer–related IMRT services is limited to those services performed in physician offices. We focused on this setting because our work showed rapid growth in this setting compared to hospital outpatient departments and because the financial incentive for providers to self-refer is most direct when the service is performed in a physician office. Services performed by non-self-referring groups in the physician office setting could include services provided in places such as freestanding cancer centers. Throughout this report, we refer to services billed through the Carrier file as services performed in physician offices.

prostate cancer–related IMRT services using diagnosis codes on the claims. Because there is no indicator or "flag" on the claim that identifies whether services are self-referred or non-self-referred and the Centers for Medicare & Medicaid Services (CMS), the agency that administers Medicare, has no other method for identifying whether a service was self-referred, we developed a claims-based methodology for identifying provider group practices as self-referring or non-self-referring.[6] Specifically, we classified groups as self-referring if the providers who administered IMRT for the group had a financial relationship with the same entity as the provider who referred the IMRT service.[7] Additionally, in order to be considered self-referring, groups had to meet other volume-related criteria, such as self-referring at least half of the courses of IMRT therapy the group provided. To ensure that how we defined our criteria were reliable, we tested alternative thresholds for defining self-referring groups and found that the observed patterns were similar regardless of the threshold used. We also analyzed trends in the utilization of prostate cancer–related IMRT services by whether the service was performed by a limited-specialty or multispecialty group. We defined groups as limited specialty in a given year if more than 75 percent of its office visits were performed by urologists, nonphysician practitioners (e.g., physician assistants), or providers whose specialty was related to the diagnosis or treatment of cancer, such as radiation oncologists. The remaining groups were comprised of providers from a large number of different specialties and were considered multispecialty groups. We examined the trends in prostate–cancer related IMRT services performed in hospital outpatient departments for context.

To examine how the percentage of prostate cancer patients referred for IMRT may differ on the basis of whether providers self-refer, we performed two separate analyses using the Medicare Part B Carrier and hospital outpatient files. First, we compared the percentage of prostate cancer patients that self-referring and non-self-referring providers referred for IMRT and other treatments within a year of being diagnosed in 2007 or 2009. We classified referring providers as self-referring if they were the

[6]An indicator or "flag" could be, for example, a modifier that a provider lists on a claim to indicate that a service is self-referred. Providers currently use modifiers to provide additional information about a service to CMS.

[7]Providers could have a financial relationship with the same entity if, for example, they are part of the same group practice.

performing provider on a claim that was paid to a self-referring provider group in the year of, before, or after a beneficiary's prostate cancer diagnosis. All other providers were considered non-self-referring. In addition, we examined how, if at all, the referral patterns for non-self-referring and self-referring providers were affected by beneficiary characteristics such as age, geographic location (i.e., urban or rural), and beneficiary health.[8] As part of our examination of beneficiary health, we examined how, if at all, provider referral patterns were affected by clinical characteristics of patients' prostate cancers, which were obtained from the New York State Cancer Registry, for beneficiaries who lived in New York and were diagnosed with prostate cancer in either 2007 or 2009. The results of the New York analysis are not generalizable to the entire Medicare population. We used clinical information from the New York State Cancer Registry because such information is not available on Medicare claims, and we determined that the geographic areas included in another common source of such information—Surveillance Epidemiology and End Results (SEER) data—did not sufficiently overlap with areas in which IMRT self-referral was prevalent during our study period. Second, we determined whether the percentage of providers' prostate cancer patients referred for IMRT and other treatments changed after they began to self-refer. Specifically, we identified a group of providers, which we called "switchers," that did not self-refer in 2006 or 2007 but began to self-refer in either 2008 or 2009. We then analyzed the change in the percentage of switchers' newly diagnosed prostate cancer patients referred for IMRT and other treatments before and after switchers began to self-refer. We compared the change for this group of providers to the change among providers who did not begin to self-refer IMRT services during this period. For both analyses, we counted IMRT and other treatments regardless of the setting in which they were performed.

We took several steps to ensure that the data used to produce this report were sufficiently reliable. Specifically, we assessed the reliability of the CMS data we used by interviewing officials responsible for overseeing these data sources, reviewing relevant documentation, and examining the data for obvious errors. We determined that the data were sufficiently

[8]We defined urban areas as metropolitan statistical areas, a geographic entity defined by the Office of Management and Budget as a core urban area of 50,000 or more population; all other settings were considered rural.

reliable for the purposes of our study. (See app. I for more details on our scope and methodology.)

We conducted this performance audit from May 2010 through July 2013 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Prostate cancer patients choose among multiple treatments that are often considered equally appropriate but can have different risks and side effects. The treatments can also vary in cost, with IMRT being one of the most costly options.

Diagnosis and Treatment of Prostate Cancer

Cancer of the prostate—a gland located at the base of the urinary bladder—is the second most common cancer among men in the United States, with approximately 1 in 6 men receiving a diagnosis of prostate cancer in his lifetime.[9] In 2010, there were an estimated 218,000 new cases of prostate cancer and approximately 32,000 deaths due to prostate cancer. Most men in the United States are diagnosed with prostate cancer as a result of an abnormal digital rectal exam or prostate-specific antigen test. After an abnormal test result, beneficiaries often undergo a prostate biopsy, during which a provider—typically a urologist—removes small amounts of prostate tissue. Another provider then examines the tissue to determine whether a beneficiary has prostate cancer.

IMRT is one of multiple treatment options available to patients with prostate cancer. The type of treatment a prostate cancer patient chooses depends on a number of different factors such as life expectancy, overall health, personal preferences, provider recommendations, and the clinical characteristics of a patient's prostate cancer. For many men, multiple

[9]National Cancer Institute. See http://seer.cancer.gov/statfacts/html/prost.html, accessed December 18, 2012. Skin cancer is the most common form of cancer.

treatment options are considered equally appropriate.[10] For instance, IMRT, brachytherapy, and a radical prostatectomy are all among the treatments considered appropriate for men with low-risk prostate cancer.[11] Even though such treatments are often considered equally appropriate, the risks and side effects for each treatment are different. Compared to IMRT, prostate cancer patients undergoing a radical prostatectomy have a higher rate of short term urinary problems and erectile dysfunction but do not face bowel-related side effects, which are experienced by some men undergoing IMRT.[12] Compared to IMRT, prostate cancer patients undergoing brachytherapy have lower rates of bowel-related side effects but about 1 in 10 patients undergoing brachytherapy experience acute urinary retention. Also, several studies have reported that physician recommendations play a large role in influencing a patient's decision,[13] and another study found that the use of a particular prostate cancer treatment decreased after its payment was reduced, suggesting that financial incentives may have influenced treatment decisions.[14] Currently, providers who self-refer IMRT services are generally not required to disclose to their patients that they have a

[10]Men can also receive a combination of therapies, such as brachytherapy combined with EBRT.

[11]National Comprehensive Cancer Network, *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines™): Prostate Cancer* (June 2011).

[12]Institute for Clinical and Economic Review, "Management Options for Low-Risk Prostate Cancer: A Report on Comparative Effectiveness and Value" (Sept. 16, 2009).

[13]Steven B. Zelladt et al., "Why Do Men Choose One Treatment over Another? A Review of Patient Decision Making for Localized Prostate Cancer," *Cancer* 106, no. 9 (May 1, 2006): 1865-74.

[14]Vahakn B. Shahinian, Yong-Fang Kuo, and Scott M. Gilbert, "Reimbursement Policy and Androgen-Deprivation Therapy for Prostate Cancer," *The New England Journal of Medicine* 363, no. 19 (Nov. 4, 2010): 1822-32.

financial interest in the service.[15] Some common prostate cancer treatments are summarized in table 1.

Table 1: Prostate Cancer Treatments

Treatment	Description
Radical prostatectomy	A radical prostatectomy is a surgical procedure in which the entire prostate gland is removed. A prostatectomy can be performed with or without robotic assistance.
Three-dimensional conformal radiation therapy (3D-CRT)	3D-CRT is a form of external beam radiation therapy (EBRT) during which multiple doses of radiation from an external source are administered over several weeks. In 3D-CRT, radiation beams are shaped in an attempt to maximize the amount of radiation the tumor receives and reduce the amount of radiation to which normal tissue is exposed.
Intensity-modulated radiation therapy (IMRT)	IMRT is a newer and an even more precise form of EBRT that allows even more radiation to be delivered to the tumor while sparing normal tissue.
Brachytherapy	Brachytherapy is a treatment that involves the implantation of radioactive sources directly inside the prostate.
Active surveillance	Active surveillance is a regimen of following a patient's condition without giving any treatment, unless the patient's condition changes. An exact regimen has not been established for active surveillance. However, typical protocols involve periodic physical examination, prostate-specific antigen testing, and repeat prostate biopsies.
Hormone therapy	Hormone therapy is a treatment that removes or blocks the actions of male sex hormones, which can cause prostate cancer to grow, in order to stop the growth of prostate cancer. Drugs, surgery, or other hormones are used to reduce hormone production or block their effects.

[15]A physician with an ownership or investment interest in a hospital and who is a member of that hospital's medical staff is required to disclose this financial interest when referring patients to that hospital under an exception to the general prohibition on Medicare self-referral (Stark law). According to Physician Hospitals of America, an advocacy group for physician-owned hospitals, approximately 265 hospitals—or less than 5 percent of all hospitals—were physician-owned as of July 2012. See 42 C.F.R. § 411.362 (2012) for more information on additional requirements concerning physician ownership and investment in hospitals under the Stark law. The Patient Protection and Affordable Care Act (PPACA) created a new disclosure requirement for physicians who self-refer certain other in-office ancillary services under the Stark Law. Pub. L. No. 111-148, § 6003, 124 Stat. 119, 697(2010). Specifically, referring physicians for certain advanced imaging services are required to inform their patients in writing at the time of the referral that the patient may obtain the service from another entity and provide the patients with a list of providers who furnish the service in the area in which the patient resides. 42 U.S.C. § 13955nn(b)(2). No such requirement exists for physicians who self-refer IMRT services. CMS noted in the preamble to the final rule detailing this disclosure requirement that the agency does not have the authority to expand the disclosure requirements to services other than the radiology services referenced in PPACA. Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed. Reg. 73,170, 73,444 (Nov. 29, 2010).

