NEJM study exposes overuse of radiation therapy when urologists profit from self-referral

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A comprehensive review of Medicare claims for more than 45,000 patients from 2005 through 2010 found that nearly all of the 146 percent increase in intensity-modulated radiation therapy (IMRT) for prostate cancer among urologists with an ownership interest in the treatment was due to self-referral, according to new research, "Urologists' Use of Intensity-Modulated Radiation Therapy for Prostate Cancer," released today in *The New England Journal of Medicine* (*NEJM*) for its October 24, 2013 issue. This study corroborates the increased IMRT treatment rates among self-referrers reported in the Government Accountability Office's (GAO) August 2013 report, "Medicare: Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny."

Authored by Jean M. Mitchell, PhD, economist and professor at the McCourt School of Public Policy at Georgetown University, the *NEJM* manuscript provides an intricate analysis of treatment patterns by urologists before and after they acquired ownership of IMRT services, compared to the treatment patterns of non-self-referring urologists and urologists who practice at National Comprehensive Cancer Network (NCCN)-designated cancer centers (also non-self-referrers).

ASTRO Chairman Colleen A.F. Lawton, MD, FASTRO, voiced the Society's grave concerns regarding this study's results, "Dr. Mitchell's study provides clear, indisputable evidence that many men are receiving

unnecessary radiation therapy for their prostate cancer due to self-referral. While I am a prostate cancer specialist impassioned to eradicating the disease, I am equally dedicated to utilizing these powerful technologies prudently and in the best interest of each individual patient. We must end physician self-referral for radiation therapy and protect patients from this type of abuse."

The two cohorts for the *NEJM* study data, obtained through Medicare claims from January 1, 2005 through December 31, 2010, include Medicare patients in 26 geographically dispersed states who were 1) treated at 35 self-referring urology groups in private practice matched to a control group of 35 non-self-referring urology groups in private practice, for a total of 38,765 patients; and 2) treated by 11 self-referring urology groups in private practice within close proximity to and matched directly to non-self-referring urologists at 11 NCCN® centers, for a total of 6,713 patients. Patient records were followed for a period of six months from the initial prostate cancer diagnosis to track treatment choices. Sixty percent of the self-referring urologists established their IMRT services during the period from January 1, 2008 through January 15, 2010.

A difference-in-differences analysis was used to isolate the impact of self-referral on changes of IMRT utilization over time, according to self-referral status. This approach controls for initial differences in practice patterns during the pre-ownership period as well as secular trends that affect the use of IMRT and are unrelated to ownership status. The analysis found that:

- IMRT utilization among self-referring groups increased from 13.1 percent to 32.3 percent once they became self-referrers, an increase of 19.2 percentage points (146 percent). In contrast, IMRT utilization by non-self-referring urologists who were peers practicing in the same community-based setting was virtually

unchanged—with a modest increase of 1.3 percentage points. Therefore, the difference-in-differences analysis reveals that self-referral accounts for 93 percent of the growth in IMRT.

- IMRT utilization among the subset of 11 self-referring urology practices near NCCN® centers increased from 9 percent to 42 percent, an increase of 33 percentage points (367 percent), from the pre-ownership to the ownership period, compared to an insignificant increase of 0.4 percentage points at the NCCN® centers.
- In addition to increased IMRT utilization, the data demonstrate decreases in utilization of other effective, less expensive treatment options by self-referring urologists. For example, brachytherapy decreased by 14.9 percentage points to just 2.7 percent of patients receiving this treatment in self-referring urology practices. These results are in stark contrast to non-self-referring urologists, for whom the study reports "virtually no change in practice patterns."

The *NEJM* report concludes 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."

At a press conference unveiling the study tomorrow, one of the nation's leading urologists, James L. Mohler, MD, of Roswell Park Cancer Institute in Buffalo, will release a joint statement on the overtreatment of prostate cancer and physician self-referral from the expert members of the NCCN® Prostate Cancer Guidelines Panel, which he chairs.

"We are concerned unanimously by the prostate cancer treatment patterns identified in today's article," says Dr. Mohler. "We are disappointed to learn that urologists who self-refer for IMRT services

use this expensive technology more than urologists who don't self-refer and more than NCCN® Member Institutions." He added, "Prostate cancer treatment recommendations should be based on the best available clinical evidence and not influenced by business or personal interests of the care provider."

"This study confirms that permitting physicians to self-refer, particularly urologists to self-refer for IMRT, leads to unnecessary treatment and added health care costs to Medicare and beneficiaries," continued Dr. Lawton. "Prostate cancer is a complicated disease that needs input from multiple specialists, not just one, to determine the best treatment for the individual patient. There are many different treatments available, and in many cases, no treatment at all is the right thing to do, particularly among the elderly. For many men with early stage prostate cancer, active surveillance, or watchful waiting, is the best option. Unfortunately, the continuous stream of data indicates that patient choice is being restricted—patients are being steered to the treatment that provides the most profit for the urologist. As a result, patients are subjected to unnecessary treatment and side effects, and millions of dollars are wasted."

