ROBOTIC PROSTATECTOMY: THE FUTURE IS NOW

Interview by Diane Johnson

Definition: Robotic Prostatectomy is a computer-enhanced minimally invasive surgery to remove the prostate. The procedure is typically performed through five-½ to 1 inch incisions in the abdomen. The abdomen is inflated with carbon dioxide gas to create space for the surgeon to work. The surgeon controls a robotic camera, that allows a 3-D magnified virtual reality image, and three separate mechanical arms (one controls an endoscope, the other two control instruments) that are inserted through the incisions. Controlled by exact finger movements, the robotic arms have more range of motion and precision than the human wrist, allowing the surgeon to separate critical nerves and blood vessels with a goal of reduced side effects, blood loss, pain, and recovery time. Based on short-term results, robotic procedures appear to have cancer control rates similar to standard radical retropubic and laparoscopic surgeries.

I recently spoke with Dr. Ashutosh Tewari, Director of Robotic Oncology at the Brady Urology Foundation. Dr. Tewari is the Ronald P. Lynch Professor of Oncology at the Weill Medical College of Cornell University. He is an internationally known author, professor, and expert on Robotic Prostatectomy and other minimally invasive robotic surgeries, having performed over 1700 robotic surgeries, including prostatectomies.

Dr. Ashutosh Tewari

DJ: Thank you for speaking with me, Dr. Tewari. There has been a lot in the news about the advantages of Robotic Prostatectomies. To begin with, can you explain why a patient would choose this procedure over a standard prostatectomy?

AT: Assuming equal cancer control and sexual and urinary function after both types of surgery, patients that prefer not to have a long incision and those concerned with blood loss could choose the robotic surgery. In addition, the post-operative catheter can be removed in half the time and there is a shorter recovery time in most cases. We have also developed some technical modifications in nerve-sparing and urinary continence that utilizes the benefits of robotic technology.

DJ: Compared to a standard non-robotic laparoscopy, what are the advantages of the robot?

AT: The answer is two-fold: Because of the 3-D image, we have depth perception and that helps in the fine precision movements that we need to do during the surgery. And the instruments are very precise. While I do the robotic procedure, I can literally use my thumb to manipulate the instruments. When I do a standard laparoscopy, I am making most of the movements using my wrists and shoulders and elbows. It’s like trying to eat rice with chopsticks—you are so tempted to start using a spoon.

DJ: How long does the patient need to stay in the hospital and what side effects can they expect?

AT: 95% of the patients go home within 23 hours of the surgery—only one night in the hospital—and come back 6 to 7 days later for a check-up. They have new PSA’s done in 3 months, 6 months, and a year, just like with standard open surgery.

(continued on pg. 7)
The Brave new world of technology is pushing the boundaries of medical care more and more through protocols that enable the healthcare professionals to improve on the delivery of quality care. One such innovation is seen in our cover story on robotic laparoscopic prostatectomy surgery. I was able to “scrub in” for the procedure and it’s a Star Wars type of experience! No longer is the surgeon required to labor physically over the patient, but rather “operates” from behind a computer console using his robotic “hands” to perform the functions previously done manually. Coupled with the enhanced vision of the system, the surgeon literally has a magnified view of the operating field that will definitely enhance quality-of-life outcomes relative to incontinence and impotence. Note though, there is a learning curve with this procedure; surgeons, who have made the transition from traditional open to the robotic laparoscopic procedure, estimate that it takes about 30 laparoscopic procedures to approximate the skill level they had with the open. Definitely the surgeon skill level needs to be discussed if contemplating this therapeutic choice!

More critically, I am compelled to voice my concern relative to the issue of the drug approval process currently in place at the Food and Drug Administration (FDA). Since its inception in 1906 under President Theodore Roosevelt and its modern day codification in 1938 under President Franklin Roosevelt, the FDA has been charged with regulating those drug and food products relative to their safety for the consuming public. That authority was significantly expanded in 1962 with the passage of the Kefauver-Harris Amendment that mandated that all new drug applications demonstrate “substantial evidence” of the drug’s efficacy in addition to existing requirements for demonstrated safety. This marked the beginning of the modern day drug approval process currently in effect.