Treatment	Description
Other treatments	Other treatments for prostate cancer include stereotactic body radiotherapy / stereotactic radiosurgery (forms of EBRT during which beneficiaries receive larger daily doses of radiation over a shorter period of time), cryosurgery (freezing prostate cancer by injecting gases through thin needles inserted into the prostate), and proton beam therapy (a form of EBRT that involves the use of particles—protons—rather than photons, which are used in the majority of EBRT treatments).

Source: GAO analysis of published literature.

Medicare Reimbursement for IMRT Services and Costs of Treatment Options for Prostate Cancer

Medicare reimbursement rates for IMRT delivery services varied over time, and rates are not directly comparable between settings. Beneficiaries receive approximately 45 separate IMRT delivery services over several weeks during a course of IMRT to treat prostate cancer. Medicare beneficiaries predominantly receive IMRT delivery services in two settings—physician offices or hospital outpatient departments. The Medicare reimbursement per IMRT delivery service increased from approximately $319 to $421 from 2006 to 2010 and then to $484 by 2013 for services performed in hospital outpatient departments.[16] For services performed in physician offices, the reimbursement rate decreased from approximately $690 to $511 from 2006 to 2010 and then to $406 by 2013.[17] The reimbursement rates for IMRT delivery services performed in physician offices and hospital outpatient departments are not directly comparable. For instance, if an IMRT delivery service was performed in a hospital outpatient department, payment includes the technical component for image guidance,[18] which is almost always furnished with an IMRT service. In physician offices, image guidance is reimbursed separately.

[16]These payment rates are those hospitals receive under the Hospital Outpatient Prospective Payment System. Not all hospitals are paid under this system.

[17]These expenditures do not include the payment reductions that may result from implementation of the Budget Control Act of 2011. Pub. L. No. 112-25, 125 Stat. 240.

[18]The technical component is intended to cover the cost of performing a test, including the costs for equipment, supplies, and nonphysician staff.

Researchers have consistently found that courses of IMRT, which include IMRT delivery and other services,[19] are more costly than other treatments for prostate cancer, with the exception of proton therapy.[20] Researchers have found IMRT to be more costly despite differences among studies in design and methodology, such as the services counted toward total treatment costs, the duration of time during which costs are studied (e.g., first year costs vs. lifetime costs), and the patient population studied. One recent study found that, among men diagnosed with prostate cancer in 2005, the cost to Medicare per course of treatment was approximately $14,000 to $15,000 higher for men receiving IMRT ($31,574) than for men who received brachytherapy ($17,076) or a prostatectomy ($16,469 or $16,762, depending on the type of prostatectomy).[21] Despite the 2013 reduction in the Medicare reimbursement rate for IMRT delivery services performed in physician offices, we found that IMRT remains substantially more expensive than other treatments for prostate cancer, with the exception of proton therapy.[22]

[19]Episodes of IMRT for prostate cancer include other services such as a radiotherapy dose plan, weekly management services, and weekly radiation physics consultations.

[20]For instance, see: Matthew R. Cooperberg et al., "Primary treatments for clinically localised prostate cancer: a comprehensive lifetime cost-utility analysis," *BJU International* 111, no. 3 (March 2013): 437-50; or Chirag Shah et al., "Brachytherapy provides comparable outcomes and improved cost-effectiveness in the treatment of low/intermediate prostate cancer," *Brachytherapy* 11 (2012): 441-45.

[21]P. L. Nguyen et al., "Cost implications of the rapid adoption of newer technologies for treating prostate cancer," *Journal of Clinical Oncology*, 29, no. 12 (2011): 1517-24. Because Medicare beneficiaries often face cost-sharing requirements, more expensive treatments likely lead to higher beneficiary costs.

[22]To determine the effect of the payment reduction, we calculated the cost of a course of IMRT to treat prostate cancer using 2013 Medicare reimbursement rates and previously published methodologies. For an example of a methodology used, see Andre Konski et al., "Using Decision Analysis to Determine the Cost-Effectiveness of Intensity-Modulated Radiation Therapy in the Treatment of Intermediate Risk Prostate Cancer," *International Journal of Radiation Oncology • Biology • Physics* 66, no. 2 (2006): 408-15.

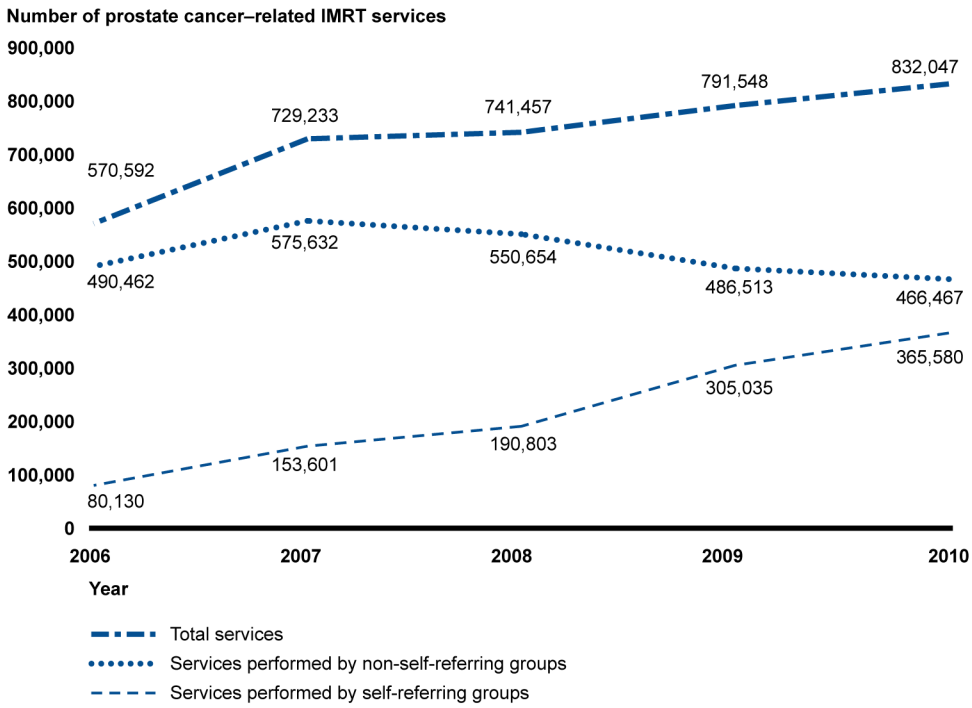
Number of and Expenditures for Prostate Cancer–Related IMRT Services Provided by Self-Referring Groups Grew Rapidly, while Declining for Non-Self-Referring Groups

We found that the number of and expenditures for Medicare prostate cancer–related IMRT services performed by self-referring groups grew rapidly from 2006 through 2010. In contrast, the number of and Medicare expenditures for prostate cancer–related IMRT services performed by non-self-referring groups declined over the period.

Number of Prostate Cancer–Related IMRT Services Performed Increased among Self-Referring Groups—Specifically, Limited-Specialty Groups—and Decreased among Non-Self-Referring Groups

From 2006 through 2010, the number of prostate cancer–related IMRT services performed by self-referring groups increased rapidly, while the number performed by non-self-referring groups decreased. The number of prostate cancer–related IMRT services performed by self-referring groups increased from approximately 80,000 to 366,000, an annual growth rate of 46 percent (see fig. 1). Consistent with that growth, the number of self-referring groups also increased rapidly over the period. In contrast, the number of prostate cancer–related IMRT services performed by non-self-referring groups in physician offices decreased from approximately 490,000 to 466,000, an annual decrease of 1 percent.

Figure 1: Number of Medicare Prostate Cancer–Related IMRT Services Performed by Self-Referring and Non-Self-Referring Groups in Physician Offices, 2006-2010



Source: GAO analysis of CMS data.

The rapid increase in prostate cancer–related IMRT services performed by self-referring groups coincided with several other trends from 2006 through 2010. First, the number of prostate-cancer related IMRT services performed in hospital outpatient departments and by self-referring and non-self-referring groups all grew from 2006 to 2007. After 2007, the rapid increase in prostate cancer–related IMRT services performed by self-referring groups coincided with declines in these services within hospital outpatient departments and among non-self-referring groups. Overall utilization of prostate cancer–related IMRT services therefore remained relatively flat across these settings after 2007, indicating a shift away from hospital outpatient departments and non-self-referring groups and toward self-referring groups. (See app. II for information on the trends in IMRT services performed in hospital outpatient departments.) Second, while the number of prostate cancer–related IMRT services provided to Medicare fee-for-service (FFS) beneficiaries has stabilized since 2007, the

percentage of newly diagnosed Medicare beneficiaries receiving IMRT has increased.[23] While seemingly contradictory, these two trends occurring simultaneously can in part be explained by (1) a decrease in the total number of Medicare FFS beneficiaries from 2006 through 2010[24] and (2) a decrease in the number of men newly diagnosed with prostate cancer.[25] Third, the increasing percentage of prostate cancer patients receiving IMRT may partially be explained by a shift from an older form of EBRT—3D-CRT—to a newer form—IMRT, though the largest effect of this substitution likely occurred earlier in our study period as IMRT largely replaced 3D-CRT by 2007.[26]

Our analysis showed that, from 2006 through 2010, the growth in prostate cancer–related IMRT services performed by self-referring groups was entirely due to an increase in the services performed by limited-specialty groups (see fig. 2). Limited-specialty groups were comprised of urologists and a small number of other specialties.[27] Over our study period, the number of prostate cancer–related IMRT services performed by limited-specialty self-referring groups increased over fivefold, from approximately

[23]Specifically, our analysis of the distribution of treatments among men newly diagnosed with prostate cancer indicates that 33.7 percent and 36.8 percent of men diagnosed with prostate cancer in 2007 and 2009, respectively, were referred for IMRT.

[24]As a result of increased enrollment in Medicare Advantage, the number of Medicare FFS beneficiaries aged 65 and older decreased from 2006 to 2010, going from approximately 27.6 million to 26.4 million.

