THE CANCER LETTER

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The Cost of Healthcare

How to Become a Urology Millionaire... Alas, One Little Problem—Overtreatment

By Paul Goldberg

If marketing materials are to be believed, the advantages of being able to perform intensity-modulated radiotherapy can be worth as much as $6 million in gross revenue per year to a urology practice. Setting up a pathology lab on the premises can be worth another $1 million.

Generally, the practice of "self-referral," or referring patients to healthcare entities in which the doctor prescribing a procedure has an interest, is verboten by the "Stark laws" that govern Medicare and Medicaid.

However, these laws leave open a loophole—for situations where such services are provided by a member of the referring physician's practice and when the services are provided in the building that houses the practice.

In urology practices, the loophole covers pathology, radiation therapy and diagnostic radiology.

(Continued to page 2)

Oncologists Don't Demand Increased Survival When Ordering Expensive Drugs, Survey Finds

A survey showed that U.S. and Canadian oncologists prescribe treatments with little consideration of their cost.

The study, led by Peter Ubel, a physician and behavioral scientist who teaches at Duke University Fuqua School of Business, found that these doctors don't demand an increased benefit, which researchers measured in months of survival, from an expensive drug than they do from a less expensive one.

The study was published in the April issue of the journal Health Affairs.

(Continued to page 5)

In Brief

Alvarez Named New President of The Society of Gynecologic Oncology; Society Restructures

RONALD ALVAREZ was elected president of the **Society of Gynecologic Oncology**.

Alvarez is a professor and director of the Division of Gynecologic Oncology at the University of Alabama at Birmingham, as well as vice-chairman of the Department of Obstetrics and Gynecology. He also holds the Ellen Gregg Shook Culverhouse Chair in gynecologic oncology.

(Continued to page 7)

Studies Say Self-Referral Drives Overuse of Biopsies, IMRT

(Continued from page 1)

How does ownership of a lab or an IMRT affect utilization of these services?

Two papers published in the April issue of the journal Health Affairs suggest that self-referral increases the number of biopsies in urology practices that own labs, and creates financial pressures that appear to direct patients with lower-risk prostate cancer to receive IMRT. There is no data that would suggest that IMRT, which costs more, is superior to other radiation treatments.

The first of the studies found that urologists are more likely to perform surgical biopsies if they are able to self-refer, as opposed to referring such patients outside their practices. This study was conducted by Jean Mitchell, a public policy professor at Georgetown University.

The second study observed that IMRT is now just as likely to be used in men with low-risk disease as in men with high-risk disease.

The proliferation raises concerns about overtreatment and increased costs—since the therapy costs $15,000 to $20,000 more than standard care, said researchers. The study was led by Bruce Jacobs, a fellow in urologic oncology, endourology, and health services research at the University of Michigan.

Pathologists and radiation oncologists are unhappy with these changes in urology, which cut into the services they have traditionally provided.

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Urologists and Self-Referral

Using Medicare claims data, Mitchell's study identified 36,261 episodes during 2005-07 in which a prostate biopsy was performed.

The goal was to determine how the "in-office ancillary services" exception affected the use of surgical pathology services and cancer detection rates associated with prostate biopsies.

The study found that self-referring urologists billed Medicare for 4.3 more specimens per prostate biopsy than the adjusted mean of 6 specimens per biopsy that non-self-referring urologists sent to independent pathology providers, a difference of almost 72 percent.

The regression-adjusted cancer detection rate in 2007 was twelve percentage points higher for men treated by urologists who didn't self-refer.

"The significantly lower cancer detection rates linked to self-referral suggests that financial incentives prompt urologists to perform prostate biopsies on marginal cases," Mitchell wrote in the study.

The author said that this points to financial incentives prompt self-referring urologists to perform prostate biopsies on men who are unlikely to have prostate cancer and support closing the loophole that permits self-referral to "in-office" pathology laboratories.

One firm, offering to set up pathology labs for urologists, said in its marketing materials that practices may be foregoing as much as $1 million a year.

