The Effects of Physician Ownership on Patient Quality of Care and Volume:

A Detailed Examination of Three Innovative Technologies for Urology Patients

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Contents

Treatment of kidney stones, prostate cancer, and benign prostatic hyperplasia (BPH) is now safer, more effective, and more available to patients – due in large part to urologists' investments in innovative technologies.

This paper reviews some of the effects of urologists' investments in three technologically advanced treatment tools: lithotripters, using extracorporeal shock wave lithotripsy (ESWL); Intensity Modulated Radiation Therapy (IMRT); and BPH (benign prostatic hyperplasia) laser treatments.

Clinical evidence establishes that these technologies improve patient care– reducing complications and re-treatments and improving quality of life.

Other results of such investment include:

- Increased patient access.
- Increased integration of technology into the continuum of care.
- Advances in the technology.

Population-based, health resource planning estimates suggest that these technologies have grown at an appropriate pace to meet the needs of patients. Continuing the current level of regulation will help to ensure that future needs are met as well.

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Abstract

Policymakers have long been concerned that physician ownership of medical facilities and equipment may result in inappropriate utilization due to financial incentives linked to ownership. Yet it is physician investment in new technologies in their communities – hospitals or mobile units or integrated physician practices– that has helped lead to some of the most important advances in urology. This paper illustrates the impact of physician investment on improving quality and access to urologic care for patients. And, it finds that current capacity is appropriate for population needs, and that it tends to follow a growth pattern trend that soon results in equilibrium. It concludes that the Stark law's IOAS exception policy has enabled the growth of integrated practices providing coordinated care and, as such, should remain in place.

The clinical evidence for the technologies discussed in this paper – lithotripsy, IMRT, and BPH laser treatment – demonstrates that they offer substantial benefits to patients: the new procedures are less invasive, have fewer complications, and produce shorter recovery times. These improvements have enabled treatment for some patients who would not have been candidates for the riskier alternatives. Physician investment in mobile technology, in particular, has had a substantial impact on geographic access in both large and small communities. Physician investment in developing integrated cancer care has improved quality by bringing together the full continuum of care for prostate cancer patients.

Medicare's payment policies have not always favored advances in urologic treatments in most inpatient hospitals. Under the inpatient hospitals payment system that was in place when initial investments in lithotripters were occurring, investment in lithotripters represented both a high initial cost and also a loss in revenue for hospitals. Improving the treatment would decrease length of stay and enable less-intensive surgeries or alternatives to surgeries that would decrease per-patient hospital revenues. While the current inpatient payment system addresses length of stay, the second disincentive remains a factor that hinders hospital investments.

Population-based health resources planning models suggest that the rate of adoption of these technologies in urology practice today is well-matched to the health needs of patients. Meanwhile, the current trends in population health suggest that current capacity must be maintained or expanded to meet future needs. With regard to meeting (but not exceeding) patient need, it is important to acknowledge the typical cycle of new medical technologies. This cycle includes a rapid growth in the adoption stage of a new technology; then, as new technologies gradually replace the old procedures, the initial rapid growth tends to slow until a state of equilibrium – that is, levels appropriate to the needs of the patient population – is reached.

An introduction to three physician-owned urologic technologies

As an illustration of the value of physician ownership, this paper reviews three physician-owned urologic technologies that improve the treatment of commonly seen urologic diseases—kidney stones, prostate cancer, and benign prostatic hyperplasia (BPH). The technologies are: lithotripters; Intensity Modulated Radiation Therapy (IMRT); and BPH lasers.

Lithotripters deliver extracorporeal shock wave lithotripsy (ESWL) to disintegrate genitourinary stones. After fluoroscopic X-ray or ultrasound is used to locate the stone, the lithotripter focuses shockwaves that pass harmlessly through the body's soft tissue but pinpoint and disintegrate stones in place. The outpatient treatment requires only 45 minutes and does not require general anesthesia.	**IMRT** uses thousands of tiny radiation beams to kill prostate cancer cells. It is used along with radiologic image guidance to improve the ability of the radiation oncologist to target the small beams directly to the tumor. "Prostate cancer fits the ideal target criteria for IMRT of adjacent sensitive dose-limiting tissue (rectal and bladder), and prostate cancer has been the most widely used application of IMRT (Arterbery, 2002)."	**BPH lasers** use fiber optics to deliver a pulse of laser-light to vaporize and thereby remove prostatic obstructions. The minimally-invasive BPH laser fiber is passed through a cystoscope so that energy can be applied under direct vision to the enlarged and obstructing prostate tissue. The average operative time is less than an hour.

The efficiency of these technologies will become more valuable as the needs of millions of newly insured patients exacerbate the physician shortage in future years. Efficient use of physician time will become even more critical. This paper demonstrates that the combination of the integrated practice model described herein and the use of technologies such as these will reduce treatment times and use physician resources more efficiently.