But where does the safety parameter begin and bureaucracy end? We have seen recently several debates caught up in controversy over protection of the public good, marketing imperatives and manifest patient need. The merits of Avanda, Vioxx, Provenge and satraplatin have been heatedly debated among FDA officials, scientists, health professionals and patient advocates with champions on both sides of the medical community. Most recently, we have seen the U.S. Court of Appeals strike down the request from the Abigail Alliance for Better Access To Developmental Drugs. Their suit posited that advanced stage and seriously ill patients should have access to those drugs that have met preliminary clinical trial protocols for safety and efficacy, though not yet approved by the FDA. To my mind, and to many patients and their caregivers, this seems a reasonable option. Since much of the endpoint measurement for drug approval stands on data collected from the worst disease stage group, why not extend the option of potential benefit to those other patients within the targeted study sector. More to the point, whose life is it anyway!?! If there are no treatment modalities available that meet accepted evidence based standards of care, yet there are developmental therapies with some demonstrated potential for either longer term survival, reduction in time to progression or improved quality-of-life (less pain, lower drug toxicity, etc.), why shouldn’t the patient and his/her doctor have access to a therapy that could be of benefit. The overarching mission statement of the National Cancer Institute has been “To Eliminate the Suffering and Death Due to Cancer”; there have been no qualifying statements that says that we will do this only for selected groups at a time, then why not let that fight happen if only one person’s life can be saved. Government “protectionism” has given oversight, if not exacerbation, to the demise of jobs and industries through programs such as NAFTA and the elimination of Fair Trade Agreements. We stand at a point where our health insurance system creates a level of non-competitiveness in global markets and has insured that more than 45 million of our fellow citizens are without healthcare insurance. We stand at a point where specialization in healthcare delivery that shows a decline in primary care physicians when many of the major disease conditions facing our society need to be addressed at a prevention level best served by that primary care doctor. We have a healthcare compensation structure that rewards performance in clinical management of illness versus prevention of disease onset. We spend more than 15% of the nations Gross Domestic Product on healthcare costs yet are deficient in serving the masses of people for whom the Government is charged with protecting Life, Liberty and the Pursuit of Happiness.

We need a new Declaration, one that insures with all certainty the RIGHT of an individual to protect his/her life. We cannot allow or afford further diminution of the health of our citizens; we must have the liberty to choose how we live, or end, our lives. Hope is what sustains all of us in fighting disease; if there is a drug that could extend my life, or make my pain lessen, or make my other drugs more effective, then I want it! If death is my only certainty versus the potential of benefit, no matter how marginal, then let me opt for hope.

The FDA must engage with the patient community and understand their needs, not from a position of paternalistic protectionism but as an active partner in facing the realities of life for the seriously ill. Freedom of choice has never made more sense than now. Never did Patrick Henry’s words resonate more – “Give me liberty or give me death!”
This column exists to introduce you to our extraordinary board members. The spotlight this month is on Michael Stoler.

They say there are no accidents. So we can assume when Virgil Simons met Michael Stoler, it was meant to be. Michael has a long and impressive resume: real estate leader and innovator, adviser and consultant to the financial and management sector, television/radio host and producer, newspaper columnist, and philanthropist. He founded Princeton Commercial Corporation which provides consulting services to public and private corporations and non-profit organizations. The company also provides financing of real estate projects across the country and advises companies on mergers and acquisitions. Michael hosts and produces two television broadcasts focused on greater New York business and real estate markets: ‘The Stoler Report’, Real Estate Trends in the Tri-State region (www.stolerreport.com) and ‘Building New York’, a weekly real estate talk show (www.buildingny.org). He writes a column for The New York Sun and other periodicals and is an Adjunct Associate Professor at the NYU School of Continuing and Professional Studies.

Somehow he finds the time to serve on several charitable organizations’ boards, including The Prostate Net. In fact, he has created two of his own. ‘The Foundation for Medical Evaluation and Early Detection’ (www.fmed.org) provides no-cost health and cancer screenings, which Michael created in 1993. This initiative has provided screenings for over 6000 people so far. In 2001, Michael co-founded the ‘ITM Hospitality Fund’ (www.itmhospitalityfund.com), providing no-cost lodging for patients and their families who are receiving treatment for major illnesses, surgery or specialized therapy. This service helps lighten the emotional and financial burdens, especially when families are away from home. The Prostate Net has been fortunate to have Michael on our Board since 2004. He has been instrumental in the launch of the Barbershop Initiative and continues to provide assistance to many of our medical center partners around the country with their local screening programs.

We look forward to more of his guidance, leadership, and innovation.

