

EDITORIAL

INTEGRATED PROSTATE CANCER CENTERS AND OVER-UTILIZATION OF IMRT: A CLOSE LOOK AT FEE-FOR-SERVICE MEDICINE IN RADIATION ONCOLOGY

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The United States spends almost 2.5 times more per capita on health care than other developed countries (1), yet produces comparably poor outcomes on measures such as life expectancy and disease specific mortality (2). Overutilization of expensive health care technology is a principal driver of this disparity (3). Radiation oncology will increasingly be under scrutiny as a significant contributor to this problem given the high cost of the technology and paucity of data supporting the use of newer, more expensive modalities (4). One analysis estimates that small-scale reform designed to restrict inappropriate use of radiotherapy could save the Medicare fee-for-service program \$5.3 billion over 10 years (5).

Although many factors influence the use of health care resources, ownership of expensive technology by referring physicians is known to substantially increase expenditures (6). A 1993 *New England Journal of Medicine* study found that joint ventures in which a non-radiation oncologist refers patients for radiation therapy on equipment in which they have an ownership interest perform 58% more procedures and bill 48% more than non-conflicted practices (7).

These data are problematic, considering the new wave of integrated prostate cancer centers in which urologists acquire an ownership interest in the intensity-modulated radiation therapy (IMRT) equipment to which they refer patients. At least two companies, UroRad Healthcare and American Kidney Stone Management, are helping to drive the trend by marketing turnkey IMRT centers to urologists. In the traditional UroRad model, a group of urologists invests \$3 million in equipment, information technology, and supplies; hires a salaried radiation oncologist for onsite work; and makes use of the company's centralized, remote dosimetry (8).

Because the technical and professional fees combine to approach \$50,000 per patient treated with IMRT, there is a clear incentive to refer patients for radiation therapy who might be better served by prostatectomy, brachytherapy, or active

surveillance. According to UroRad data, for a practice with 14 urologists, an average of 1.5 new IMRT patients per urologist per month generates an annual return of more than \$425,000 per physician (8).

In this article, we rebut the pro-competitive arguments used to support urologist ownership of IMRT equipment. We then discuss the legal environment surrounding physician referral to entities in which they possess an equity interest. Next, we critique solutions offered by the American Medical Association and American Society for Radiology Oncology, and finally conclude with recommendations for payment reform.

REBUTTING THE ARGUMENTS SUPPORTING UROLOGIST OWNERSHIP OF IMRT EQUIPMENT

There are three potential arguments for why urologist ownership of IMRT equipment may enhance the quality and reduce the cost of professional services. First, it allows for the provision of integrated, rather than piecemeal, services (9). Urologist oversight of IMRT may allow for faster recognition and better management of rare complications such as urethral stricture. Record-keeping may also be more reliable than a system that relies on duplication and transfer of information between offices.

Second, integrated prostate cancer centers may treat higher volumes of patients, given that the vast majority of prostate cancers are diagnosed by urologists and such integrated facilities do not have to rely on outside referrals for business. Higher patient volumes may translate into greater technical expertise, with potentially superior outcomes. Although the issue has never been empirically examined for radiation therapy, there is ample evidence that high volume hospitals—and in some instances high volume surgeons—achieve better surgical outcomes, at least for complex procedures (10).

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Finally, ancillary ownership should theoretically allow quality to rise while costs decline solely because of the increased competition associated with lower barriers to entry (9). The absence of governmental regulations restricting urologist ownership of IMRT equipment puts pressure on both integrated and traditional radiation oncology practices to adopt new technology, focus on customer service, and accept lower reimbursement. Decreased barriers to entry may even help to ensure that needed facilities are constructed.

Although moderately persuasive at first glance, each of these pro-competitive arguments fails to support a system in which urologists are permitted to refer patients for IMRT in which they have an ownership interest. The first two arguments are disputable on empirical grounds. Radiation oncologists, for instance, may be equally as good as urologists at diagnosing and arranging care for urological complications of radiation therapy. And prostate IMRT may be sufficiently straightforward that, after a small critical mass, there is no correlation between volume and technical expertise. The empirical debates, however, are largely moot because both arguments hold true for all integrated services, regardless of the ownership arrangement. An integrated prostate cancer center owned by outside investors that employed salaried urologists and radiation oncologists would offer the same benefits without the risk of overutilization.