Physician investment has promoted quality of care

Length of stay decreased an average of 3 days and duration of treatment by 30 minutes with ESWL, against comparable kidney stone treatments.
(Srisubat, 2009)

Each of these three technologies offers improvements in treatment over previously available options. They lower complication rates or length of treatment or have other benefits. They have also made treatment possible for patients who did not have other options.

Lithotripters

A prominent example of treatment that has enhanced quality of care is the lithotripter, delivering ESWL. Before its invention, the removal of genitourinary stones was accomplished through invasive surgical treatment – with a high rate of associated complications. With the innovation of ESWL, treatment of stones in the urinary system became a noninvasive, outpatient surgical procedure. Development and maintenance of improved treatment has been important because urinary stones are so widespread in the U.S. population. The prevalence of problematic kidney stones alone is 6.3 percent of the male population and 4.1 percent of the female population (National Institute of Diabetes and Digestive and Kidney Diseases, 2010).

The clinical benefits to patients were apparent early in the lifecycle of ESWL: an early, critical review of the literature on the regulation, costs, and benefits of ESWL stated, "ESWL appears to be a highly desirable technology from every standpoint . . . Not only does it achieve excellent results with lower complication rates than invasive therapies, but even given the higher cost of lithotripters, it may cost less per treatment than the surgical procedures it replaces" (Havighurst & McDonough, 1986). Time in the field confirmed the benefits of the newer treatment. Complications, length of stay in a hospital, and duration of treatment were all lower for ESWL than were seen with the more invasive surgeries available before its introduction (Srisubat, 2009); (Nabi, 2007).

Many urologists began to recognize that they could further improve patient care by investing in the equipment. Dr. Buckley Gillock is a urologist who connected with other area urologists in southwestern Virginia in an effort to upgrade the treatment of their patients. He felt that the lithotripter owned by his local hospital had some maintenance issues that he believed were resulting in relatively high retreatment rates, so he and the local urologists bought the CON [certificate of need] from the hospital, "thus giving us the ability to upgrade and purchase newer, more effective machines. Since then, there have been lower re-treatment rates and no increase in complications" (unpublished communication, May 18, 2010). Dr. Gillock and his partners also found that owning lithotripters allowed them to provide patients with more comprehensive information about the device and procedure, allowing them to make well-informed choices when choosing a treatment and site of care.

IMRT

Investment in IMRT has allowed integration of radiation therapy into the continuum of total cancer care for patients with prostate cancer. This type of cancer is by far the most commonly diagnosed cancer among American men, and it remains the second leading cause of cancer death in men. Incidences range from 62 cases per 100,000 Caucasian men under 65 to 1,396 cases per 100,000 African American men over 65 (National Cancer Institute, 2010). There were more than 190,000 new cases of prostate cancer in the U.S. in 2009 (National Cancer Institute, 2010) and just over 27,000 deaths from prostate cancer in 2009 (Jemal, Siegel, Ward, Hao, Jiaquan, & Thun, 2009). However, early detection and important advances in treatment like the IMRT have made this form of cancer one of the most treatable cancers. Even so, no single mode of treatment is appropriate for all patients with prostate cancer, and more research is needed to determine the optimal treatment for each patient.

Cancer patients who underwent IMRT reported their quality of life had returned to normal by 18 months after surgery.

IMRT is the most recent improvement in the use of external radiotherapy to treat cancer, a technology dating to the 1950s. The new technologies improve physicians' ability to apply higher doses of radiation without substantial injury to or destruction of surrounding tissue. Before IMRT, the standard was three-dimensional conformal radiation therapy, or 3D-CRT (Arterbery, 2002). 3D-CRT was relatively inaccurate at targeting radiation because it used a single, strong beam. It was especially limited in its ability to treat tumors with a concave shape, and approximately 30% of these cancers exhibit concave features (Nutting and Dearnaley,).

Studies demonstrate that IMRT's technical advances compared to 3D-CRT offer important benefits to patients. Patients' battle against cancer is eased somewhat by IMRT's ability to decrease damage to adjacent healthy tissue. Within 18 months of treatment, the urinary symptoms, emotional, social, cognitive, and physical impairments they suffered at that time had dissipated (Marchand, 2009). There are also lasting, long-term effects that improve the quality of life compared to 3D-CRT (Namiki, 2009): At 60 months, patients who had 3D-CRT had a greater loss of sexual function, significantly worse bowel function, and more general physical discomfort than the IMRT group. Additional research may improve IMRT further, lowering toxicity and increasing its effectiveness (Martin & Bayley, 2009).