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In Memoriam

During our work sessions of the Prostate Cancer Research Program at the department of Defense, we always start off with a Moment of Silence that serves to focus our attention on the matter at hand – finding the best research that can eradicate prostate cancer. These moments can be predictable, much as other things in our lives like, prayers at night, brushing your teeth, etc. Then there are those moments, when something occurs to jar you from your complacency, which make you re-focus on what’s really real in life.

One such moment for me was the passing of Judge Ralph Burnett. Ralph was a veteran of Vietnam, an effective jurist for the Maryland District Courts and an advocate for those fighting against prostate cancer. Ralph became a leader within the National Prostate Cancer Coalition and worked with others to gain an increase in Federal funds for prostate cancer research. More to the point, he was a true survivor of prostate cancer who battled the “beast” for himself and for others. He will be remembered for all of his good works and because he was, and forever will be, my friend.

- VHS
About 10 percent longer than in a primary care visit in the U.S. runs Australian patients spend. Although is about half the time New Zealand with a primary care physician. That total of about 30 minutes annually that the average American spends a three countries, the study found BMJ. Using survey data from the Fund-supported study published in Australia and New Zealand, say the far less face time with primary care physicians than do patients in that the paradigm of negative impact on medically underserved communities through their demonstrated leadership, implementation of novel strategies and/or commitment in time, energy and resources.

In June, Cytokinetics (NASDAQ: CYTK) announced results from the analyses of three Phase II clinical trials sponsored by the National Cancer Institute (NCI), each designed to evaluate the safety and efficacy of ispinesib administered as monotherapy: one in patients with hepatocellular cancer, one in patients with melanoma, and one in patients with hormone-refractory prostate cancer. Additional details can be seen at: http://www.money.cnn.com/news/newsfeeds/articles/marketwire/20070814/nci/.

Takeda Pharmaceutical Co., Japan’s largest drugmaker, had a 5.1 percent jump in first-quarter profit, helped by higher sales of its diabetes medicine Actos. Sales of Leuplin, a treatment for prostate cancer and endometriosis, gained 3.3 percent to 33.8 billion yen. Full report at: http://www.prostate.com/apps/news/?pid=20601100&sid=acs5269rL40&refer=germany

HIV patients are at greater risk of developing one of 20 cancers, almost seven times the number of tumors previously linked to the virus. Details of the study by researchers at the University of New South Wales in Australia can be viewed at: http://www.bloomberg.com/apps/news/?pid=20601087&sid=aElgF9rzeL40&refer=home

Patients in the United States have far less face time with primary care physicians than do patients in Australia and New Zealand, say the authors of a new Commonwealth Fund-supported study published in BMJ. Using survey data from the three countries, the study found that the average American spends a total of about 30 minutes annually with a primary care physician. That is about half the time New Zealand patients spend and one-third the time Australian patients spend. Although a primary care visit in the U.S. runs about 10 percent longer than in

( continued from page 3 )

GPCBiotech AG (NASDAQ: GPCB) announced that it has withdrawn the satraplatin capsules New Drug Application (NDA) filed for accelerated approval for the treatment of hormone-refractory prostate cancer patients whose prior chemotherapy has failed. The Company based its decision on the vote by the Oncologic Drugs Advisory Committee (ODAC) to the U.S. Food and Drug Administration (FDA) on July 24, 2007 that the FDA should wait for the final survival analysis of the SPARC trial before deciding whether satraplatin is approvable. Full detail at: http://www.ad-hoc-news.de/CorporateNews/en/12704560/GPC-Biotech-Withdraws-Satraplatin-NDA-Filed-for-Accelerated

For the past two years The Prostate Net has presented our Annual “In The Know” Awards that have honored those individuals, agencies and/or corporations that have made significant strides in helping to eliminate health disparities. These awards are designed to honor those who have gone beyond the routine to change the paradigm of negative impact on medically underserved communities through their demonstrated leadership, implementation of novel strategies and/or commitment in time, energy and resources.

The next Awards Gala will be held on September 21, 2007; awards will be presented in the following categories:

- Government: National and Local
- Corporate: healthcare; non-healthcare
- Clinical or Epidemiological Research Excellence
- Medical Center / Clinician
- Outstanding Oncology Nurse
- Local Community Service
- Patient Advocacy
- Media: print; electronic; Internet
- Barber of the Year

Nominations should be submitted as soon as possible, but no later than August 31, 2007. Awardees will be notified by September 7th or sooner; all travel and accommodations expense for the event will be paid as part of the Award.