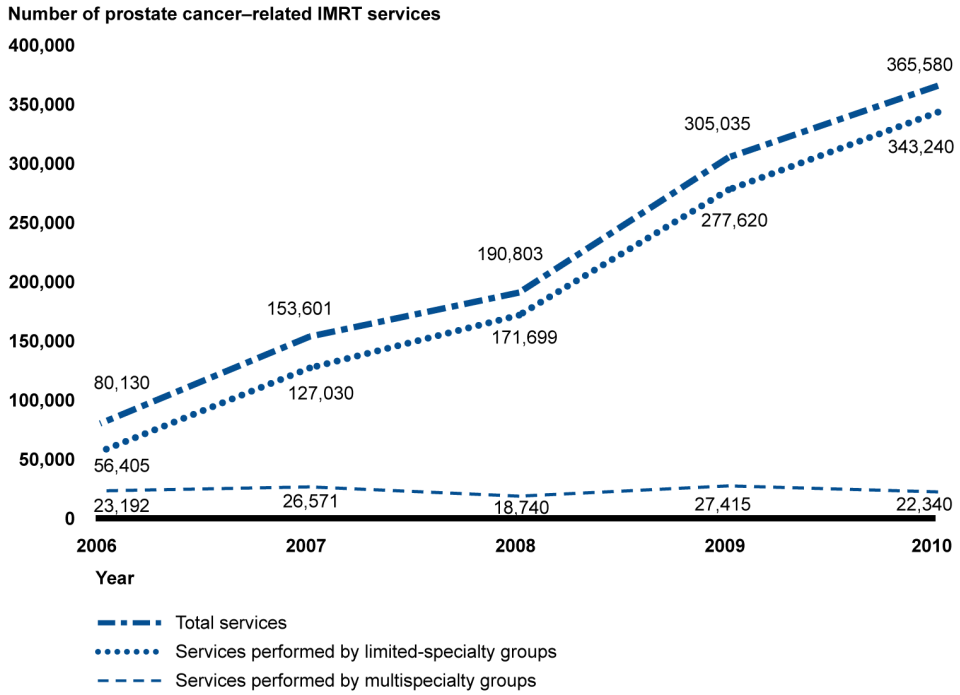
[25]In our analysis of the distribution of treatments among men newly diagnosed with prostate cancer, we found a 19 percent decrease in the number of Medicare FFS beneficiaries who were diagnosed with prostate cancer and met our other inclusion criteria in 2009 compared to 2007—58,289 and 71,834, respectively. In accordance with that, the number of prostate biopsies provided to Medicare FFS beneficiaries, which some researchers have used as a proxy for prostate cancer diagnoses, stayed relatively flat from 2006 to 2007 but then decreased by approximately 20 percent from 2007 through 2010. Others have also noted a decline in reported prostate cancer incidence over a similar period. For instance, see: David H. Howard, "Declines in Prostate Cancer Incidence After Changes in Screening Recommendations," *Archives of Internal Medicine* 172, no. 16 (Sept. 10, 2012): 1267-68.

[26]Bruce L. Jacobs et al., "Growth of High-Cost Intensity-Modulated Radiotherapy for Prostate Cancer Raises Concerns About Overuse," *Health Affairs* 31, no. 4 (April 2012): 750-59.

[27]In 2010, urologists performed approximately 89.1 percent of office visits billed under limited-specialty groups, compared to 5.7 percent for multispecialty groups. Additionally, the average number of specialties that billed office visits under limited-specialty groups in 2010 was 3.3, compared to 36.2 for multispecialty groups.

56,000 to 343,000. In contrast, the number of such services performed by multispecialty self-referring groups, which were comprised of a large number of different provider types, declined slightly, going from approximately 23,000 to 22,000.

Figure 2: Number of Medicare Prostate Cancer–Related IMRT Services Performed by Limited-Specialty and Multispecialty Self-Referring Groups, 2006-2010



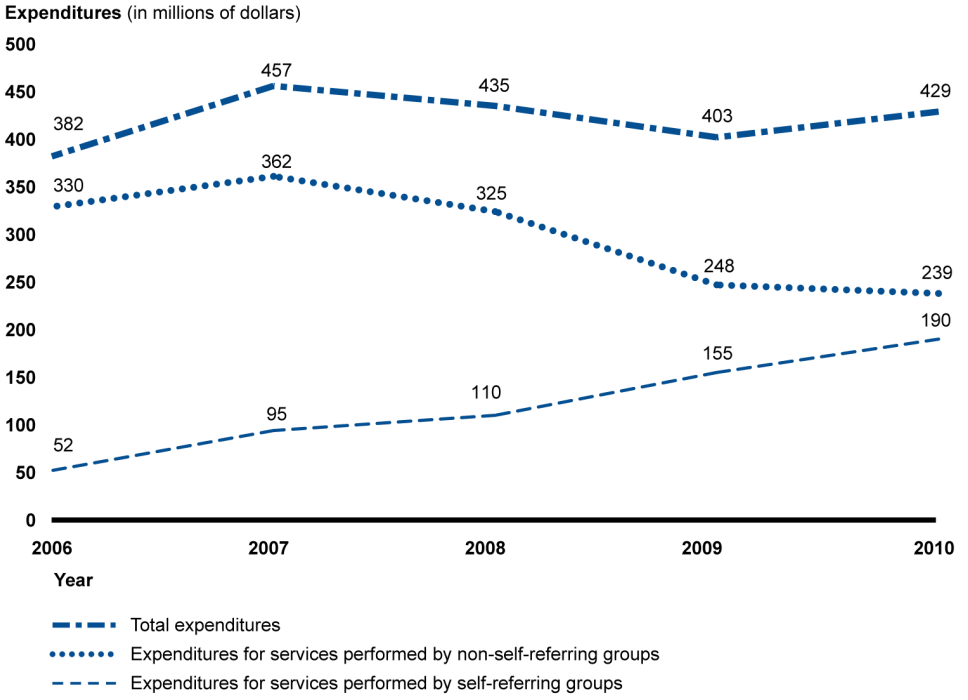
Source: GAO analysis of CMS data.

Notes: In 2006 and 2008, less than 1 percent of total services could not be attributed to either limited-specialty or multispecialty groups. We defined groups as limited specialty in a given year if more than 75 percent of its office visits were performed by urologists, nonphysician practitioners (e.g., physician assistants), or providers whose specialty was related to the diagnosis or treatment of cancer, such as radiation oncologists. The remaining groups were comprised of providers from a large number of different specialties and were considered multispecialty groups.

Expenditures for Prostate Cancer–Related IMRT Services Performed by Self-Referring Groups Increased Rapidly, while Declining for Non-Self-Referring Groups

Medicare expenditures for prostate cancer–related IMRT services performed by self-referring groups increased rapidly from 2006 through 2010, while decreasing for services performed by non-self-referring groups. Specifically, expenditures for prostate cancer–related IMRT services performed by self-referring groups increased from $52 million to $190 million, an average increase of 38 percent a year (see fig. 3). In contrast, expenditures for prostate cancer–related IMRT services performed by non-self-referring groups in physician offices declined by an average of 8 percent a year. For comparison, expenditures for prostate cancer–related IMRT services performed in hospital outpatient departments grew an average of 7 percent a year during the period we studied. (For more information about hospital outpatient department expenditure trends, see app. II.)

Figure 3: Changes in Medicare Prostate Cancer–Related IMRT Expenditures for Services Performed by Self-Referring and Non-Self-Referring Provider Groups in Physician Offices, 2006-2010



Source: GAO analysis of CMS data.

Self-Referring Providers Referred Their Prostate Cancer Patients for IMRT More Frequently than Non-Self-Referring Providers

Self-referring providers were more likely to refer their Medicare prostate cancer patients for IMRT and less likely to refer them for other treatments when compared to non-self-referring providers. In addition, after providers began self-referring IMRT services, they substantially increased the percentage of their prostate cancer patients they referred for IMRT, in contrast to providers who did not begin to self-refer IMRT services during the same period.

Self-Referring Providers Were 53 Percent More Likely to Refer Their Prostate Cancer Patients for IMRT than Non-Self-Referring Providers

Self-referring providers were more likely to refer their prostate cancer patients for IMRT and less likely to refer them for other treatments compared to non-self-referring providers. Self-referring providers referred approximately 52 percent of their patients who were newly diagnosed with prostate cancer in 2009 for IMRT, while non-self-referring providers referred 34 percent of their patients for IMRT (see table 2). Self-referring providers also referred a lower percentage of their prostate cancer patients for nearly all other types of treatments compared to non-self-referring providers, with the largest differences among patients being referred for brachytherapy or a radical prostatectomy.[28] Other differences were smaller—self-referring providers were about 8 percent less likely to refer their patients for active surveillance compared to non-self-referring providers. (For alternative groupings in which beneficiaries are sorted into discrete treatment categories, see app. III.)

[28]Other than IMRT, the only type of treatment for which self-referring providers did not refer a lower percentage of their prostate cancer patients compared to non-self-referring providers was proton therapy.

Table 2: Percentage of Self-Referring and Non-Self-Referring Providers' Medicare Patients Referred for a Given Treatment after a Diagnosis of Prostate Cancer in 2009

Prostate cancer treatment	Percentage of non-self-referring providers' patients referred for a given treatment (N=48,298)	Percentage of self-referring providers' patients referred for a given treatment (N=9,991)	Percentage point difference	Percentage more or less likely self-referring providers were to refer patients for a given treatment compared to non-self-referring providers
Intensity-modulated radiation therapy	33.7%	51.7%	18.0	53.5%
Active surveillance	22.9	21.0	-1.9	-8.2
Radical prostatectomy	18.0	13.1	-4.9	-27.0
Hormone therapy only[a]	11.4	7.7	-3.8	-32.9
Brachytherapy	14.0	7.0	-7.0	-50.0
Other treatments[b]	6.0	3.2	-2.8	-46.5
Three-dimensional conformal radiation therapy / other external beam radiation therapy	2.4	1.1	-1.3	-55.2

Source: GAO analysis of CMS data.

Notes: Treatment categories do not sum to 100 percent because, with the exception of active surveillance and hormone therapy only, a patient was counted in more than one treatment category if he received a combination of therapies. Including combinations involving hormone therapy, self-referring and non-self-referring providers referred nearly equal percentages of their patients for a combination of treatments—27 percent and 26 percent, respectively.