BPH laser

The development of lasers to treat benign prostatic hyperplasia (BPH) illustrates one of the most important contributions that urologist ownership has made to improving patient access to high quality care. BPH is a health issue for many: 4.5 million visits to physicians are made annually for symptoms of prostate enlargement. More than half of men in their 60s and as many as 90 percent in their 70s and 80s have some symptoms of BPH (National Institute of Diabetes and Digestive and Kidney Diseases, 2010).

BPH laser treatment, approved by the FDA in 1996, represents a significant advancement in treatment options for BPH**:** Before its introduction, treatment options for an enlarged prostate were either an open surgical or an endoscopic surgical procedure, the endoscopic treatment, called TURP (transurethral resection of the prostate), becoming the "gold standard" of treatment. Unfortunately these surgical procedures carried with them the potential for a high rate of complications, especially blood loss at the time of surgery and impotence and incontinence following the operation. Over time, new surgeries and drug regimens were designed to treat, but not cure, early or mild cases of BPH. However, most doctors recommend removal of the enlarged part of the prostate as the best long-term solution for patients with BPH (National Institute of Diabetes and Digestive and Kidney Diseases, 2010).

Studies show that laser ablation of BPH tissue results in better patient outcomes than TURP and is equally efficient at removing the prostatic enlargement, thus reducing the risk of complications. Clinical research has found that laser prostatectomies have shorter lengths of stay, shorter periods of catheterization following a procedure, fewer adverse events, and good quality of life. It also is less costly than TURP treatment (Bouchier-Hayes, Van Appledorn, Bueja, Crowe, Challacombe, & Costello, 2009). This new technology has made treatment possible for those patients who have bleeding disorders or are on anticoagulants.

Dr. Dan Murtagh, national medical director for American Kidney Stone Management (AKSM) and a practicing urologist in Toledo, Ohio, noted the benefits to patients in settings with in-office equipment: "Hospitals don't buy lasers and instead use contractors who have absolutely no consistency in their service, which creates a scheduling problem for both technologists and patients. As with the ESWL technology, owning the laser has given us access to more qualified technologists and allowed us to track patient data through electronic health records" (unpublished communication, June 3, 2010).

Quality is improved with integrated practices providing coordinated care

Physician ownership has allowed urologists to create specialized practices to treat kidney stones, prostate cancer, and BPH. In these focused practices, everyone on the team is experienced and proficient in the use of each in-office technology. The "focused factory" characteristics of the urology practices described in this paper are designed to improve patient outcomes through high volumes for physicians and facilities.

BPH laser treatments result in fewer adverse events and complications – and cost 22% less than TURP
(Bouchier-Hayes et al., 2009)

Strong evidence concerning integrated practice points to the benefit of developing a link between a doctor and his team, a link that provides high volumes which lead to high quality outcomes for patients. Two recent studies conclude that physicians who have high volumes produce better results for patients (Gasper, Glidden, Jin, Way, & Patti, 2009) and (Lee, et al., 2010). A review of 135 population-based studies by Halm, Lee, and Chassin showed that 71% of studies published over two decades "reported statistically

significant associations between higher volume and better outcomes" across a wide array of procedures (Halm & Lee, 2002). Another literature review undertaken by Dr. R. Adams Dudley and his colleagues explored the link between mortality and high volume in articles published between 1983 and 1998. Examining over 58,000 patient cases, they discovered that not only is high volume linked to higher quality and lower mortality but also that it is beneficial for a patient to be referred specifically to high-volume providers (Dudley, Johansen, Brand, Rennie, & Milstein, 2000).

The benefits of this practice integration and resulting high volume are particularly noteworthy for patients with a prostate cancer diagnosis, and physician investment has been the key to providing such patients with access to the full range of therapy options. Most important to note is that integrated cancer care provides coordination that follows patients from diagnosis to aftercare, regardless of treatment modality. As IMRT has replaced 3D-CRT, it has become one option among several for patients, including surgery, brachytherapy, cryotherapy, and hormones.

An integrated urology practice offers equal access to all modes of treatment for prostate cancer. At an integrated practice, urologists screen patients, make diagnoses, and educate patients about their options based on the needs of the patient. Urologists make the diagnosis but do not make the decision to use any type of radiation therapy, including IMRT. If patients choose to consider any type of radiation therapy, including IMRT, urologists refer them to the practices' radiation oncologists. Radiation oncologists serve as the gate keeper, evaluating patients for specific radiation therapies and helping guide them through their choice of treatment. When patients choose radiation therapy, radiation oncologists are the ones who provide and supervise the treatment. In an integrated practice, patients return to their original urologists for follow-up care, and this continuity of care is one of the strengths of the integrated practice model.