Submissions should be no more than 2 pages in length, prepared in MS Word format and, where appropriate, include a photo of the nominee or representation of the program. Details should include examples of the work done, results to date and any other measurable criteria to support the level of excellence demonstrated. A committee from The Prostate Net Board of Directors and Board of Medical Advisors will decide winners. Nominations should be submitted by email to: support@prostatenet.org or via Postal Mail to:

The Prostate Net
In The Know Awards
P.O. Box 2192
Secaucus, NJ 07096-2192

Information on previous years Awards can be seen at: www.theknowledgenet.info click on “Programs”.

More than 200 people attended last year’s event and we anticipate more this year. The Awards Luncheon will be held on September 21st at 12:00:

- New York University
- Kimmel Center for University Life
- Rosenthal Pavilion
- 60 Washington Square South
- New York, NY

Attendance is free to patient support group leaders, healthcare professionals, community health workers, cancer researchers, Government agency staff, social service workers, academic staff and patients/survivors and caregivers. Call 1.888.477.6763 to reserve a seat.

SPONSORSHIP PACKAGES ARE AVAILABLE

Presenting - $10,000
Platinum - $7500
Gold - $5000
Silver - $2500

Sponsors will receive an Ad Page in the Luncheon Journal, mention in all Press Announcements pre- and post-event, Podium Mentions and all other promotional efforts.

Sponsors will receive one 2x6 table on which to exhibit/distribute consumer/patient educational materials.

Sponsors will be given one table that will be for invited guests of the sponsor.

Individual Tickets
Tickets for sponsors or corporate supporters only may be purchased at a cost of $250 each.

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We’ve seen the most recent statistics from the American Cancer Society and others, which have documented a decline in overall cancer deaths, yet have shown a continuing rise among minority communities. Many of us within the scientific and healthcare communities, myself included, work assiduously and passionately towards the minimization, if not elimination, of disparities in health care education, access, treatment and quality of life.

But are we making progress or merely thrusting at an amorphous enemy called “RACE”, the reality of which may never be touched. Within the scientific community, “race” does not exist: the genetic make-up of over 98% of the world’s population is the SAME, regardless whether we are Asian, Caucasian or African and all the subsets within. “Race” in reality is a political construct created to justify and quantify issues of societal, economic and/or political hierarchy as determined by those with the power to define. Who is African-American? For a close at hand example, my paternal grandfather was an Irish Jew who emigrated to America and married a Native American Eastern Cherokee; their union produced my father, who “chose” to be white at times to earn his living as a jockey, then subsequently married my mother, an Alabama Black woman whose roots probably equated with Alex Haley’s. Yet our “chose-to-be-Black” family was also commingled with the admixture from the rape of Black women by Caucasian landowners whose progeny also chose to be either “Black” or “white” as opportunity afforded itself to them.

In the news today, we are holding up as a new standard of a Black leader a Senator born of a Caucasian Kansan mother, an African Muslim father and raised in Hawaii. Despite our shared Illinois heritage Barack Obama would not have been the typical “Boy in my ‘hood”; yet we’re both “Black” because we choose to be as much as society has defined us to be.

Let me take the discussion further with an example from a study done at Columbia University (NYC) College of Physicians and Surgeons on breast cancer genetics and Ashkenazi Jews. The study sought to explain the increased risk for hereditary breast cancer through “Jewish ancestral mutations.” However, the linking of a disease to a specific group based on supposed or suspected genetic differences can produce gaps in access to overall healthcare. The Columbia report codified an element of this disparity. Ashkenazi Jewish women had access to a test that detects the mutation of the suspected gene; the test was available to them at a cost of $415 compared with $2,975 for non-Ashkenazi Jewish women with no known family mutations.

Many geneticists, again quoting from the Columbia study, interpreted Jewish history to support Ashkenazi genetic uniqueness. They viewed the Ashkenazim as isolated, persecuted and subjected to extreme population contractions and expansions, all of which created “founder effects” or genetic mutations that would stay isolated within that population. However, history showed that the reality was much different. The study went on to show that a number of recent genetic surveys – including Spanish, German, Dutch, Polish and Hispanic women – have shown a high presence of the so-called “ancestral Jewish mutations” in non-Ashkenazi and non-Jewish groups. In fact, a large study of Spanish women with breast cancer reported that one of the three mutations accounted for 16.7% of all mutations in the gene.