[a]Prostate cancer patients also commonly receive hormone therapy in conjunction with other treatments. Self-referring providers referred 31.9 percent of their prostate cancer patients for any hormone therapy, while non-self-referring providers referred 33.7 percent.

[b]"Other treatments" consists of cryoablation, stereotactic body radiotherapy / stereotactic radiosurgery, and proton therapy. Self-referring providers were less likely to refer their patients for cryoablation and stereotactic body radiotherapy / stereotactic radiosurgery compared to non-self-referring providers, but both types of providers referred the same percentage of their patients for proton therapy—approximately 1 percent.

The difference between self-referring and non-self-referring providers in the percentage of their prostate cancer patients referred for IMRT was largely due to self-referring providers who belonged to limited-specialty groups. Self-referring providers who belonged to a limited-specialty group referred approximately 52 percent of their patients diagnosed with prostate cancer in 2007 or 2009 for IMRT.[29] In contrast, self-referring

[29]Because only a small percentage of beneficiaries were referred by providers who belonged to a multispecialty group, we combined beneficiaries diagnosed with prostate cancer in 2007 or 2009. Of that population, approximately 92 percent were referred by a provider who belonged to a limited-specialty group, compared to 8 percent who were referred by a provider who belonged to a multispecialty group.

providers who belonged to a multispecialty group referred approximately 36 percent of their patients diagnosed with prostate cancer in 2007 or 2009 for IMRT, only moderately higher than the 33 percent of non-self-referring providers' patients diagnosed with prostate cancer in 2007 or 2009 who were referred for IMRT.

Differences in the percentage of prostate cancer patients referred for IMRT between self-referring and non-self-referring providers persisted after accounting for differences in age, geographic location (i.e., urban or rural), and beneficiary health, including clinical characteristics of prostate cancers for a subset of beneficiaries who lived in New York.

Age

Differences between self-referring and non-self-referring providers in the percentage of prostate cancer patients that were referred for IMRT could not be explained by differences in age. The average age when a beneficiary was diagnosed with prostate cancer was the same for patients of both self-referring and non-self-referring providers, and, regardless of their patients' ages, self-referring providers were more likely to refer their patients for IMRT compared to non-self-referring providers. The average age when a beneficiary was diagnosed with prostate cancer was 74 years old for patients of both self-referring and non-self-referring providers. Depending on the age range, self-referring providers were anywhere from 48 percent to 62 percent more likely to refer their patients for IMRT compared to non-self-referring providers. For more information about how the percentage of prostate cancer patients referred for IMRT and other treatments by self-referring and non-self-referring providers changed on the basis of the age of a beneficiary, see appendix IV.

Geographic Location

Differences between self-referring and non-self-referring providers in the percentage of prostate cancer patients that were referred for IMRT could not be explained by differences in geographic location. Self-referring providers were more likely to refer their patients for IMRT compared to non-self-referring providers, regardless of differences in geographic location.[30] Self-referring providers were 52 percent more likely to refer their patients that lived in urban areas for IMRT compared to non-self-referring providers. Similarly, self-referring providers were 42 percent

[30]Approximately 84 percent of self-referring providers' prostate cancer patients lived in urban areas compared to approximately 68 percent of non-self-referring providers' patients.

more likely to refer their patients that lived in rural areas for IMRT compared to non-self-referring providers.

Beneficiary Health

Differences between self-referring and non-self-referring providers in the percentage of prostate cancer patients that were referred for IMRT could not be explained by differences in beneficiary health. Self-referring and non-self-referring providers' prostate cancer patients had a similar average health status, and self-referring providers were more likely to refer their patients for IMRT compared to non-self-referring providers, regardless of whether their patients had low-, intermediate-, or high-risk prostate cancer. Self-referring providers' patients had an average risk score—a proxy for health status—of 0.94 in 2009, and non-self-referring providers' patients had an average risk score of 0.92, indicating that the two patient populations had a similar average health status.[31] In cases where we had information on the clinical characteristics of patients' prostate cancer, we found that self-referring providers were more likely than non-self-referring providers to refer their patients for IMRT, although the difference decreased as prostate cancer risk level increased. Specifically, self-referring providers were 91 percent, 41 percent, and 33 percent more likely than non-self-referring providers to refer patients with low-, intermediate-, and high-risk prostate cancer for IMRT, respectively.[32] The difference in IMRT referrals made by self-referring and non-self-referring providers narrowed as patients' prostate cancer risk level increased in part because non-self-referring providers increased IMRT referrals and decreased brachytherapy referrals as cancer risk levels increased. In comparison, self-referring providers referred similarly small percentages of patients for brachytherapy for all three risk levels,

[31]A beneficiary's risk score is a proxy for health status and is equivalent to the ratio of expected health care expenditures for the beneficiary under Medicare FFS relative to the average health care expenditures for all Medicare FFS beneficiaries. For example, a beneficiary with a risk score of 1.05 would have expected expenditures that were 5 percent higher than an average Medicare FFS beneficiary.

[32]Self-referring providers were also 43 percent more likely to refer their patients for IMRT compared to non-self-referring providers for patients who could not be assigned a risk category. Because the New York State Cancer Registry contains some cancer characteristics obtained after patients received treatment, we also reran this analysis twice after restricting the population to patients (1) for whom the extent of the cancer was determined before treatment and (2) who did not receive a radical prostatectomy. For both of these analyses, the results were similar to the original analysis—self-referring providers were between 25 percent and 87 percent more likely to refer their patients for IMRT compared to non-self-referring providers, depending on whether the cancer was low, intermediate, or high risk.

and their IMRT referrals increased only moderately as their patients' risk level increased.[33]

Providers Substantially Increased the Percentage of Their Prostate Cancer Patients They Referred for IMRT after They Began to Self-Refer

Providers that switched from being non-self-referring to self-referring—that is, switchers—referred a greater percentage of their prostate cancer patients for IMRT after they began to self-refer (see table 3). Specifically, switchers referred 37 percent of their patients who were diagnosed with prostate cancer in 2007 for IMRT. After beginning to self-refer, switchers referred 54 percent of their patients who were diagnosed with prostate cancer in 2009 for IMRT. While providers that did not begin to self-refer—that is, self-referrers and non-self-referrers—referred different percentages of their patients who were diagnosed with prostate cancer in 2007 for IMRT, the percentages of their patients they referred for IMRT remained relatively consistent over the same period when switchers dramatically increased the percentage of their patients they referred for IMRT. This suggests that the increase seen among switchers was likely not due to provider characteristics that were relatively stable over time or changes in the way all providers treated prostate cancer in response to such things as changing treatment guidelines. (See app. V for more information about how the percentage of beneficiaries switchers, non-self-referring providers, and self-referring providers referred for a given treatment.)

Table 3: Change in the Percentage of Medicare Prostate Cancer Patients Providers Referred for IMRT after a Diagnosis of Prostate Cancer in 2007 or 2009

Type of provider	Percentage of providers' patients referred for IMRT among beneficiaries diagnosed in 2007	Percentage of providers' patients referred for IMRT among beneficiaries diagnosed in 2009	Percentage point change from 2007 to 2009	Percentage more or less likely providers were to refer patients for IMRT in 2009 compared to 2007
Non-self-referring	31.4%	33.1%	1.7	5.5%
Self-referring	55.7	52.9	-2.8	-5.1
Switcher	37.0	54.2	17.2	46.6

Source: GAO analysis of CMS data.

[33]While the difference between self-referring and non-self-referring providers narrowed, non-self-referring providers were still more likely to refer their patients with intermediate- and high-risk prostate cancer for brachytherapy compared to self-referring providers. This includes brachytherapy as a sole treatment or brachytherapy received in combination with another treatment, such as a form of EBRT.

Notes: We define switchers as those providers that did not self-refer in 2006 or 2007 but began to self-refer in either 2008 or 2009. In 2007, switchers, self-referring providers, and non-self-referring providers referred 4,903, 1,776, and 42,471 prostate cancer patients for treatment, respectively. In 2009, switchers, self-referring providers, and non-self-referring providers referred 4,156, 1,244, and 34,107 prostate cancer patients for treatment, respectively.

Conclusions

IMRT has been shown to be an effective treatment option for localized prostate cancer and allows radiation to be delivered to the tumor while minimizing damage to normal tissue. Proponents of self-referral arrangements contend that the self-referral of IMRT services does not affect clinical decision making and that patients benefit from self-referral through, for example, improved coordination among the providers who diagnose and treat patients. However, our review indicates that Medicare providers that self-referred IMRT services—particularly those practicing in limited-specialty groups—were substantially more likely to refer their prostate cancer patients for IMRT and less likely to refer them for other, less costly treatments, especially brachytherapy or a radical prostatectomy, compared to providers who did not self-refer. The relatively higher rate of IMRT referrals among self-referring providers cannot be explained by beneficiary age, geographic location, or health. Consistent with these findings, we also found that after providers began to self-refer IMRT services they substantially increased the percentage of their prostate cancer patients they referred for IMRT, while providers that did not begin to self-refer experienced much smaller changes over the same period. Taken together, our findings suggest that financial incentives were likely a major factor driving the increase of IMRT referrals among self-referring providers in limited-specialty groups.

The greater use of IMRT by self-referring Medicare providers to treat prostate cancer raises two potential concerns. First, because physician recommendations play a large role in influencing a patient's treatment decision, a financial interest in one treatment option may diminish the role that other criteria—such as life expectancy, overall health, patient preferences, and clinical characteristics of the prostate cancer—play in the decision-making process. Despite the fact that several treatment options are often considered equally appropriate, the higher use of IMRT among providers who self-refer seems problematic because prostate cancer treatments differ in terms of their risks and side effects, such as the likelihood of developing sexual, urinary, or bowel-related side effects. To the extent that providers' financial interests are shaping treatment decisions, some patients may end up on a treatment course that does not best meet their individual needs. Second, because IMRT costs more than most other treatments, the higher use of IMRT by self-referring providers

results in higher costs for Medicare and beneficiaries. To the extent that treatment decisions are driven by providers' financial interest and not by patient preference, these increased costs are difficult to justify.