Dr. Kevin Khoudary of Cary Urology in North Carolina describes the value of integrated care for prostate cancer: "It involves rearranging silos of single specialties into a patient-centered structure that facilitates feedback and permits the team to make tissue-sparing adjustments during the course of treatments. ... It occurs when the urologist and the radiation oncologist cooperatively plan dosage and approach during the course of radiation therapy. It is enhanced when physical therapists and urologic therapy nurses provide immediate real-time feedback to the treatment planning team for use in dose planning (letter to the NC Division of Health Service Regulation, August 8, 2008)."

Dr. Stephen Koff, Chief of Pediatric Urology at Nationwide Children's Hospital, echoes this assessment: "Strong monitoring is important for improving quality as well as preventing future episodes. The integrative model cultivates personalized care and specialized oversight for the patient. If physician ownership were restricted or excluded, there would be less optimal treatment selection and lower quality of care" (unpublished communication, May 19, 2010).

In 2009, Gruen and his colleagues reported on their systematic review of 101 publications involving more than 1 million patients with different types of cancer. While there were some mixed results, the study confirmed that high volume has important benefits for some cancer patients. If more patients were treated in higher-volume practices, they

could achieve better-regained function, fewer side effects, and some deaths could be prevented. (Gruen, Pitt, Green, Parkhill, & Campbell, 2009).

Summary
Medicare's payment policies do not promote advances in urologic treatments in most inpatient hospitals. Improving treatments enables less-intensive surgeries or alternatives to surgeries which decrease hospital revenues. The physician payment system does have incentives for integrating cancer care (to keep more patients within the practice) and developing high-volume teams (to protect total revenue) which has prompted these innovations which have improved access to and quality of care. Physicians have invested in new technologies in their communities –hospitals or mobile units or integrated physician practices. Physician demand has helped lead to technologic improvements in urology.

Physician investment has promoted access to care

Lithotripsy

The spread of ESWL to replace invasive surgery with a non-invasive treatment was a direct result of physicians coming together in groups to jointly-purchase the very costly lithotripters. In some cases these partnerships included the local hospital, thus mitigating the revenue effect of the purchase. Urologists, especially those in rural areas, also sought to purchase mobile units, which could travel from community to community, vastly expanding access to the treatment.

As a direct result of the demands from physicians, innovations were fueled that led to design enhancements that increased the equipment's mobility. The original water-bath lithotripters could be made mobile in a 54-foot tractor-trailer. Continued demand and innovation led to machines that could be transported in small, simple trucks and wheeled in and out of procedure rooms.

Early lithotripters were first available to the public in the mid-1980s. Each unit sold for more than $5.3 million (in 2010 dollars) and required an operating room of about 600 square feet, "putting them out of reach of many smaller group practices and community hospitals, particularly those facilities that had low patient volume but still wanted to offer patients onsite lithotripsy. (Health Industry Today, 1997)."

Some hospitals that had sufficient capital were reluctant to invest in the expensive new technology. One likely disincentive for hospital investment in the early 1980s concerned the reimbursement for hospital stays after surgery for a stone: "An uncomplicated surgical lithotomy requires an average stay of one to three weeks. A percutaneous nephrolithotomy requires four to eight days of hospitalization (Castaneda-Zuniga, 1982)." Initially, ESWL patients had one- to-three-day stays, but the clinical results of ESWL therapy showed that it could be an outpatient procedure. Hospitals investing in the technology could anticipate lost revenue from the shorter lengths of stay and from hosting fewer intensive, open surgical procedures.

Dr. Dan Murtagh remembers his experience trying to expand lithotripter capacity to meet patient needs in the late-1980s: "The two hospital systems in my community did not want

to invest in additional lithotripter capacity… Our investment in these machines allowed us to schedule higher quality, dedicated technicians for multiple shifts, which would not be possible in a hospital setting." (unpublished communication, June 3, 2010).

Such resistance to purchasing lithotripters on the part of hospitals was likely a response to economic factors. The high incidence of kidney stones and early adoption and sophistication of North Carolina's regulation make it a case study for the technology: "ESWL thus posed an economic threat to both urologists and hospitals in North Carolina. If treatment of stones in the kidney and upper urinary tract were suddenly concentrated in a small number of lithotripsy centers, the impact on the providers losing that business would be substantial. [It] also threatened to accentuate a flow of patients away from community hospitals (Havighurst & McDonough, 1986)."

Stark law and IMRT

The clinical benefits of providing patient access to the most appropriate treatment for their condition was the driving consideration behind an important regulation and exemption and the development of integrated cancer care including IMRT.