Columbia Professor of Sociomedical Sciences Sheila Rothman, PhD, and a co-author of the study has said: “Serendipity may initiate a scientific quest, but should it continue to drive it – and to whose benefit?” In my eyes there will never be a “Black” bullet for cancer that cuts across the stratum that is called “race”; but we can beat back the beast called cancer based on the geography of its incidence, the inequity of its nutrition sources, the economics of its access to information and treatment, as well as true genotyping of individual risk. As all politics are local, so are all cures personal; cancer is color-blind and so must we be.
There are approximately 300,000 men diagnosed each year with prostate cancer and there are 30,000 deaths. I am a member of the first group, and without a magic bullet soon, will almost certainly be in the second. I have no family history of cancer and had no genito-urinary tract symptoms or bone pain prior to swinging a golf club in late 2005 and collapsing in agony on the golf course with upper back pain. I later learned I had shattered a thoracic vertebra into fragments that then pressed on my spinal cord. CT scanning showed I had massive bone metastases from pelvis to neck subsequently linked to prostate cancer. The “horse was out of the barn” so to speak with such extent and aggressiveness that I was not a candidate for today’s highly successful prostate surgery and/or radiation therapy - overnight I was essentially incurable. My burning questions all along have been, how this could happen in the modern era of medicine and specifically, how could this cancer have spread so extensively and unseen via tissue extension, bloodstream, and lymphatic circulation? I had yearly PSA screening tests and DRE’s (digital rectal exam) for almost twenty years reported as normal (0-4 ng/ml) during that time by three different caring, competent, professional internists. I’ve sensed in my gut for this past year and a half that there was a missing link, that if known, might have given me and perhaps some of those 30,000 a year other men an early diagnosis and a likely high chance for a cure.

And then the mail arrived “coincidentally” just ten days ago. In it was a newsletter called IN THE KNOW- Confronting Prostate Cancer, produced by an educational grant from Sanofi Aventis, and published by THE PROSTATE NET, Inc., (thank you to colleague, Publisher and Editor-In-Chief, Virgil Simons). Prostate Net is an excellent advocacy group known to me for several years from my work in oncology at Bayer Pharma. On page one and three was the lead article, a Q & A with William J. Catalona, MD, a prostate cancer researcher and surgeon, Professor of Urology at Northwestern University Feinberg School of Medicine, and Director of the Clinical Prostate Cancer Program at Northwestern’s Robert H. Lurie Comprehensive Cancer Clinic. I eagerly read things I had not seen or heard before. Some of his key points:

- Dr. Catalona enrolled 36,000 men in a PSA clinical trial spanning 12 years (initially published in NEJM 1991)
- In 1995 based on his sample, he advocated setting a new standard PSA cut-off for normal of 2.5 ng/ml and the point at which one recommends a biopsy. In lieu of the well known 4.0.
- Using the 4.0 cut-off, 30% of cancers have already metastasized
- If cancer is found with a PSA between 2.5 and 4.0 the cure rate is almost 90% and drops precipitously if PSA is over 4.0.
- The PSA “Velocity” often gives a better idea of how aggressive a prostate cancer is than the total PSA value does.
- To that end Dr. Catalonia cited the work of Dr. H. Ballentine Carter and associates from Johns Hopkins in the 11/06 Journal of The National Cancer Institute. If the PSA rose by more than 0.35 ng/ml per year it indicated cancer and correlated with the ultimate likelihood of dying from the disease. Carter had essentially introduced this concept in 1987 (with initially slower Velocity data).

Could it be that my burning question of “How?” now had possible answers? I went to the file and rechecked my 20 years of “normal” PSA’s to discover that I hit the 2.5 ng/ml cut-off proposed by Dr. Catalona eight years ago. My last PSA a year before my errant golf shot was 3.6. There were three times I exceeded the PSA Velocity of 0.35 from year to year as proposed by Dr. Carter. I then checked the patient lab sheets for “normal range” that are sent to the ordering physician from Quest Labs and to this day they list PSA Normal as 0-4.0. The number is not bold-faced and denoted as H until it is over 4.0. There is no reference to PSA Velocity. So this is the format repeatedly viewed every day, patient after patient, and presumably imprinted by our primary care clinicians. I then obviously wondered what a biopsy of my prostate would have shown if done at that much earlier 2.5 cut-off and if my situation today would be different. At the least I would have loved to have had a discussion of the issues and options available to me, but none of us knew so no discussions/action.