Given self-referral's potential effect on both the Medicare program and beneficiaries, it is imperative that CMS improve its ability to identify and monitor the effects of such services. CMS is not currently well-positioned to address self-referring providers' financial incentive to refer their prostate cancer patients for IMRT, as CMS currently does not have a method for easily identifying such services. Without a way to identify self-referred services, such as a self-referral flag on Medicare Part B claims, CMS does not have the ongoing ability to monitor self-referral and its effects on beneficiary treatment selection and costs to both Medicare and beneficiaries.

In addition, Medicare providers who self-refer IMRT services are generally not required to disclose their financial interest in IMRT. Thus, beneficiaries may not be aware that their provider has an incentive to recommend IMRT over alternative treatments which may be equally effective, have different risks and side effects, and are less expensive for Medicare and beneficiaries. Beneficiaries need to select among different prostate cancer treatment options, and beneficiary knowledge of a referring provider's financial interest in IMRT may be an important consideration in making these selections. Currently, the Department of Health and Human Services (HHS), the agency that administers CMS, lacks the authority to establish a disclosure protocol for providers who self-refer IMRT services.

Matter for Congressional Consideration

To increase beneficiaries' awareness of providers' financial interest in a particular treatment, Congress should consider directing the Secretary of Health and Human Services to require providers who self-refer IMRT services to disclose to their patients that they have a financial interest in the service.

Recommendation for Executive Action

We recommend that the Administrator of CMS insert a self-referral flag on its Medicare Part B claims form, require providers to indicate whether the IMRT service for which a provider bills Medicare is self-referred, and monitor the effects that self-referral has on costs and beneficiary treatment selection.

Agency and Third-Party Comments and Our Evaluation

We provided a draft of this report to HHS for comment. HHS provided written comments, which are reprinted in appendix VI. We also obtained oral comments from representatives of three professional associations selected because they represent stakeholders with specific involvement in prostate cancer–related IMRT services.

The three associations were the American Society for Radiation Oncology (ASTRO), which represents radiation oncologists; the American Urological Association (AUA), which represents urologists; and the Large Urology Group Practice Association (LUGPA), which represents large urology group practices. We summarize and respond to comments from HHS and representatives from the three professional associations in the following sections.

HHS Comments

In its comments, which are reprinted in appendix VI, HHS stated that it did not concur with our recommendation. HHS did not comment on the matter for congressional consideration or the main finding of the report—that self-referring providers, particularly those belonging to limited-specialty groups, referred a substantially higher percentage of their prostate cancer patients for IMRT.

HHS did not concur with our recommendation that CMS insert a self-referral flag on its Medicare Part B claims form, require providers to indicate whether the IMRT service for which a provider bills Medicare is self-referred, and monitor the effects that self-referral has on costs and beneficiary treatment selection. HHS stated that flagging self-referred services and tracking their effects would not address overutilization that occurs as a result of self-referral, would be complex to administer, and may have unintended consequences, which HHS did not delineate. In addition, HHS stated that the President's fiscal year 2014 budget proposal includes a provision to exclude certain services from the in-office ancillary services (IOAS) exception. To the extent that self-referral for IMRT services continues to be permitted, we believe that including an indicator or flag on the claims would be an effective way to identify and track self-referral and would give CMS the ability to analyze the effects of self-referral on utilization patterns. Furthermore, we do not believe an indicator or flag on the claims would be complex to administer, as CMS requires providers to use similar indicators to provide additional information about certain other services.

On the basis of HHS's written response to our report, we are concerned that HHS does not appear to recognize the effects IMRT self-referral can have on beneficiaries and the Medicare program. HHS did not comment on our matter for congressional consideration or our key finding that self-referring providers, particularly those belonging to limited specialty groups, referred a substantially higher percentage of their prostate cancer patients for IMRT. Given the magnitude of these findings, we continue to believe that CMS should take steps to monitor the impact that IMRT self-referral has on costs and treatment selection.

HHS also provided technical comments that we incorporated as appropriate.

Professional Association Comments

American Society for Radiation Oncology

ASTRO representatives generally agreed with our findings but thought our recommendation and matter for congressional consideration should be stronger. They said we should recommend that Congress close the IOAS exception because the findings from the report, in combination with previous self-referral research we and others have published, indicate the necessity for such an action. An examination of the IOAS was beyond the scope of our work. To the extent that IMRT self-referral is still permissible, ASTRO representatives also said that inserting a self-referral flag would not be an effective way to identify self-referral. Instead, they suggested implementing reporting requirements similar to the financial transparency requirements for physician-owned specialty hospitals under PPACA and requiring self-referring providers to indicate on their Medicare provider enrollment forms their financial interest in referrals. Further, ASTRO representatives said that self-referring providers should be required to notify patients that they may receive IMRT at alternative locations and that other treatment options are available. We continue to believe that inserting a self-referral flag on Medicare Part B claims would be an effective way to track and monitor self-referral and that beneficiary awareness of their providers' financial interests is important. However, to the extent that other strategies exist that would allow CMS to increase beneficiary awareness and monitor self-referral, such efforts would be consistent with the intent of our recommendation and matter for congressional consideration.

American Urological Association

AUA representatives said we did not have sufficient evidence to link financial incentives to the increase in IMRT use among self-referring providers and disagreed with our conclusion that financial incentives for self-referring providers belonging to limited specialty groups were likely a major factor driving the increase in the percentage of prostate cancer patients referred for IMRT. Specifically, AUA representatives said the flat trend in the utilization of prostate cancer-related IMRT services from 2007 through 2010 indicates utilization has simply shifted from hospital outpatient departments to physician offices and that this trend undermines our conclusion that financial incentives increase IMRT use. As explained in our report, the trend in the percentage of patients newly diagnosed with prostate cancer referred for IMRT was not flat; instead, it increased over the study period. This increase occurred while the utilization of IMRT services remained about the same in part because the annual number of Medicare FFS beneficiaries who were diagnosed with prostate cancer declined by about 20 percent over our study period. In addition, we found that self-referring providers, which were predominantly from limited-specialty groups, referred a higher percentage of their Medicare FFS patients for IMRT than did other providers and that their higher IMRT referral rate could not be explained by differences in age, geographic location, or beneficiary health. As a result, we continue to believe that financial incentives were likely a major factor driving the higher IMRT referral rate of self-referring providers from limited-specialty groups.

AUA representatives had several other critiques of our report. Specifically, they indicated that we did not put enough emphasis on the patient's role in choosing a treatment and expressed concern that we did not include more clinical information on patients' prostate cancer, such as information on cancer stage and grade, or include Medicare Advantage beneficiaries in our study population. We address two of these critiques in the report. Specifically, we note that patient preference is one of many factors that affect a beneficiary's treatment decision, and we include clinical information on patients' prostate cancer for a subset of beneficiaries from New York.[34] However, we did not include Medicare

[34]We used clinical information from the New York State Cancer Registry because such information is not available on Medicare claims, and we determined that the geographic areas included in another common source of such information—Surveillance Epidemiology and End Results (SEER) data—did not sufficiently overlap with areas in which IMRT self-referral was prevalent during our study period.

Advantage beneficiaries in our study population because Medicare Advantage plans are not required to submit claims to CMS, and, thus, we do not have detailed information on the services Medicare Advantage beneficiaries receive or the providers who refer and perform those services.

Finally, AUA representatives stated that the declining percentage of self-referring providers' patients referred for brachytherapy from 2007 to 2009 could reflect a change in practice standards, as they said brachytherapy is no longer recommended as a sole treatment for intermediate- and high-risk prostate cancer. While we note that brachytherapy use has declined even among providers who do not self-refer, we do not believe that changing guidelines or the possibility of differences in guideline adherence between non-self-referring and self-referring providers could explain in totality why self-referring providers refer a smaller percentage of their patients for brachytherapy. First, self-referring providers referred a substantially lower percentage of their patients for brachytherapy, even after accounting for the decline in brachytherapy use for both non-self-referring and self-referring providers from 2007 to 2009. Second, among those patients for whom we had clinical data, the biggest differences in IMRT and brachytherapy use between self-referring and non-self-referring providers were for patients with low-risk cancer, which would not be affected by the change in practice guidelines for intermediate- and high-risk prostate cancer the AUA representatives referenced.

Large Urology Group Practice Association

LUGPA representatives disagreed with our conclusion that financial incentives for self-referring providers—specifically those in limited-specialty groups—were likely a major factor driving the increase in the percentage of prostate cancer patients referred for IMRT. Instead, they said patient preference and an increase in the number of self-referring providers explain the increase in IMRT utilization by self-referring providers. While we did not perform our trend analysis at the provider level, we do note in the report that the number of self-referring groups increased substantially over our study period. This corresponds with a shift in the location where patients received IMRT, from hospital outpatient departments to physician offices. However, these trends that we note do not negate our analysis of the referral patterns of self-referring providers. Specifically, self-referring providers who belonged to a limited-specialty group referred a higher percentage of their newly diagnosed prostate cancer patients for IMRT, and, thus, the increased number of

self-referring providers has also resulted in a higher percentage of patients receiving IMRT. Also, LUPGA representatives said the increase in the percentage of self-referring providers' patients referred for IMRT could be due to such patients more frequently consulting with radiation oncologists before initiating treatment, which one study indicated leads to higher utilization of radiation therapy, defined as EBRT or brachytherapy.[35] We believe it is unlikely that access to a radiation oncologist drove the differences in IMRT referrals between self-referring and non-self-referring providers because self-referring providers who belonged to a multispecialty group referred a substantially lower percentage of their patients for IMRT compared to self-referring providers who belonged to a limited-specialty group, despite the likelihood that patients in both instances had access to a radiation oncologist within the group practice.