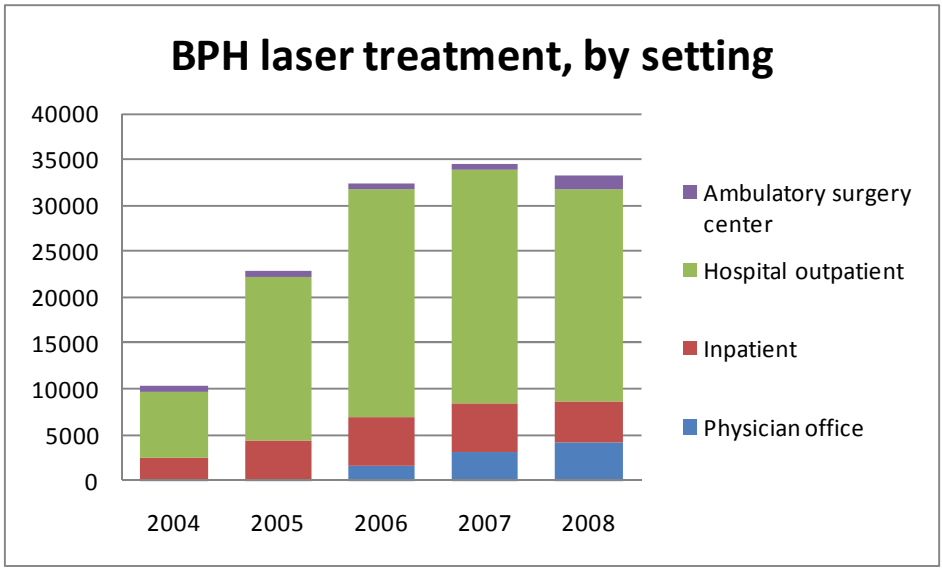
Congress enacted the Stark self-referral law to address concerns about overutilization and overpayment related to certain services paid for by taxpayers through Medicare. The in-office ancillary services exception (IOASE) to the Stark law allows owners and employees of a medical practice that qualifies as a "group practice" under the Stark law to refer Medicare patients within the group for in-office services, including radiation therapy services (Gottlieb, Radiation Oncology: Stark Contrast, 2010). The exemption balances the value of maintaining access to quality care for beneficiaries with the need to prevent abuses in the Medicare program. The IOASE allows integrated group practices to adopt IMRT and level the field, to offer patients better, convenient access to the full continuum of treatments and coordination of care. Otherwise, patients would be required to leave their urologist's practice for some treatments but not others.

The Centers for Medicare and Medicaid Services, among others, has re-examined the IOASE several times since its implementation to assure that it is consistent with overall Medicare goals. Urologists, and other physicians, have continued to use their resources to create integrated group practices despite the uncertain legal and regulatory environment because they believe in the clinical benefits of equal access to treatment. Dr. Klump, a urologist in an integrated practice based in Ohio, has noted a striking difference in the treatments provided to his patients based on their insurance. For many patients with prostate cancer, his practice provides either watchful waiting, brachytherapy, or cryosurgery as the most appropriate treatment for their condition. In his observation, however, "Patients whose insurance requires prostate cancer to be managed in the hospital always get IMRT (unpublished communication, May 18, 2010)." The referral to the hospital also leads to discontinuity in care because patients do not return to his practice in a timely fashion and because complications and treatment success or failure are not reliably communicated to the urologist.

BPH lasers

The scenario for the development of BPH lasers is very similar to that of lithotripters. As with the lithotripsy treatment of genitourinary stones, the use of lasers to treat BPH has become one of the most important contributions to improving patient access to high quality care in urology. Physicians have been willing to make investments to keep pace with this new and rapidly changing technology. Although hospital outpatient departments made the largest purchase of the BPH lasers five years ago, the changes in technology were so rapid that hospitals that did not have significant patient volumes could not justify changing machines as the technology improved. In contrast, the purchase of the BPH lasers in physician offices and primarily physician-owned ASCs rose significantly. In the most recent data available, hospital outpatient treatments declined (Figure 1.).

Figure 1. Rates of growth differ by setting, 2004 to 2008



source: Strategic Health Care analysis of Centers for Medicare and Medicaid Services' Physician/Supplier Procedure Summary files (most recent years available)