The final argument—that lower barriers to entry increase competition and decrease costs for patients—similarly fails to support urologist ownership of IMRT. Permitting physicians to advise their patients to visit their own ancillary entities may, in fact, inhibit competition and therefore increase prices. By narrowing the options patients consider, urologists may be able to secure business for their own facilities when an informed patient making an unencumbered choice would have preferred an alternative center or an alternative treatment. Furthermore, an increase in the supply of providers does not automatically equate with greater clout for payers. Fee schedules are not determined by supply and demand, but rather by the cost to physicians of providing the service, and technocratic assessments of the level of skill required (11). In medicine, there tends to be a tight correlation between capacity and utilization that is independent of ownership, and thus any reduction in price is almost certain to be offset by inappropriate increases in volume (12).

LEGAL LANDSCAPE

There are two principal federal statutes that restrict self-referral (*i.e.*, physicians' ability to refer patients to ancillary entities in which they have a financial interest). Both laws pertain only to federally insured patients. The Anti-kickback Act is a criminal statute that prohibits knowingly providing any remuneration in exchange for referrals (13). The Stark Law prohibits a physician from referring Medicare patients to a facility with which the physician (or an immediate family member) has a financial relationship through ownership or compensation (14).

The Stark Law would be implicated by the traditional Ur-oRad model were it not for the in-office ancillary exception. This exception permits physicians to refer patients for self-owned services so long as (a) the referring physician maintains some supervisory or managerial role and (b) the services are provided in a building used by the referring physician (15). Because the IMRT is generally provided onsite by the urologist-owned integrated centers, there is no violation of the Stark Law.

State legislatures and regulatory bodies have also promulgated statutes and regulations that restrict the extent to which physicians can legally refer patients to their own ancillary facilities. Approximately half of the states regulate the referral of privately insured or uninsured patients in addition to individuals who receive governmental benefits (16). Many states permit physicians to refer patients to an entity with which they have a financial relationship, but they require that the relationship be disclosed to the patient. Finally, under the assumption that small equity interests are unlikely to influence physicians' judgment, some states make use of percentage of ownership limitations. All of these laws, however, have little bite in the context of IMRT ownership because most replicate the general form of the Stark Law, including the in-office ancillary exception.

Certificate of need laws, which are present in approximately 36 states, restrict ownership of IMRT by requiring state approval before the purchase of capital equipment or construction of a health care facility (17). These laws have been the principal legal deterrent to the growth of physician-owned specialty hospitals (18). One can expect new, urologist-owned prostate cancer centers to be almost exclusively located in states without certificate of need restrictions.

MISGUIDED SOLUTIONS

About a dozen states use mandatory disclosure to patients as a way of mitigating the conflict of interest inherent in self-referrals (16). The American Medical Association's Code of Professional Ethics argues that, when self-referral arrangements are justified by a medical need that otherwise would go unfilled, disclosure will help to prevent over-utilization (19). A large body of social science research, however, demonstrates that disclosure may be an ineffective solution to professionals' conflicts of interest (20). This is true for two principal reasons. First, individuals fail to sufficiently discount the advice they receive from partial advisors. Second, mandatory disclosure of conflicts of interest may increase the extent to which conflicted individuals offer biased advice. Physicians may strategically exaggerate the patient's need for treatment, or over-promote self-owned services under the assumption that disclosure adequately protects patients' interests. Thus, not only may disclosure requirements fail to curb overutilization, but they may exacerbate the problem as urologists inappropriately refer more patients for IMRT.

American Society for Radiology Oncology is currently lobbying Congress and the Obama administration to exclude radiation therapy from the in-office ancillary exception to the

Stark Law. This would bring urologist-owned prostate cancer centers under the purview of the legislation, making it illegal for urologists to own IMRT equipment, hire a salaried radiation oncologist, and earn profits in accordance with self-referrals. Although the in-office exception has perversely encouraged conflicts of interests throughout medicine, proper integration of specialties and the requisite cross referrals can be beneficial to patients. Academic medical centers are exempted from the Stark Law by a separate regulation (21), but elimination of the in-office ancillary exception for radiotherapy might hinder legitimate business relationships and integration of services for cancer patients. It would be difficult to draft an amendment to the Stark Law that adequately differentiates between appropriate integration and that in which the benefits are outweighed by the risk of overutilization.

More importantly, eliminating the in-office ancillary exception might simply encourage a restructuring of the integrated centers that is equally as likely to promote overutilization of IMRT. The “physicians’ services” exception to the Stark Law permits any referral where the individual performing the ancillary service is part of the same “group practice” as the referring physician (22). Self-referral to IMRT would presumably be legal if the urologists and radiation oncologists partnered and shared profits equally such that no physician was directly compensated for referrals (23). Several prominent radiation oncologists have contended that this arrangement would mitigate, if not eliminate, the conflict of interest (24). This argument, however, relies on the questionable assumption that pressure placed on an (employee) radiation oncologist by an unscrupulous urologist employer is more likely to generate inappropriate treatment than profit incentives. It is doubtful that urologists are more likely than radiation oncologists to fall subject to self-serving bias. So long as compensation is tied to treatment, the disproportionate reimbursement for IMRT compared to other prostate cancer therapies will present a significant risk of overutilization.