LUGPA raised several other points of concern about our review. First, LUGPA representatives said our assertion that IMRT, brachytherapy, and a prostatectomy are clinically equivalent treatments is inappropriate. We disagree with LUGPA's characterization of our discussion of IMRT, brachytherapy, and a prostatectomy as treatment options. We recognize that these treatments are not equally appropriate for all men diagnosed with prostate cancer and do not assert that in our report. Rather, we say that these treatments are often—not always—considered equally appropriate and give an example of when they are considered equally appropriate—men with low-risk prostate cancer. We also recognize that, for any particular patient, a given treatment might not be appropriate due to considerations such as age and comorbidities. Second, LUGPA representatives said that we did not acknowledge that all sites of services have essentially identical financial incentives to perform services for which they receive compensation. They said our work showed the percentage of newly diagnosed prostate cancer patients referred for active surveillance was nearly equal between self-referring and non-self-referring providers and that this was evidence that self-referring providers treat patients based on patient choice and sound clinical decision making. We disagree with LUGPA's assertion that the percentage of newly

[35]Thomas L. Jang et al., "Physician Visits Prior to Treatment for Clinically Localized Prostate Cancer," *Archives of Internal Medicine* 172, no.5 (March 8, 2010): 440-450.

diagnosed prostate cancer patients referred for active surveillance was nearly equal between self-referring and non-self-referring providers, as self-referring providers were approximately 8 percent less likely to refer their patients for active surveillance than were non-self-referring providers. As we note in the report, IMRT is more costly than other treatments for prostate cancer, resulting in a financial incentive for self-referring providers to refer their patients for IMRT over other treatments. We found that self-referring providers referred a higher percentage of their patients for IMRT than did non-self-referring providers and that the difference in IMRT referral rates could not be explained by variations in patient age, geographic location, or patient health status. As a result, we continue to believe that self-referring providers' higher IMRT referral rates are driven by a financial incentive for these providers to refer newly diagnosed prostate cancer patients for IMRT. Third, LUGPA representatives said we should have studied the use of IMRT for conditions other than prostate cancer. The use of IMRT to treat other conditions was outside the scope of our work. Finally, LUGPA representatives indicated that our estimates of 3D-CRT utilization for newly diagnosed prostate cancer patients are too low. We believe our calculation of the percentage of patients who were newly diagnosed with prostate cancer in 2009 and referred for 3D-CRT is accurate. We solicited input from multiple physician associations, including members of LUGPA, regarding the appropriate HCPCS codes to use to track 3D-CRT and examined 100 percent of claims from the Medicare Carrier and hospital outpatient department files to identify all 3D-CRT services received by newly diagnosed prostate cancer patients.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services, interested congressional committees, and others. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff has any questions about this report, please contact me at (202) 512-7114 or cosgrovej@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix VII.

James C. Cosgrove
Director, Health Care

List of Requesters

The Honorable Max Baucus
Chairman
Committee on Finance
United States Senate

The Honorable Chuck Grassley
Ranking Member
Committee on the Judiciary
United States Senate

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
House of Representatives

Appendix I: Scope and Methods

This section describes the scope and methodology used to analyze our two objectives: (1) comparing trends in the number of and expenditures for Medicare prostate cancer–related intensity-modulated radiation therapy (IMRT) services provided by self-referring and non-self-referring groups from 2006 through 2010 and (2) examining how the percentage of Medicare prostate cancer patients referred for IMRT may differ on the basis of whether providers self-refer.

To compare trends in the number of and expenditures for prostate cancer–related IMRT services provided in physician offices or hospital outpatient departments from 2006 through 2010, we analyzed IMRT claims from the Medicare Part B Carrier and hospital outpatient files.[1] We identified IMRT services on the basis of Healthcare Common Procedure Coding System (HCPCS) codes associated with the delivery of IMRT—77418 and 0073T.[2] We classified IMRT services as related to prostate cancer if the principal diagnosis code was 185 or 233.4—malignant neoplasm of the prostate or carcinoma in situ of prostate, respectively—or if one of these codes was billed on an IMRT claim and no other diagnosis code related to another cancer was billed on the same claim.

To determine whether prostate cancer–related IMRT services from 2006 through 2010 were performed by self-referring or non-self-referring provider groups, we first limited our analysis to only those IMRT services in the Medicare Part B Carrier file.[3] Because there is no indicator or "flag" on the claim that identifies whether services are self-referred or non-self-referred and the Centers for Medicare & Medicaid Services (CMS), the

[1]We also used the Part B National Summary Data Files to track the total number of prostate biopsies from 2006 through 2010. The Medicare Part B Carrier File contains final action Medicare Part B claims for noninstitutional providers, such as physicians. The Medicare hospital outpatient file contains final action, fee-for-service claims data submitted by institutional outpatient providers, such as hospital outpatient departments.

[2]Medicare expenditure amounts for these codes include beneficiary cost sharing throughout this report. IMRT delivery codes represent individual treatment sessions during which patients receive radiation. In addition to receiving radiation, patients receive several different types of services during a course of IMRT.

[3]Our analysis of self-referred prostate cancer–related IMRT services is limited to those services performed in physician offices. We focused on this setting because our work showed rapid growth in this setting compared to hospital outpatient departments and because the financial incentive for providers to self-refer is most direct when the service is performed in a physician office. We refer to services billed through the Carrier file as services performed in physician offices.

agency that administers Medicare, has no other method for identifying whether a service was self-referred, we developed a claims-based methodology for identifying provider group practices as self-referring or non-self-referring.[4] We classified groups, identified by taxpayer identification numbers (TIN)—an identification number used by the Internal Revenue Service—as self-referring in a given year if: (1) we could identify a prostate biopsy for at least 50 percent of the prostate cancer–related IMRT episodes provided by groups,[5] (2) at least 50 percent of these episodes were self-referred, and (3) a group had a minimum number of 10 self-referred IMRT episodes.[6] The remaining groups were considered non-self-referring.[7] To ensure that how we defined our criteria were reliable, we tested alternative thresholds for defining self-referring groups and found that, regardless of specification, the rapid growth of services performed by self-referring groups persisted and that the growth was due to limited-specialty groups. A patient's episode of prostate cancer–related IMRT was considered self-referred if the provider who performed his prostate biopsy and the performing provider(s) on the IMRT claim(s) billed to the same TIN in the year(s) the IMRT services were performed, the year the biopsy was performed, or the year between, if applicable.[8] To find prostate biopsies for beneficiaries, we searched through 2 years of their claims history to find the prostate biopsy nearest to, but not after, the date of their first IMRT service. If a beneficiary received multiple episodes of IMRT from 2006 through 2010,

[4]An indicator or "flag" could be, for example, a modifier that a provider lists on a claim to indicate that a service is self-referred. Providers currently use modifiers to provide additional information about a service to CMS.

[5]From 2006 through 2010, beneficiaries could receive multiple episodes of prostate cancer–related IMRT. We defined an episode of IMRT as a contiguous group of IMRT services not separated by more than 7 days. If a beneficiary had more than one prostate-cancer related IMRT episode over the course of our study, we classified each episode as self-referred or non-self-referred separately.

[6]Respectively, these restrictions were made to ensure that we (1) did not classify groups as self-referring on the basis of a small percentage of the IMRT episodes they provided, (2) classified groups on the basis of the predominant way in which the group practiced, and (3) had an adequate number of IMRT episodes to accurately categorize groups.

[7]Services performed by non-self-referring groups in the physician office setting could include services provided in places such as freestanding cancer centers.

[8]Self-referral occurs when providers refer their patients to entities—such as themselves or a group practice—in which they or a member of their families has a financial relationship. We used TINs to identify financial relationships between the provider who performed the prostate biopsy and the provider(s) who administered IMRT.

we searched back 2 years from the date of the first IMRT service for each episode. We further defined self-referring provider groups as either limited-specialty or multispecialty groups. We defined groups as limited specialty if more than 75 percent of its office visits in a given year were performed by urologists, nonphysician practitioners, or physicians whose specialty was related to the diagnosis or treatment of cancer, such as radiation oncologists. The remaining self-referring groups were comprised of providers from a large number of different specialties and were considered multispecialty groups.

To examine how the percentage of prostate cancer patients referred for IMRT may differ on the basis of whether providers self-refer, we first identified a list of Medicare beneficiaries who were newly diagnosed with prostate cancer in 2007 or 2009. We used a Medicare claims-derived date from the Chronic Condition Data Warehouse (CCDW), a CMS database, that indicates the first occurrence of prostate cancer as a proxy for the date on which a beneficiary was diagnosed with prostate cancer. We further narrowed the list of prostate cancer patients we studied to those who (1) were at least 66 years of age on their date of diagnosis, (2) were continuously enrolled in Medicare Parts A and B in the year of, before, and after they were diagnosed,[9] and (3) received a prostate biopsy on the same day as or within 1 year prior to their diagnosis.[10] We then analyzed prostate cancer–related claims from the Medicare Part B Carrier and hospital outpatient files to determine what types of treatments these beneficiaries received from their diagnosis date through 1 year after that date.[11] We used the provider who performed a beneficiary's prostate biopsy that was nearest to his date of diagnosis as a proxy for the provider who referred the beneficiary for treatment. We classified referring

[9]This requirement includes not being enrolled in Medicare Advantage in the year of, before, or after a beneficiary's prostate cancer diagnosis.

[10]These restrictions removed beneficiaries for whom the diagnosis date could have been unrelated to when they were actually diagnosed with prostate cancer. For instance, a 65-year-old beneficiary could have been diagnosed with prostate cancer before aging onto Medicare, and, therefore, the claims-based diagnosis date could have represented when the beneficiary became eligible for Medicare rather than when he was first diagnosed.

[11]We did not determine whether treatments were curative or palliative. We also did not differentiate on the basis of the order of different treatment combinations or the duration of treatments. A prostate cancer patient was considered to have undergone active surveillance if he—in addition to meeting the general inclusion criteria—did not receive a service indicating that he received any other prostate cancer treatment within one year of diagnosis.

providers as self-referring if they were the performing provider on a claim that was paid to a self-referring provider group in the year of, before, or after a beneficiary's prostate cancer diagnosis. All other providers were considered non-self-referring. Similarly, we classified providers as belonging to a limited-specialty group if they were the performing provider on a claim that was paid to a limited-specialty provider group in the year of, before, or after a beneficiary's prostate cancer diagnosis. If a provider did not belong to a limited-specialty group, we considered the provider to belong to a multispecialty group.