"Our estimate is that each member of your group can *net* over $50,000/partner/year without doing extra work," said a flyer from TwinCrest Group. "You get paid instead of your current pathology laboratory."

Bernie Ness, a co-founder of TwinCrest, which is now called In-Office Pathology of Lake Forest, IL, said the old brochure was phrased differently from the marketing materials he uses now, but he stands by the numbers.

"Each urologist is, on average, sending out 1,000 prostate biopsies a year," said Ness. The national average is about $100 per biopsy. "It's not bad. Those numbers are correct. We are not blowing smoke."

Ness said that since 2005, his company has set up about 40 labs, only six of them in urology. The others are based at gastroenterology and dermatology practices.

Ness readily acknowledges that the system functions on financial incentives. "They make a major investment to put a lab in their practice," he said. "If you make a major investment, you get a return on that investment. If you put up a half-a-million dollars, you certainly don't want to lose money on it, and this is still

America, so making a profit is not a totally dirty word."

Ness disputes the assertion that ownership of labs induces urology practices to perform more biopsies. "The people that we have talked to, that we do business with, say, 'Bernie, I have malpractice insurance, these are invasive procedures,'

"You want to know the biggest concern that every urologist has? It's sepsis. You don't walk into a urologist's office off the street and they say, 'Hey, you look like a candidate for a prostate biopsy, get on the table.'"

Ness's company has posted a rebuttal to Mitchell's paper, posted at http://www.iopathology.com/. "She is basically doing her job as dictated by the grant money she got," Ness said. "It's a paid study. Enough said."

Disclosure states that the research was supported by an unrestricted educational research contract between Georgetown University and the American Clinical Laboratory Association, in conjunction with the College of American Pathologists. The paper is posted at http://content.healthaffairs.org/content/31/4/741.abstract?ijkey=ezMzOzUWRa6sA&keytype=ref&siteid=healthaff.

"This study suggests that men are at heightened risk of unnecessary and costly prostate cancer biopsies when under the care of a physician who benefits financially through self-referral," said Alan Mertz, president of the American Clinical Laboratory Association.

"This is a serious unintended consequence of a legal loophole that needs to be corrected immediately by Congress. For the sake of patient safety and government spending, Congress must end loopholes permitting self-referral of surgical pathology testing."

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MAKE A MILLION: ***A flyer circulated by TwinCrest Group circa 2006.*** *The company, now doing business under another name, no longer uses this material.*

"There is no Better Source of Revenue"

The rapid spread of IMRT in prostate cancer is a part of the shift of radiation delivery from oncologists to urologists.

According to the Jacobs paper, some companies that market IMRT to urologists claim that treating 1.5 new patients monthly with IMRT can generate more than $425,000 in new revenue, per physician, each year.

Capital investment can create incentives to sell IMRT to patients who may be considered marginal, pushing them toward selecting IMRT.

Altogether, the researchers focused on 125,299 men diagnosed with prostate cancer. Patients undergoing IMRT and three-dimensional conformal therapy within one year of diagnosis were identified using the Healthcare Common Procedure Coding System codes from the carrier (that is, the physician) and outpatient files.

With these methods, researchers identified 19,846 men treated with IMRT and 16,644 men treated with three-dimensional conformal therapy.

Researchers observed rapid adoption of IMRT among men diagnosed with prostate cancer from 2001 through 2007, despite uncertainty about its relative effectiveness.

Researchers found that in the early period of IMRT adoption (2001–2003) men with high-risk disease were more likely to receive IMRT, whereas after IMRT's initial dissemination (2004–2007) men with low-risk disease had fairly similar likelihoods of receiving IMRT as men with high-risk disease.

"With limited financial resources, our health care system must establish that 'Cadillac' therapies, such as IMRT, are truly worth the investment before they become the standard," Jacobs said in a statement. "We must ensure that incentives used to encourage the utilization of new technology do not unintentionally create incentives for overuse."

The paper is posted at http://content.healthaffairs.org/content/31/4/750.abstract. The authors report no competing interests.

FAQ'S

Why should we integrate radiation oncology into our practice?