I am now speculating that the Catalona / Carter et. al. data, from obviously highly credible researchers and esteemed medical institutions, is not mainstream nor apparently has it been mass disseminated horizontally to primary care clinicians who are the ones seeing the entry level patients. I am aware of the debates nationally about the value of the PSA as a screening device and the concerns about false positives and negatives. However, it is the best we have at the moment, and there are reasonable answers to the concerns from credible clinical scientists such as Catalona, Carter, and Stephen Strum, MD, (latter is co-author of Primer On Prostate Cancer, 2005). It is absurd not to offer patients the benefits of our latest knowledge. It can be life or death. To me as a primary care physician, consumer, AND now a terminal cancer patient, I would rather these “new” but apparently decades old clinical concepts be widely known and applied in practice in order to find prostate cancer very early so that I, and you and yours, have treatment options prior to metastases and ultimate death. ¥
The Prostate Net has always counseled patients that the oncology nurse is an integral part of their treatment team, oftentimes providing information, feedback and support when the doctor may not have been able to give it. Their de facto leadership in the medical office can insure a positive overall outcome for the patient in helping to fight the disease being faced.

Thus it came as no little surprise when we received a call from a group of senior nursing students who were looking to develop their Capstone Project prior to graduating based on prostate cancer awareness and screening. These four young women from disparate geographic and ethnic backgrounds (Africa, Russia and the Caribbean) came together in Bloomfield, New Jersey to set their academic foundations and community commitment.

In partnership with the Bloomfield Department of Public Health, they developed an awareness campaign utilizing a Public Service Announcement written and produced by them in conjunction with their university’s audio/visual department as well as recruiting a local City Councilman as the featured celebrity. They then established on-site educational centers at various Government locations, Post Offices and shopping centers to get the message of awareness out to their community. They utilized material from The Prostate Net to provide enhanced educational sessions in churches and local social service agencies. They created their own media blitz to galvanize the community.

Their efforts were rewarded on the day of the screening wherein they were able to attract more men for the PSA test than had ever been recruited by the Public health Department previously! Synergy at its best. Our highest level of praise goes to Vanessa Vazquez, Lillian Oduwole, Lioubov Smirnova and Karlene Morrison!!!

**Highlights**

**Financial News**

The European Commission has released figures showing that there has been a dramatic and concerning increase in pharmaceutical counterfeiting, with seizures in Europe hitting an all time high of over 2.5m items. The most popular targets for counterfeiters over 2006 were Pfizer’s blockbuster drug Viagra (sildenafil citrate), Eli Lilly’s Cialis (tadalafil) and Bayer’s Levitra (vardenafil) - all products for the treatment of erectile dysfunction. Other medicines commonly faked over the past year included anti-cholesterol and osteoporosis drugs and those used to control hypertension. Read the full story at: [http://www.in-pharmatechnologist.com/news/ang.070510&ID=6878792](http://www.in-pharmatechnologist.com/news/ang.070510&ID=6878792)

The Pentagon-appointed Task Force on the Future of Military Health has endorsed higher TRICARE fees, deductibles and co-payments for under-65 retirees and their families in an interim report sent to Congress. Details on the report can be seen at: [http://www.projo.com/news/veteransjournal/veterans11_06-11 -07_J65VEFF.2707e5d.html](http://www.projo.com/news/veteransjournal/veterans11_06-11 -07_J65VEFF.2707e5d.html)

**Medical News**

Where minority patients get health care can influence the quality of care they receive and may be a major underlying cause of health care disparities, according to an article published today by the Health Research and Educational Trust (HRET) in the Archives of Internal Medicine. An abstract of the study can be viewed at: [http://archinte.ama-assn.org/cgi/content/full/334/7606/1261](http://archinte.ama-assn.org/cgi/content/full/334/7606/1261)

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**The European Commission** has released figures showing that there has been a dramatic and concerning increase in pharmaceutical counterfeiting, with seizures in Europe hitting an all time high of over 2.5m items. The most popular targets for counterfeiters over 2006 were Pfizer’s blockbuster drug Viagra (sildenafil citrate), Eli Lilly’s Cialis (tadalafil) and Bayer’s Levitra (vardenafil) - all products for the treatment of erectile dysfunction. Other medicines commonly faked over the past year included anti-cholesterol and osteoporosis drugs and those used to control hypertension. Read the full story at: [http://www.in-pharmatechnologist.com/news/ang.070510&ID=6878792](http://www.in-pharmatechnologist.com/news/ang.070510&ID=6878792)
This month we spotlight another of our survivor counselors, Marty Birnbaum, who provides real-life, personal experience on various treatment protocols. After a diagnosis of prostate cancer, patients and their families are asked to make informed decisions as to treatment preference, but often without all of the necessary knowledge to choose most appropriately. Marty and the rest of our team step in to provide that needed perspective. Here’s his story:

Confused and scared I was fortunate enough to discover Virgil Simons and the Prostate Net. The decision process was simplified and made easier by understanding the different options available to me, and what each treatment could bring in side effects etc.

The Prostate Net was invaluable in providing me with the information I needed to make an informed and confident decision. I chose to have radiation seeds implanted. After several months of Lupron injections to shrink the tumors I went to Morristown Hospital in New Jersey and had the procedure. I went home that night and had no complications.

This past St. Patrick’s Day I turned 69. It is almost 10 years since my treatment. I am regularly checked and my PSA has not gone above 0.2. I am semi retired and live a full and very happy life.

I have on several occasions spoken to people diagnosed with Prostate Cancer to allay their fears and share with them my experiences. I have always referred them to the Prostate Net so that they can get the latest information on the constant battle to kill the beast.

I am grateful for the work that the Prostate Net does and proud to be a part of that work whenever I’m needed. I can’t imagine how I would have coped with all my fears and confusion without its help.

Marty Birnbaum

By Diane Johnson / July 2007

All of the controversy about whether the PSA is a reliable test falls away when you find out you have prostate cancer. Men who have had that life-altering experience know that they live or die by that number…literally. Research findings presented at this year’s conferences confirm the viability of PSA as a screening and diagnostic tool and verify the efficacy of using PSA kinetics to monitor and manage the course of the disease. First, a definition:

Biomarker: proteins that are produced either by a tumor or by the body in response to a tumor; found in blood, urine, or body tissues.

The Prostate Specific Antigen marker is not perfect. Robert Getzenberg, PhD (Prostate Cancer Symposium, 2007), lists some of the reasons why:
1. It is a prostate specific antigen, not a prostate cancer specific antigen
2. It is elevated from benign diseases such as BPH and prostatitis
3. It does not measure the aggressive nature of prostate cancer
4. It is not an accurate measure of disease burden

While the search for a more sensitive and specific marker continues, the PSA is still the best way to determine when treatment should be initiated and to monitor its efficacy. PSA levels before treatment can be indicative of whether the disease is likely to be cured or might recur; after treatment, it can show whether the disease is progressing and how rapidly.

Two measurements in particular, PSA doubling time (PSADT) and PSA velocity (PSAV), have shown great promise.

PSA Doubling Time: time it takes for PSA to double

Slawin et al (Prostate Cancer Symposium, 2007) described the ideal model—“PSADT calculation begins with the first PSA above 2.0 ng/ml and requires at least 3 separate values each separated by at least 2 weeks.” The shorter the doubling time, the higher the risk of aggressive cancer. “A short PSADT becomes the most significant predictor of aggressive cancer.”

PSA Velocity: rate of rise in PSA level, usually measured over a full year

Numerous studies confirm that PSAV is a potent tool in assessing prostate cancer risk, even when measured before diagnosis. Slawin et al, (Prostate Cancer Symposium, 2007) concluded that “men whose PSA level increases by more than 2.0 ng/ml during the year before diagnosis are at increased risk of death from prostate cancer despite undergoing radical prostatectomy.” In a study published in May of this year, D’Amico et al concur. “The solitary presence of a PSAV of greater than 2.0 ng/ml was associated with an increased risk of prostate cancer mortality after surgery or radiation treatment when compared with men with any other single high-risk factor. Understanding the impact that the value of the PSA velocity…has on the risk of prostate cancer mortality…is important when counseling men facing prostate cancer…”

Loeb et al (Prostate Cancer Symposium, 2007) found that a “PSA increase of 0.3 to 0.5 ng/ml in a year is a stronger predictor of prostate cancer risk than age, race, or family history in men with a total PSA of less than 4.” In a presentation at 2007’s American Urological Association conference, they concluded study “results further validate that PSAV is a marker for prostate cancer aggressiveness and is a significant predictor of the Gleason score and extracapsular extension in the radical prostatectomy specimen. PSAV may be useful in making treatment decisions and in assessing the likelihood of long-term cancer control.” Slawin, et al continued, “The time component of the change in PSA levels over time is at
Low Testosterone Levels Continue to Afflict Men