To assess the possibility that beneficiary characteristics affected the types of treatments for which self-referring and non-self-referring providers referred their prostate cancer patients, we examined beneficiaries' (1) age at the time they were diagnosed with prostate cancer, (2) geographic location (i.e., urban or rural), and (3) health, including clinical characteristics of prostate cancers for a subset of beneficiaries who lived in New York. We determined a beneficiary's age at diagnosis using a beneficiary's date of birth and the date on which he was diagnosed with prostate cancer. We defined urban settings as metropolitan statistical areas, a geographic entity defined by the Office of Management and Budget as a core urban area of 50,000 or more population. We used rural-urban commuting area codes—a Census tract–based classification scheme that utilizes the standard Bureau of Census Urbanized Area and Urban Cluster definitions in combination with work-commuting information to characterize all of the nation's Census tracts regarding their rural and urban status—to identify beneficiaries as living in metropolitan statistical areas.[12] We considered all other settings to be rural. We used CMS's risk score file to identify average risk score, which serves as a proxy for beneficiary health status. For a subset of beneficiaries who lived in New York, we obtained clinical information on the beneficiaries' prostate cancer—including information used to determine whether the localized cancer was low, intermediate, or high risk—from the New York State Cancer Registry.[13] To establish whether a prostate cancer was low, intermediate, or high risk, we used a beneficiary's Gleason score, prostate-specific antigen (PSA), and tumor

[12]We considered a location with a rural-urban commuting area code of 1.0, 1.1, 2.0, 2.1, or 3.0 to be a metropolitan statistical area.

[13]This analysis includes beneficiaries who were diagnosed with prostate cancer in either 2007 or 2009.

stage from the New York State Cancer Registry.[14] The results of the New York analysis are not generalizable to the entire Medicare population.

We also determined whether the percentage of a provider's prostate cancer patients referred for IMRT changed after providers began to self-refer. Specifically, we identified a group of providers, which we called "switchers," that did not self-refer in 2006 or 2007 but began to self-refer in either 2008 or 2009. We then calculated the change in the percentage of switchers' patients referred for IMRT and other treatments among those diagnosed with prostate cancer in 2007 and 2009. We then compared the change among switchers to the change experienced by providers that did not change whether or not they self-referred IMRT services from 2007 to 2009. Specifically, we compared the change in the percentage of switchers' prostate cancer patients they referred for IMRT to the percentage of patients referred for IMRT by (1) self-referring providers—providers that self-referred in 2007, 2008, and 2009 and either self-referred or did not bill Medicare in 2006 and 2010 and (2) non-self-referring providers—providers that did not self-refer in 2007, 2008, and 2009 and either did not self-refer or did not bill Medicare in 2006 and 2010.[15]

We took several steps to ensure that the data used to produce this report were sufficiently reliable. Specifically, we assessed the reliability of the CMS data we used by interviewing officials responsible for overseeing these data sources, including CMS and Medicare contractor officials. We also reviewed relevant documentation and examined the data for obvious errors, such as missing values and values outside of expected ranges. We determined that the data were sufficiently reliable for the purposes of our study.

[14]Such information is not available on Medicare claims. Researchers commonly use the National Cancer Institute's Surveillance Epidemiology and End Results (SEER) data to obtain clinical information about Medicare patients who were diagnosed with cancer. We did not use SEER data because we examined treatments received by men diagnosed with prostate cancer in 2007 and 2009, and, in 2007, IMRT self-referral was concentrated in states not included in SEER data. Respectively, low-, intermediate-, and high-risk prostate cancers were defined as follows: T1-T2a, Gleason score 2-6, and PSA < 10 ng/ml; T2b-T2c, Gleason score 7, or PSA 10-20 ng/ml; and T3a, Gleason score 8-10, or PSA > 20 ng/ml.

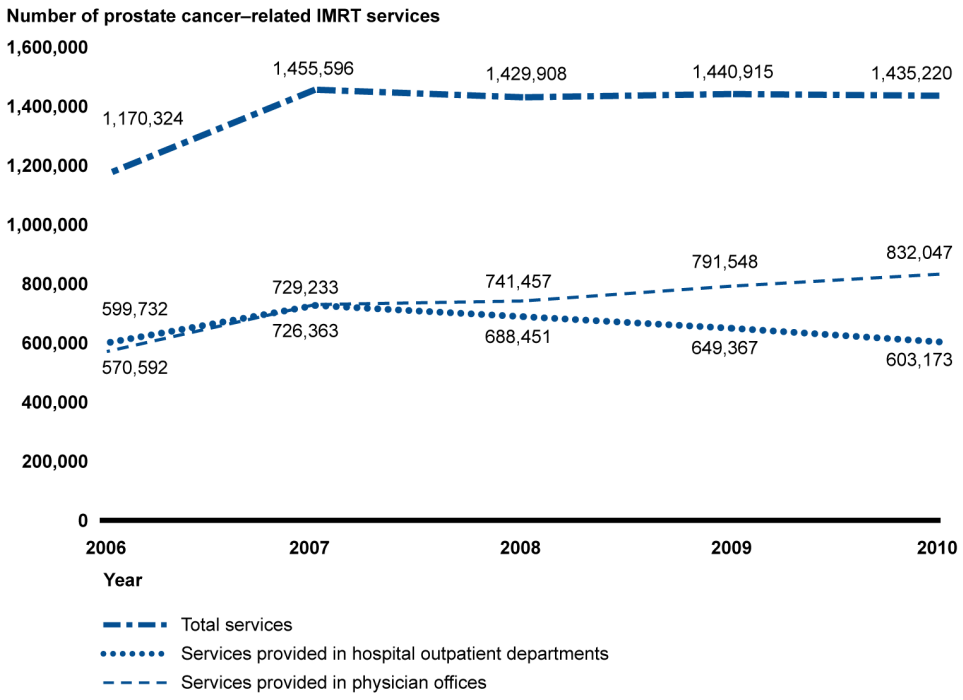
[15]For this analysis and our analysis of all providers who referred a Medicare beneficiary in our study who was diagnosed with prostate cancer in 2007 or 2009, we counted IMRT and other treatments regardless of the setting in which they were performed.

We conducted this performance audit from May 2010 through July 2013 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Change in Prostate Cancer–Related IMRT Services and Expenditures by Setting

Medicare prostate cancer–related intensity-modulated radiation therapy (IMRT) utilization varied substantially between settings (see fig. 4). From 2006 through 2010, utilization grew at an annual rate of 10 percent in physician offices, whereas there was almost no growth in the hospital outpatient department. Moreover, while the utilization of prostate cancer–related IMRT services in the hospital outpatient department was nearly the same in 2006 as it was in 2010, utilization in this setting actually peaked in 2007 and declined thereafter.

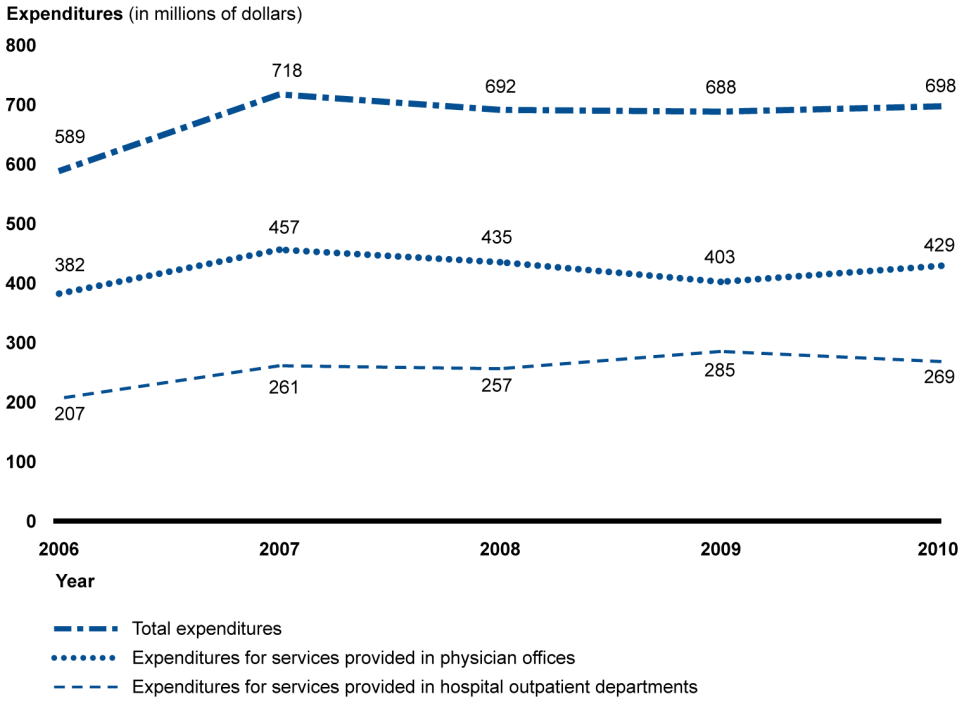
Figure 4: Number of Medicare Prostate Cancer–Related IMRT Services by Setting, 2006-2010



Source: GAO analysis of CMS data.

Total prostate cancer–related IMRT expenditures grew from $589 million to $698 million over our study period, but growth rates varied by setting (see fig. 5). In contrast to the growth in utilization, expenditures increased faster for services performed in hospital outpatient departments than those performed in physician offices—7 percent and 3 percent annual growth rates, respectively. This is due to the fact that reimbursement rates for IMRT services have been increasing for services performed in hospital outpatient departments and declining for those performed in physician offices.

Figure 5: Expenditures for Medicare Prostate Cancer–Related IMRT Services by Setting, 2006-2010



Source: GAO analysis of CMS data.

Appendix III: Discrete Prostate Cancer Treatment Categories

The higher percentage of patients that self-referring Medicare providers referred for intensity-modulated radiation therapy (IMRT) compared to non-self-referring providers was due to self-referring providers referring their patients for IMRT only and IMRT in conjunction with hormone therapy more often (see table 4). Including all combinations, self-referring and non-self-referring providers referred nearly equal percentages of their patients for a combination of treatments—27 percent and 26 percent, respectively.