Volumes level as technologies mature

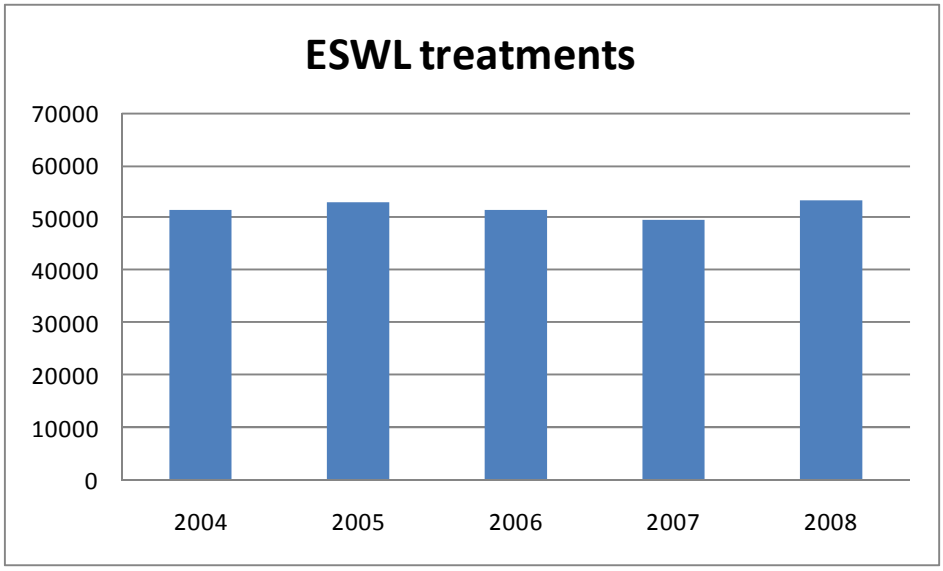
Policymakers are often concerned about rapid growth in the use of services, especially if there is the possibility that physician owners are inappropriately creating demands for services. If rapid growth is not justified, policymakers may take steps to slow the growth. The growth of each of the three key urologic technologies provide examples of how the growth in related services was rapid during the adoption phase as clear patient benefits were being delivered but, then, rapid growth ceased and stability developed as some moderate regulation (the IOASE and some states using additional regulations) was put in place with the result that the technological capacity fit the needs of the population.. For ESWL (delivered via lithotripters) and IMRT, and even for the relatively young technology of laser treated BPH, utilization trends suggest that the adoption phase growth

has already begun to slow. Population planning models demonstrate for the two older technologies—lithotripters and IMRT—that an appropriate level has been reached to meet the needs of patients.

Case #1: Volume for Lithotripters

Today, lithotripsy is the standard of care for genitourinary stone treatment. Figure 2 illustrates that this mature technology has reached an equilibrium point. Over the past five years, the total volume of ESWL has remained virtually unchanged.

Figure 2. Volume of lithotripsy in the Medicare population, 2004-2008: No Growth in Utilization



source: Strategic Health Care analysis of Centers for Medicare and Medicaid Services' Physician/Supplier Procedure Summary files (using most recent data available)

The utilization pattern for ESWL suggests that if policy makers had responded during the growth phase of ESWL in the 1980s by placing tight restrictions or prohibitions on urologists' investments, it is likely that not only would volume not have reached this stable level and access would have been impaired, but also it would have exacerbated the lag between innovation and the raising of the standard of care for patients. As a further indication of how this technology has matured, the costs of the machines have fallen dramatically, and today there are compact lithotripters on the market for less than $500,000.

As earlier noted, the high incidence of kidney stones and early adoption and sophistication of North Carolina's regulation make it a case study for the technology, so this paper uses a population-based needs assessment tool from the North Carolina Certificate of Need process (North Carolina Department of Health and Human Services, 2008) to estimate the number of lithotripters that are needed now.

North Carolina estimates that the capacity of a lithotripter is 1,000 to 1,500 treatments annually. The number of machines in the U.S. is between 550 and 700 (Jernigan, 2010). The model suggests that the current capacity for ESWL treatment is between one-half million and one million per year. (Note that the State of New York which also has a strong CON program also reviews the state's capacity for lithotripters but applies a capacity estimate of 600 treatments annually.) The most recent figures from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) indicate that there were nearly 3 million visits to physician offices and hospital outpatient departments in 2000 for urinary stone treatment and follow-up, putting the incidence of problematic stones at between 1 and 1.5 million (National Institute of Diabetes and Digestive and Kidney Diseases, 2010). As such, incidence rates correlate with capacity for annual treatments, and it appears that the number of lithotripters in the U.S. has grown to a level that is adequate to meet the current need for treatment.

Most states do not regulate the purchase of lithotripters (or other urologic technologies) with CON. Thus, if the treatment of genitourinary stones were supply sensitive and physicians could have continued to purchase lithotripters in most of the country and drive use rates up, we would have expected to see national capacity exceed the amount required by population health needs. Instead, the pattern of natural maturation of the technology which did appear, suggests that physician ownership is not driving over-utilization of ESWL. The other urological technologies discussed in this paper illustrate this point as well.

Case #2: IMRT Volume

Given prostate cancer's high incidence and high mortality rate, the development and maintenance of adequate capacity for treatment is critical. According to North Carolina's regulatory guidelines, the capacity of an IMRT facility is 6,750 treatments per year and the average utilization is 5,425. The number of centers using IMRTs is about 2,247 *(Ballas, Elkin, & Schrag, 2006)*. This suggests that the current capacity for IMRT facilities for all cancer is about 15 million treatments per year.