In light of decreasing LHRH and rising overhead, urologists need to seriously begin considering new revenue sources, and there is no better revenue source available to urologists than IMRT. In fact, the opportunity cost associated with IMRT is very high. Every month that a group with the necessary critical mass delays in developing a center is potentially a loss of over $500,000 of gross revenues PER month.

What is the breakeven point for an IMRT center?

The breakeven point would be 4 new patients per month. This would approximately yield each of the 14 physicians an annual return of $8,600. However, the more typical rate of new patients per physician is between 1 and 2 new patients per month. With a new patient rate of 1 per physician, the projected annual return per physician is approximately $255,000 per physician. At an average rate of 1.5 new patients per month, the projected annual return per physician is over $425,000. These projections are based on current prevailing Medicare reimbursement.

What are the estimated total costs to develop an IMRT center (construction, equipment, and preparation)?

The estimated cost to develop a prostate IMRT center is between $2.5 & $2.9M. This figure includes the complete Varian IMRT package, a refurbished GE CTi machine, vault, land, facility, computers & equipment, furniture & fixtures, physics equipment and other related IMRT supplies. However, one caveat to this estimate is that the cost of real estate and build-out vary depending on geographical location.

What is the estimated turnaround time associated with the development of an IMRT center?

Once the project is given the "green light," it is conceivable that a center can be developed and in operation within four to six months. Building from "scratch" may extend the time frame a few months. However, using Urorad's established relationships, the time frame associated with a new construction scenario can be compressed significantly. The important point to remember is that every month of delay represents hundreds of thousands of dollars and quickly over a million in 2 short months!

FOR A FEW MILLION MORE: ***Excerpts from a fact sheet distributed by Urorad Healthcare Inc., laying out the economics of IMRT for urology practices.***
The company remains in business, but no longer makes these materials public.

The issue is important because, according to industry figures, almost one in five urology practices now own an IMRT unit.

A flyer by a Texas company, Urorad Healthcare Inc., provided the business rationale for installing an IMRT unit: "In light of decreasing [luteinizing hormone releasing hormone] and rising overhead. Urologists need to seriously begin considering new revenue sources, and there is no better revenue source available to urologists than IMRT.

"In fact, the opportunity cost associated with IMRT is very high. Every month that a group with the necessary critical mass delays developing a center is potentially a loss of over $500,000 of gross revenues PER month."

Urorad's website appears to have been taken down, but the company is still in business. The undated FAQ

sheet, obtained by The Cancer Letter, is posted at http://www.cancerletter.com/categories/documents. Company officials didn't return a call from The Cancer Letter.

The American Society of Therapeutic Radiology and Oncology, which represents radiation oncologists, said that IMRT can yield benefits to some prostate cancer patients.

"At the same time, all patients may not be ideal candidates for IMRT and patients should be presented with all of their options, including active surveillance," ASTRO said in a statement. "The problem identified by the authors is not caused by the reimbursement rate of IMRT, which has declined by about 30 percent over the last six years, but rather its overuse on patients who don't need it."

ASTRO said it would continue to work with Congress to close the self-referral loophole.

The American Urological Association didn't return calls from The Cancer Letter.

Study: Oncologists Abandon Price Thresholds In Clinical Scenarios

(Continued from page 1)

This finding may not be surprising, because an increasing number of new oncology drugs are approved based on their ability to delay progression of disease. An argument can be made that the findings point to acceptance of this metric.

"Insensitivity to prices may contribute to the ever-escalating costs of new cancer medicines," Ubel said in a statement. "If oncologists' expectations of a treatment don't rise in accordance with the price of the treatment, the pricing of these drugs will be skewed. This can lead to very expensive, ineffective medicines."

The team surveyed 1,389 ASCO members in the U.S. as well as English-speaking oncologists in Canada, presenting scenarios aimed at gauging how much benefit oncologists believe new treatments need to provide in order to justify the costs of these treatments.

The survey presented a hypothetical new chemotherapy drug and asked oncologists how much benefit—in terms of life expectancy gain—the drug would need to provide.