Table 4: Percentage of Self-Referring and Non-Self-Referring Providers' Medicare Patients Referred for a Given Treatment or Combination of Treatments after Diagnosis of Prostate Cancer in 2009

Prostate cancer treatment	Percentage of non-self-referring providers' patients referred for a given treatment (N=48,298)	Percentage of self-referring providers' patients referred for a given treatment (N=9,991)	Percentage point difference
IMRT only	12.8%	27.0%	14.2
IMRT and radical prostatectomy	1.2	0.9	-0.3
IMRT and brachytherapy	4.7	2.6	-2.0
IMRT and hormone therapy	13.2	20.1	6.9
Active surveillance	22.9	21.0	-1.9
Radical prostatectomy only	15.5	11.5	-4.0
Radical prostatectomy and hormone therapy	1.1	0.6	-0.5
Hormone therapy only	11.4	7.7	-3.8
Brachytherapy only	6.5	3.5	-3.0
Brachytherapy and hormone therapy	2.2	0.7	-1.5
Other treatments only[a]	4.4	2.5	-2.0
Other treatments and hormone therapy	1.3	0.6	-0.7
Three-dimensional conformal radiation therapy(3D-CRT) / other external beam radiation therapy (EBRT) only	0.2	0.0	-0.1
3D-CRT / other EBRT and hormone therapy	0.3	0.1	-0.2
Other combinations[b]	2.2	1.1	-1.1

Source: GAO analysis of CMS data.

Notes: Percentages do not sum to 100 percent due to rounding. Beneficiaries were sorted into "IMRT and brachytherapy" and "IMRT and radical prostatectomy" if they received IMRT plus the treatment or IMRT plus the treatment and hormone therapy. Beneficiaries sorted into "IMRT and hormone therapy" did not receive any other treatments. Men were considered to have received a combination of therapies if they received at least one service from two or more different types of treatments. We did not differentiate on the basis of the order of different treatment combinations or the duration of treatments.

[a]"Other treatments" consists of cryoablation, stereotactic body radiotherapy / stereotactic radiosurgery, and proton therapy.

[b]"Other combinations" includes any combination of treatments that does not have a separate category, such as 3D-CRT / other EBRT and brachytherapy.

Appendix IV: Distribution of Prostate Cancer Treatments by Age

While self-referring Medicare providers were more likely to refer their prostate cancer patients for intensity-modulated radiation therapy (IMRT) regardless of age, the type of treatment they were less likely to refer their patients for varied based on the age of the beneficiary (see table 5). For instance, among beneficiaries 80 years of age or older at the time they were diagnosed with prostate cancer, self-referring providers were less likely to refer their prostate cancer patients for hormone therapy only, active surveillance, and brachytherapy compared to non-self-referring providers. In contrast, among beneficiaries 66 to 69 years old, nearly the entire difference between self-referring and non-self-referring providers was due to self-referring providers referring a smaller percentage of their prostate cancer patients for a radical prostatectomy or brachytherapy.

Table 5: Percentage of Self-Referring and Non-Self-Referring Providers' Medicare Patients Referred for a Given Treatment after a Diagnosis of Prostate Cancer in 2009 by Age of Beneficiary

	Age category (in years)							
	Percentage of non-self-referring providers' patients referred for a given treatment by age category (years)				Percentage of self-referring providers' patients referred for a given treatment by age category (years)			
Prostate cancer treatment	**66-69 (N=12,988)**	**70-74 (N=16,710)**	**75-79 (N=11,025)**	**≥80 (N=7,575)**	**66-69 (N=2,636)**	**70-74 (N=3,434)**	**75-79 (N=2,340)**	**≥80 (N=1,581)**
IMRT	29.1%	36.3%	40.7%	25.7%	46.6%	54.5%	60.1%	41.8%
Active surveillance	18.1	20.7	25.9	31.4	16.1	20.1	22.4	29.0
Radical prostatectomy	35.8	20.5	5.1	0.6	28.3	14.1	3.2	0.4
Hormone therapy only	4.1	6.2	11.8	35.0	2.7	3.9	7.1	25.1
Brachytherapy	15.5	16.6	14.4	5.2	8.9	8.4	6.2	2.0
Other treatments[a]	5.2	6.7	7.4	3.9	3.2	3.3	3.6	2.7
Three-dimensional conformal radiation therapy / other external beam radiation therapy	2.2	2.7	2.9	1.8	1.0	1.1	1.3	1.0

Source: GAO analysis of CMS data.

Notes: Treatment categories do not sum to 100 percent because, with the exception of active surveillance and hormone therapy only, the categories are not mutually exclusive.

[a]"Other treatments" consists of cryoablation, stereotactic body radiotherapy/ stereotactic radiosurgery, and proton therapy.

Appendix V: Change in Prostate Cancer Treatment Patterns over Time for Different Types of Providers

The increased percentage of Medicare patients referred by switchers for intensity-modulated radiation therapy (IMRT) was accompanied by a decrease in the percentage of patients referred for several other treatments, especially brachytherapy (see table 6). Some of the changes in the percentage of patients referred by switchers for a given treatment were consistent with the patterns for other types of providers—such as in the case of three-dimensional conformal radiation therapy (3D-CRT) / other external beam radiation therapy (EBRT)—while some of the other changes were not.

Table 6: Change in the Percentage of Medicare Prostate Cancer Patients Providers Referred for a Given Treatment after a Diagnosis of Prostate Cancer in 2007 or 2009

Prostate cancer treatment	Type of provider	Percentage of providers' patients referred for a given treatment among beneficiaries diagnosed in 2007	Percentage of providers' patients referred for a given treatment among beneficiaries diagnosed in 2009	Percentage point change from 2007 to 2009	Percentage more or less likely providers were to refer patients for a given treatment in 2009 compared to 2007
IMRT	Non-self-referring	31.4%	33.1%	1.7	5.5%
	Self-referring	55.7	52.9	-2.8	-5.1
	Switcher	37.0	54.2	17.2	46.6
Active surveillance	Non-self-referring	19.3	22.6	3.3	17.3
	Self-referring	17.3	20.7	3.4	19.6
	Switcher	18.1	20.1	2.0	11.2
Brachytherapy	Non-self-referring	17.6	14.4	-3.2	-18.2
	Self-referring	4.7	2.3	-2.5	-52.4
	Switcher	20.7	9.9	-10.8	-52.2
Radical prostatectomy	Non-self-referring	16.6	18.0	1.4	8.5
	Self-referring	13.1	15.1	2.0	15.7
	Switcher	13.0	11.1	-1.9	-14.5
Hormone therapy only	Non-self-referring	14.3	11.6	-2.7	-18.6
	Self-referring	8.6	7.9	-0.7	-8.6
	Switcher	13.1	8.0	-5.1	-39.1
3D-CRT / other EBRT	Non-self-referring	5.0	2.5	-2.5	-50.4
	Self-referring	0.8	0.7	-0.1	-14.3
	Switcher	4.0	1.3	-2.7	-68.7
Other treatments[a]	Non-self-referring	5.7	6.3	0.6	10.8
	Self-referring	1.8	2.5	0.7	38.3
	Switcher	4.8	1.9	-2.8	-59.7

Source: GAO analysis of CMS data.

Notes: Treatment categories for each type of provider do not sum to 100 percent because, with the exception of active surveillance and hormone therapy only, the categories are not mutually exclusive. In 2007, switchers, self-referring providers, and non-self-referring providers referred 4,903, 1,776, and 42,471 prostate cancer patients for treatment, respectively. In 2009, switchers, self-referring providers, and non-self-referring providers referred 4,156, 1,244, and 34,107 prostate cancer patients for treatment, respectively. Because some treatments were relatively rare, some provider type, treatment group, and year categories, such as patients referred for 3D-CRT / other EBRT by self-referring providers in 2009, have relatively few beneficiaries. However, the results of this analysis are consistent with the trends observed when referral patterns for self-referring and non-self-referring providers were studied for all beneficiaries diagnosed in 2007 and 2009.

[a]"Other treatments" consists of cryoablation, stereotactic body radiotherapy / stereotactic radiosurgery, and proton therapy.

Appendix VI: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

JUN 11 2013

James C. Cosgrove, Director
Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Cosgrove:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, entitle, "MEDICARE: Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny" (GAO-13-525).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "MEDICARE: HIGHER USE OF COSTLY PROSTATE CANCER TREATMENT BY PROVIDERS WHO SELF-REFER WARRANTS SCRUTINY" (GAO-13-525)

The Department appreciates the opportunity to review and comment on this draft report.

GAO Recommendation

GAO recommended that the Administrator of CMS insert a self-referral flag on its Medicare Part B claims form, require providers to indicate the IMRT service for which a provider bills Medicare is self-referred, and monitor the impact self-referral has on costs and beneficiary treatment selection.

HHS Response

HHS does not concur. We do not believe this recommendation will address overutilization that occurs as a result of self-referral. We believe that adding a self-referral flag on the Medicare Part B claims form and requiring physicians to indicate whether the service is self-referred will be complex to administer and may have unintended consequences. We believe other payment reforms will better address overutilization than a new checkbox on the claim form. If a claim indicated that a service was self-referred, there would not be any information about whether such self-referral met the criteria for being an acceptable referral. For example, when a referral occurs outside the physician group or clinic context, the claim could indicate that the service was not "self-referred," but it nevertheless could be a referral that potentially violated the physician self-referral law.

Further, the President's Fiscal Year 2014 Budget proposal included a provision to exclude certain services from the in-office ancillary services exception to the physician self-referral law. The proposal notes the in-office ancillary services exception was intended to allow physicians to self-refer quick turnaround services and that some of these services, such as radiation therapy and advanced imaging, are rarely performed on the same day as the related physician office visit. The proposal is designed to encourage more appropriate use of certain services by excluding them from the in-office ancillary services exception to the prohibition against physician self-referrals, except in cases where a practice meets certain accountability standards.

1

Appendix VII: GAO Contact and Staff Acknowledgments

GAO Contact

James C. Cosgrove, (202) 512-7114 or cosgrovej@gao.gov

Staff Acknowledgments

In addition to the contact named above, Thomas Walke, Assistant Director; Manuel Buentello; Krister Friday; Gregory Giusto; Brian O'Donnell; Daniel Ries; and Jennifer Whitworth made key contributions to this report.