The federal "Ethics in Patient Referrals Act," also known as the self-referral law, prohibits physicians from referring a patient to a medical facility in which he or she has a financial interest in order to ensure that medical decisions are made in the best interest of the patient without consideration of any financial gain that could be realized by the treating physician. However, the law includes an exception that allows physicians to self-refer for so-called "ancillary services," including radiation therapy. Over the years, abuse of the in-office ancillary services (IOAS) exception has weakened the self-referral law and diminished its policy objectives, making it simple for physicians to avoid the law's prohibitions by structuring arrangements that meet the technical requirements of the law, thereby circumventing the intent of the law.

Numerous studies have shown that physician self-referral leads to increased utilization of services that may not be medically necessary, poses a potential risk of harm to patients and costs the health care system millions of dollars each year.

To-date, the GAO has issued three reports in a four-part series on physician self-referral, the most recent one, from August 2013, also details abuse in radiation therapy treatment for prostate cancer. The report found a 356 percent increase in IMRT utilization by self-referrers, compared to a 5 percent decrease by non-self-referrers, and that the number of treatments rose by 509 percent compared to a 3.8 percent decrease at non-self-referring multi-specialty groups. In July 2013, the GAO report, "Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer," found that self-referring providers likely referred nearly one million more unnecessary anatomic pathology services than non-self-referring providers, costing Medicare approximately $69 million. "Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions," the first GAO report in November 2012 on self-referral in advanced diagnostic imaging, found that "providers who self-referred likely made 400,000 more referrals for advanced imaging services than they would have if they were not self-referring"—at a cost of more than $100 million in 2010. The final report, expected by the end of this year, will detail self-referral for physical therapy services.

"Unfortunately, when you look at the numbers in this report, you start to wonder where health care stops and where profiteering begins," said Senate Finance Committee Chairman Max Baucus (D-Mont.), in a statement about the GAO's August 2013 report on radiation therapy self-referral. "Enough is enough. Congress needs to close this loophole and fix the problem."

"ASTRO urges Congress to promptly pass the 'Promoting Integrity in

Medicare Act of 2013' (PIMA), introduced August 1, 2013, by Rep. Jackie Speier (D-Calif.) and Rep. Jim McDermott (D-Wash.). PIMA will close the self-referral loophole for radiation therapy, advanced imaging, anatomic pathology and physical therapy services, resulting in better care for patients and billions of Medicare dollars saved that could offset the costs of repealing the Medicare physician payment formula (sustainable growth rate—SGR).

"PIMA closes the self-referral loophole in a conscientious and strategic manner that abolishes abuse while allowing truly integrated multi-specialty groups and high-performing health systems to continue to provide high-quality and efficient care," concluded Dr. Lawton. "This blatant abuse of our patient's trust and our country's limited financial resources endangers our ability to work with health policy leaders in developing a new quality- and value-based payment system for Medicare. Closing the self-referral loophole will protect patients, restore trust, reduce costs and strengthen Medicare."

Reps. Speier's and McDermott's PIMA legislation would enact the recommendations of influential bipartisan groups who have examined self-referral abuse. In September 2012, a New England Journal of Medicine article, authored by leading health policy experts including former CMS administrator Donald Berwick, MD, MPP, called for closing the self-referral loophole for radiation therapy and other so-called "ancillary services." The Center for American Progress agreed with narrowing the IOAS exception, as well as several notable bipartisan groups, including the Bipartisan Policy Center, under the leadership of former Senate Majority Leaders Tom Daschle (D-S.D.) and Bill Frist (R-Tenn.), and the Moment of Truth Project, headed by Erskine Bowles and former Senator Alan Simpson (R-Wyo.). President Obama's proposed FY 2014 Budget also recommended closing the self-referral loophole and estimated savings of more than $6 billion during the standard 10-year budget window for Medicare.

A November 2012 Bloomberg News investigative report scrutinized questionable IMRT treatment for prostate cancer by a self-referring urology clinic in California and concluded that physician self-referral resulted in mistreated patients and higher health care costs. The Wall Street Journal, The Washington Post and The Baltimore Sun have published similarly critical reports since 2009 to call attention to the mounting evidence that limited specialty [urology] groups who own radiation therapy equipment have utilization rates that rise rapidly and are well above the national norms for radiation treatment of prostate cancer.

Provided by American Society for Radiation Oncology