"When presented with general hypothetical questions about the cost effectiveness of medicines, more than two-thirds of respondents said treatments costing greater than $100,000 per year of life were not good value for money," Ubel said. "But this attitude contradicts their answers to our survey questions about a specific clinical scenario, when oncologists endorsed spending several hundred thousand dollars per year of life gained. In other words, they are sensitive to price in the abstract, but they abandon their notions of a price threshold when considering treatment for an individual patient."

The paper is posted at http://content.healthaffairs.org/content/31/4/709.abstract.

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ASCO Publishes Top Five Measures to Improve Care

The American Society of Clinical Oncology published a list of measures oncologists can take to improve care by limiting the use of common tests and treatments that are not supported by clinical evidence.

The paper, published in the Journal of Clinical Oncology, coincides with the announcement of several "top five" lists as part of the Choosing Wisely campaign. ASCO is one of nine specialty societies participating in the campaign, which is sponsored by the American Board of Internal Medicine Foundation and Consumer Reports magazine.

ASCO is one of nine specialty societies participating in the campaign to improve the quality and value of care by curbing use of common tests and treatments that are not supported by clinical evidence.

The campaign is sponsored by the American Board of Internal Medicine Foundation.

An article published in the Journal of Clinical Oncology summarizes each element of the oncology Top Five list, which includes: unnecessary use of chemotherapy for patients with advanced cancers who are unlikely to benefit; use of advanced, costly imaging technologies for staging of early breast and prostate cancers and for detection of breast cancer recurrence; and overuse of drugs to stimulate white blood cell production in patients receiving chemotherapy.

"As oncologists, we have a responsibility to help ensure that all cancer care is high-value care," said Michael Link, president of ASCO. "That means providing the highest quality of care to our patients, while avoiding treatments that have little or no proven benefit. In the process, we also do our part to address the unsustainable cost increases that threaten our nation's health care system."

The concept for the Choosing Wisely campaign was first proposed in 2010 commentary in the New England Journal of Medicine by Howard Brody, director of the Institute for the Medical Humanities and a family medicine professor at the University of Texas.

Brody challenged medical specialties to take a critical look at their fields and to each identify five practices that are commonly performed despite a lack of supporting evidence.

"At ASCO, we took this challenge to heart," Lowell Schnipper, lead author of the JCO article and chair of ASCO's Cost of Care Task Force, said in a statement.

"By tackling the overuse of treatments and tests for some of the most common cancers, we hope to achieve substantial improvements in the quality of cancer care in the U.S.

"The Top Five list is just the first step in an ongoing ASCO effort to help physicians and patients implement these recommendations."

The Top Five list was developed by members of ASCO's Cost of Cancer Care Task Force, a multidisciplinary group of oncologists that seeks ways to increase the value of cancer care.

The list follows:

1. Avoid unnecessary anticancer therapy, including chemotherapy, in patients with advanced solid-tumor cancers who are unlikely to benefit, and instead focus on symptom relief and palliative care.

Data have shown that a significant number of cancer patients receive chemotherapy in the last two weeks of life, even though such treatment generally does little to improve survival or quality of life, causes side effects and carries the unintended consequence of increasing costs. Data have shown that as many as 10 to 15 percent of patients with cancer receive chemotherapy in the last two weeks of life. Such care may also postpone patients' access to palliative care, including hospice care.

ASCO recommends that cancer-directed therapy not be used for solid tumor patients with the following characteristics: low performance status (3 or 4), no benefit from prior evidence-based interventions, not eligible for a clinical trial, and no strong evidence supporting the clinical value of further anti-cancer treatment. Because further treatment is unlikely to be effective in these patients, emphasis should be placed on palliative and supportive care, which can increase quality of life and, in some cases, extend survival.

2-3. For early-stage breast cancer (2) and prostate cancer (3) that are at low risk of spreading, do not use advanced imaging technologies (positron emission tomography (PET), CT and radionuclide bone scans) for determining the cancer's spread.