Given the NCI figures of the incidence of prostate cancer at about 200,000 annually and that radiation therapy is appropriate for about one-half of all cancers, it is reasonable to conclude that about 100,000 prostate cancer patients could need access to IMRT treatments. The average prostate cancer patient requires treatment 5 days per week for 8 weeks. Thus, 100,000 patients would require 4 million treatments annually.

Several other prevalent types of cancers can also be treated with IMRT, including breast cancer and lung cancer. Thus, the total capacity of IMRT facilities must be apportioned among many patients in addition to prostate cancer patients. Prostate cancers are 13 percent of all cancers but adequate treatment could consume over 25 percent of the total national capacity. In breast cancer, the use of radiation has been increasing as the efficacy of breast-conserving surgery in conjunction with chemotherapy has been demonstrated and applied in practice; using IMRT can reduce the length of treatment and side-effects compared with other radiation modalities (Vincini, 2002). For lung cancer, IMRT can be used on tumors which cannot be removed surgically. Using radiation to treat lung cancer is technically challenging given the potential for harming tissues near the tumor; however, IMRT reduces collateral damage and can make treatment possible in cases which would be inoperable otherwise.

North Carolina has one of the highest rates of prostate cancer mortality in the United States. To ensure access, that state includes geographic-accessibility criteria to plan for one machine per 120,000 people and to plan for an additional machine if more than 45 percent of the patients using an existing machine have to travel from outside of the service area. The table below uses North Carolina's criteria to suggest that as many as 34 states do not have sufficient capacity to treat their prostate cancer patients, i.e., many patients have to travel inconvenient distances or simply do not have access to IMRT as a treatment option. Note that the list includes four of the nation's five most populous states (California, Texas, New York, and Illinois), which are also very large geographically. Meanwhile, many small-population states are very large geographically, again requiring some patients to drive long distances. This can be true even in states with sufficient capacity on paper. For example, while North Dakota's need ratio does suggest over-capacity, even that relatively high number may merely be to address geographically dispersed need.

It is important, again, to recognize that IMRT capacity may not be adequate to also meet the needs of other cancer patients who can benefit from this treatment, including those with breast cancer and lung cancer.

34 states do not have enough IMRTs to treat their prostate cancer population

State	State Population	Prostate cancers	Number of IMRTs needed	Number of IMRTs in state
California	36,961,664	20,790	308	197
Texas	24,782,302	13,130	207	157
New York	19,541,453	12,520	163	155
Illinois	12,910,409	7,590	108	107
Michigan	9,969,727	7,010	83	63
Georgia	9,829,211	5,210	82	62
North Carolina	9,380,884	6,130	78	64
New Jersey	8,707,739	6,060	73	56
Virginia	7,882,590	4,830	66	48
Washington	6,664,195	4,680	56	42
Arizona	6,595,778	3,530	55	49
Massachusetts	6,593,587	4,200	55	34
Missouri	5,987,580	3,620	50	48
Maryland	5,699,478	3,580	47	40
Minnesota	5,266,214	4,910	44	31
Colorado	5,024,748	3,070	42	28
South Carolina	4,561,242	2,910	38	23
Oregon	3,825,657	2,510	32	23
Oklahoma	3,687,050	2,190	31	28
Connecticut	3,518,288	2,400	29	24
Iowa	3,007,856	2,330	25	22
Mississippi	2,951,996	1,990	25	24
Arkansas	2,889,450	2,140	24	22
Utah	2,784,572	1,570	23	11
Nevada	2,643,085	1,660	22	20
New Mexico	2,009,671	1,400	17	16
Idaho	1,545,801	1,170	13	12
New Hampshire	1,324,575	910	11	7
Maine	1,318,301	1,130	11	7
Hawaii	1,295,178	860	11	10
Rhode Island	1,053,209	650	9	5
Delaware	885,122	550	7	6
Alaska	698,473	360	6	3
Vermont	621,760	540	5	4
National total	**307,006,550**	**192,300**	**2558**	**2247**