PAYMENT REFORM

Overutilization is virtually unavoidable in a fee-for-service system. Despite the professional ethos to promote the interest of the patient above all else, physicians inevitably and unconsciously succumb to inappropriately recommending therapy in which they have a financial interest. The movement toward evidence-based medicine has attempted to counteract conflicts of interest, but new treatment technologies are rarely accompanied by sufficient research to fully understand which patients will benefit from therapy. Furthermore, manufacturers and other entities poised to profit from recent Food and Drug Administration approval of novel technology are loathe to conduct research that will contribute to the development of practice guidelines, since doing may harm profitability. Scientific ambiguity and weak self-referral laws allow the US medical marketplace to select out the therapies that have a generous fee schedule, particularly on the technical side. Integrated prostate cancer centers are a salient example of abuse

because they involve infiltration of one specialty by another and disruption of established models of patient care delivery.

President Obama has acknowledged the contribution of physician-induced demand to rising health care costs and discussed the importance of payment reform (25). His health care plan proposes to use the crudest method of dealing with overutilization of a medical technology: straightforward reductions in Medicare reimbursement (26). A reduction in technical fees for IMRT, however, may render treatment financially unsustainable. Physicians’ dismal track record with lifesaving but underreimbursed preventive care such as smoking cessation services and influenza vaccines demonstrates that underpayment can be more harmful than supra-competitive fees (27). Even if payment is sufficient for economically efficient equipment owners to earn a profit, facilities that have failed to develop the necessary managerial abilities may cease offering IMRT.

Other forms of payment and delivery reform, particularly those that move away from fee-for-service fee schedules, may present more optimal solutions. Reimbursement for short-term, fragmentary encounters and procedures encourages providers to maximize billable units, such as face-to-face consultations, and radiotherapy quantity and complexity. Payment should ideally focus on long-term outcomes such that physicians have an incentive not only to administer the current standard of care, but to develop innovative regimens that promote patient health.

On a theoretical level, risk-adjusted, comprehensive, long-term capitation contracts coupled with real-time outcome data perfectly align physicians’ incentives with the long-term health of patients (28). Under this system, a multidisciplinary group of providers would accept lump sum payment in exchange for providing all necessary care for a multiyear period. Payments would be adjusted according to the patients’ anticipated long-term costs such that provider teams reap the savings of cost-effective care. Mandatory outcome reporting, coupled with centralized analysis and dissemination of the information, would ensure that physicians do not skimp on necessary care.

It will be practically difficult, however, to design a sufficiently precise risk adjustment system that adequately rewards capitated providers for enrolling the sick, and generate outcome data that ushers patients toward top-performing providers. These goals will require significant time and iterative experimentation to achieve. In the interim, legislators are tinkering with alternatives to fee-for-service reimbursement such as shared savings, pay-for-performance algorithms, bundled payments and partial capitation. Paradoxically, there is concern expressed in some legal quarters that the current Stark Law impedes development of these new delivery and payment systems (29).

If the political process requires that fee schedules continue, which is likely, reimbursement might be adjusted in accordance with cost-effectiveness. This would help to promote the development and use of treatments that offer true value, rather than those that are merely resource intensive. While the government’s commitment to fund cost-effectiveness

research is a step in the right direction (30), an agency such as the United Kingdom's National Institute for Health and Clinical Excellence may be a model for adoption. Such an organization would be empowered not only to evaluate comparative effectiveness, but to promulgate recommendations that impact payment policies.

CONCLUSION

Urologist-owned prostate cancer centers that self-refer patients for IMRT present a significant risk of overutilization, threatening to further contribute to the US cost crisis. None of the available pro-competitive arguments for integrated centers justify an ownership model in which

urologist income correlates with referrals for radiation therapy. Facilities are currently able to escape regulatory control by locating in a state without certificate of need laws and taking advantage of the in-office ancillary exception to the Stark Law.

The UroRad model is not an isolated problem, but rather a symptom of a systemic illness that plagues US health care. Fee-for-service reimbursement encourages physicians to overuse health care resources regardless of their source of referrals. Radiation oncologists must avoid advocating only for self-serving change, and concomitantly promote health system reform that aligns physicians' interests with the long-term health of patients.

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