ASCO recommends against using these imaging tests for staging in patients with:

Newly identified stage I or II breast cancer or ductal carcinoma in situ (DCIS), which are unlikely to have spread beyond the breast and nearby lymph nodes at the time of diagnosis. (In these patients, staging is done according to a physical examination, the size of the tumor and nearby lymph nodes, and common blood tests.)

Newly diagnosed low-grade prostate cancer (Gleason score less than or equal to 6) in men with a PSA level of less than 10 ng/ml.

For these patients, the use of advanced imaging technologies to search for cancer spread has not been shown to improve detection of additional tumors or to extend survival. Rather, these tests are known to increase the risk of misdiagnosis or false-positive results, which can lead to unnecessary invasive procedures or treatments that can ultimately diminish quality of life or even shorten patients' lives.

4. For individuals who have completed curative treatment for breast cancer, and who have no symptoms of recurrence, advanced imaging tests (PET, CT and radionuclide bone scans) and routine blood tests for certain biomarkers (CEA, CA 15-3, CA 27-29) should not be used to screen for cancer recurrences.

The majority of individuals diagnosed with breast cancer today have early-stage disease and, because of treatment advances, most have a normal life expectancy with a very low risk of recurrence. While current guidelines emphasize that routine physical exams and mammography are the safest and most effective strategies for detecting recurrences, many individuals also undergo additional blood and imaging tests, even though they have not been shown to improve survival.

The authors note that false-positive results are very common with these tests and can lead to invasive procedures, over-treatment and misdiagnosis that can severely affect quality of life.

5. Avoid administering white blood cell stimulating factors to patients who have a very low risk for febrile neutropenia (less than 20 percent).

White blood cell growth factors, also called colony-stimulating factors (CSF), boost the body's production of white blood cells, which can be destroyed during certain chemotherapy regimens. Extremely low levels of white blood cells can lead to a highly dangerous side effect of chemotherapy called febrile neutropenia. ASCO guidelines recommend that white blood cell stimulating factors be used only when the risk of febrile neutropenia from chemotherapy is greater than 20 percent and effective alternative therapies are unavailable. However, data suggests these drugs are often not used according to evidence-based guidance, costing health systems millions and potentially causing unnecessary side effects for patients (e.g., bone aches, low-grade fever and malaise). In one study, 10 percent of patients at low risk (less than 20%) for febrile neutropenia received these treatments. Another study showed that Medicare spent at least $40 million in 2005 on CSF therapy for women with ER-positive breast cancer, even though studies have not demonstrated a benefit for such patients.

The JCO article notes that important exceptions exist for all five elements of the top-five list, based on specific patient circumstances. For example, in the case of recommendation No. 5, guidelines allow for use of white blood cell stimulating factors for patients at higher risk for chemotherapy-related febrile neutropenia due to age, medical history or disease characteristics.

Over the coming months, ASCO will work with its more than 30,000 members, and with other partners in the cancer community, to help implement these recommendations. ASCO is developing additional tools and publications for physicians, along with new resources to help patients have informed discussions with their physicians about the quality and value of the care they receive.

Additional information is posted at www.asco.org/topfive.

In Brief

Alvarez Named SGO President; Society Creates Foundation

(Continued from page 1)

Alvarez is currently a co-principal investigator in cervical neoplasm vaccine projects included in the John Hopkins/UAB Cervical SPORE.

Alvarez serves as a board member of the Gynecologic Oncology Group and is co-chair of its protocol development committee. He is also on the editorial board of Gynecologic Oncology.

THE SOCIETY OF GYNECOLOGIC ONCOLOGY announced it would restructure itself during its **Annual Meeting on Women's Cancer**.

The society's membership approved incorporating a 501(c)(6) not-for-profit entity with the current 501(c)(3) philanthropic organization. A single governing board will oversee both organizations. The newly created 501(c)(3) will be known as the Foundation for Gynecologic Oncology, and will be responsible for education, research, development and fundraising to complete the mission of both groups.

The Society of Gynecologic Oncology, the assumed 501(c)(6), will be responsible for clinical practice, government relations, coding and membership activities.

"This move solidifies SGO as a strong and viable organization that is becoming more independent of pharmaceutical and medical device industry funding to support our member education," said newly elected president Ronald Alvarez.