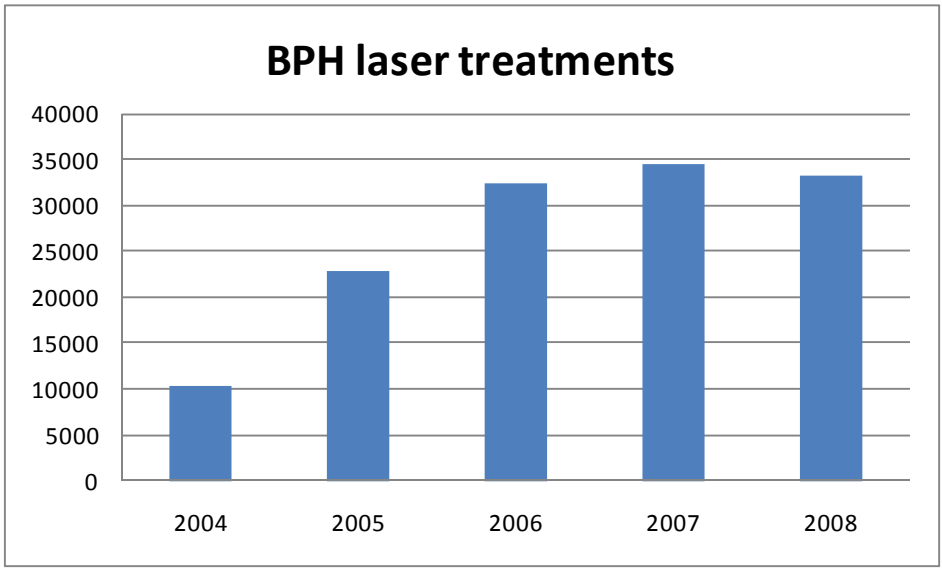
States with adequate IMRTs : FL, PA, OH, IN, TN, WI, AL, WV, NE, MT, LA, KY, KS, SD, ND, WY, DC

Sources: State Population from US Census Bureau, Population Division, December 2009; New cancer incidence from CA: A Cancer Journal for Clinicians"Cancer Statistics, 2009"; Number of IMRTs from Int. Journal of Radiation Oncology 2006; Number of IMRTs needed based on Strategic Health Care analysis

Case #3: BPH Laser Volume

Although the BPH laser technology is younger than IMRT, it already shows signs of market maturity in terms of Medicare volume. As Figure 2 demonstrates, the use of BPH lasers grew at an increasing rate each year from 2004 to 2007; between 2007 and 2008, its use slightly declined.

Figure 3. Volume of BPH laser treatments in the Medicare population, 2004-2008: Rate of Growth Slowed and Then Reversed



source: Strategic Health Care analysis of Centers for Medicare and Medicaid Services' Physician/Supplier Procedure Summary files (most recent years available)

Given the relative youth of this technology, it is not in its own category for review under CON and state health planning laws. However, clinical indicators suggest that it will follow the patterns of lithotripters and IMRT and be adopted as the new standard of care for BPH. Informed patients will chose this treatment because of lower risks, fewer side effects, and no need for an inpatient stay. Given that the growth in volume has leveled off in recent data, it seems unlikely that states will introduce CON review.

Summary

Physician investment, if policy-makers continue to allow it, will encourage the adoption and diffusion of the technology to meet population needs. The growth patterns of each of the three technologies in this paper illustrate the natural growth of services to appropriate levels with only moderate regulation.

Benefits of physician ownership outweigh concerns

This paper includes first-hand observations by physicians who witnessed resistance from hospitals and health systems to purchase such important technological treatment tools as the three described in this paper. While improved, the health care payment system still presents disincentives for hospital investment in these technologies, in part because providing less-intensive procedures reduces total per-patient revenue and because the newer technologies divert use from previously purchased technologies.

Physician investment has contributed to increases in quality of care and access for thousands of urologic patients. For this reason, the Stark law IOAS exception should remain in place. Maintaining the exception for urologist ownership would assure continuation of current services that provide quality benefits to patients, assure continued patient access to less-intense interventions, and promote continued medical advances in the technologies.

> Maintaining the IOAS exception will allow continuation of current services, assure access to less-intense interventions, and promote advances in current and future medical technologies.

Regulated physician investment has resulted in widespread access to the best and most current treatments available, better integration of technology, and the continuum of care. Evidence suggests that the technologies and treatments discussed in this paper—lithotripters, IMRT, and BPH laser—can provide critical clinical benefits to patients compared to earlier treatments – including improved mortality, decreased length of treatment, shortened stay in a hospital, fewer infections and complications, and improved long-term recovery of gastro-intestinal health and sexual function. Though no one treatment is appropriate for every patient, these technologies broaden the therapeutic options for most patients and allow some patients to be treated who would have no other option.

Additionally, physician ownership of mobile technology has allowed practices to bring lithotripters and laser BPH to many small communities where the population could not support adequate use of the machines or the trained technologists and staff that must accompany them.

Utilization trends of ESWL and IMRT show that such mature technologies reach an equilibrium level of volume. For BPH lasers, the adoption phase growth has already begun to slow. Policy-makers should allow BPH laser technology to mature as ESWL and IMRT have, and further assure that physicians will remain able and willing to invest in new technologies yet to come.

Policy-makers should not only work to protect physician ownership of lithotripters, IMRT, and BPH lasers, but they should also work to encourage it. With such strong evidence and anecdotal physician testimonials linking ownership, volume, and quality, efforts to promote the advancement of technologies can only mean better outcomes for patients and lower relative costs to health care systems.

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