ROBERT BRISTOW was appointed the first **Philip J. DiSaia Chair in Gynecologic Oncology** at University of California-Irvine.

The chair is named for UC Irvine's former chief of the Department of Obstetrics and Gynecology's Division of Gynecologic Oncology, Philip DiSaia, who is chair of the Gynecologic Oncology Group.

As chair, Bristow will also serve as the division's chief. The chair may be held for a renewable five-year term.

TIMOTHY PAWLIK was named director of surgical oncology at the **Johns Hopkins University School of Medicine**.

Pawlik is head of the Hopkins Liver Tumor Center

and an associate professor and co-director of the center for Surgical Trials and Outcomes Research.

He takes the place of **Richard Schulick**, who is moving to head the surgery department at the University of Colorado. Pawlik is an executive council member of the Society of Surgical Oncology, the American Hepato-Pancreato-Biliary Association and the Association for Academic Surgery.

Additionally, the Hopkins Department of Surgery created two new sections: hepatobiliary and pancreatic surgery, and gastrointestinal oncology, breast, melanoma, sarcoma and endocrine section. Surgeon **Christopher Wolfgang** will lead the hepatobiliary and pancreatic section, and **Nita Ahuja**, a surgical oncologist, will lead the other.

Wolfgang, an associate professor in the departments of surgery, oncology and pathology, is currently head of the pancreatic surgery section and co-director of Hopkins' Multidisciplinary Pancreatic Cyst Clinic.

Ahuja is currently the head of the Gastrointestinal Sarcomas and co-director of the Peritoneal Surface Malignancy Program. She is also an associate professor in the departments of surgery and oncology and is a member of the Stand Up to Cancer Dream Team on epigenetic therapy.

DAVID SPENCER was appointed chief scientific officer of **Bellicum Pharmaceuticals Inc**.

Spencer was vice chairman of pathology and immunology at Baylor College of Medicine and co-founded Bellicum.

He helped invent chemical induction of dimerization technology, which is used to control certain biologic functions in cells. It's used in two of Bellicum's lead product candidates. Spencer's team used CID technology to create a much more potent vaccine against poorly immunogenic self-peptides. He also developed a series of state-of-the-art, non-immunogenic suicide genes for gene therapy, which utilize endogenous caspase family proteases and CID technology.

THE LUSTGARTEN FOUNDATION awarded nearly **$4 million in new research grants**. The funding will go to scientists at seven research centers working to better understand pancreatic cancer.

The Lustgarten Foundation grant recipients, along with their institutions and their specific research projects, are outlined below:

Ralph Hruban, Johns Hopkins University School of Medicine, focusing on the sequencing analysis of the DNA of families with a history of pancreatic cancer to identify genes that may be involved in predispositions to the disease.

Channing Der, University of North Carolina Lineberger Comprehensive Cancer Center, focusing on identifying promising drug combinations for potential future use in clinical trials.

Rakesh Jain and **Robert Langer**; Massachusetts General Hospital and The David H. Koch Institute for Integrative Cancer Research at Massachusetts Institute of Technology. Their project seeks to improve drug delivery in pancreatic cancer by widening blood vessels surrounding the cancer to more effectively access the tumor.

Anirban Maitra and **Wells Messersmith**; Johns Hopkins University School of Medicine and University of Colorado. Their project analyzes tissue samples collected from patients participating in a clinical trial that uses a new drug to target the NOTCH signaling pathway in advanced pancreatic cancers.

Hidde Ploegh, Kai Wucherpfennig, and **J. Christopher Love**; The Koch Institute at MIT, Dana-Farber Cancer Institute, and the Whitehead Institute for Biomedical Research. Their project seeks to develop a mouse model that would mimic the human immune system, which could then be used as a tool to help develop immunotherapy agents for human clinical trials.

Daniel Laheru, and **Ana De Jesus-Acosta**; Johns Hopkins University. Their project analyzes tissue samples collected from patients participating in a clinical trial that used a new combination of drugs to target and destroy the stem cell population in pancreatic cancers.