By: Theresa Morrow, Men’s Health Network

While it is estimated by the US Food and Drug Administration that more than 4 - 5 million men suffer from low testosterone, only 5 percent are receiving treatment. Low testosterone is a condition that affects many men as they grow older and can cause a decreased enjoyment of life through uncomfortable and distressing symptoms. However, there are ways to combat low testosterone and help men live more fulfilling lives. Through continuing education of the condition, encouraging men to be free from any embarrassment they may feel, and the continuing development of treatments low testosterone will become a condition that is discussed freely and easily treated.

Testosterone is the most important sex hormone in the male body and is responsible for the development of characteristics such as muscle growth and strength, a deep voice, and body and facial hair. It also contributes to the production of sperm, promotes sexual function, and advances sex drive. Naturally, as a man gets older the ability to produce testosterone declines although certain medical conditions such as conditions associated with the testicles, pituitary gland, and hypothalamus may also lead to low testosterone levels. Both physicians and patients should be watchful for the symptoms that may indicate a decreased level of testosterone production including:

- Low sex drive
- Erectile dysfunction (ED)
- Increased irritability or depression
- Fatigue
- Reduced muscle mass and strength
- Inability to concentrate
- Decreased bone density; osteoporosis
- Upper body and abdominal fat.

More recently reports have also shown ties between poor health and low testosterone. According to WebMD Medical News, as men with problems like obesity, diabetes, and high blood pressure grow older they are twice as likely to have low testosterone levels than other men their age. This news is troubling because dealing with these conditions is difficult enough without compounding it with the effects of low testosterone.

A number of treatment options are available and as demand grows and discussions about the problem continue it is likely they will continue to evolve. Treatments range from a capsule to deep muscle injections to gels to a recently approved tablet that adheres to the gums. While each option has its benefits and drawbacks it is likely that there is a treatment that will work for every man, but each man should speak freely with their doctor about the best option for them. As testosterone replacement therapy becomes more popular researchers are also discovering its adverse effects on prostate health and the likelihood of developing prostate cancer so men receiving such treatment should be closely monitored with regular prostate cancer screenings. Hopefully, as research continues to develop we can discover ways to treat low testosterone without the consequence of deteriorated prostate health.

We must continue to encourage physicians to pay close attention to the indicators of low testosterone even if the patient may be trying to ignore them. Physicians should also encourage men to have their testosterone levels tested and patients need not be afraid to ask for the simple blood test. The detection of low testosterone and the appropriate follow-up treatment can lead to an increased sex drive, the ability to think and act more quickly at work, and an all around more enjoyable life.

To learn more please visit our website exclusively dedicated to the issue of low testosterone at: http://www.tuneupyourt.com. For more insight into other men’s health issues please visit the Men’s Health Network online at: www.menshealthnetwork.org.

Did You Know?

Drinking coffee and exercising may prevent cancer in sun-damaged skin cells by spurring production of a tumor-blocking protein in the body, a study found. Exercise and caffeine, used in combination, doubled levels of a tumor-suppressing protein called phospho-p53. Full details of the report can be viewed at: http://www.bloomberg.com/apps/news?pid=20601091&sid=aqOHxw6uIQ&refer=india

An article in the New York Times reported that the potential for profit from the prescription of certain oncology drugs allegedly influenced doctors’ pattern of treatment. A lawsuit in Federal court in Boston contends that pharmaceutical manufacturers caused patients and health insurers to be overcharged versus prices actually charged to doctors.

The mineral zinc is an important component of healthy skin, especially for acne sufferers. In fact, acne itself may be a symptom of zinc deficiency. Zinc acts by controlling the production of oil in the skin, and may also help control some of the hormones that create acne. Zinc is also required for proper immune system function, as well as for the maintenance of vision, taste, and smell. Zinc consumption is also strongly linked to a reduction of prostate cancer. Foods rich in zinc include fresh oysters, pumpkin seeds, ginger, pecans, Brazil nuts, oats, and eggs. Zinc can be purchased in supplement form, in both liquid concentrates and tablets. http://www.newstarget.com/021773.html

Urinary tract infections (UTIs) refer to a number of different illnesses, including urethritis (infection of the urethra, which carries urine from the bladder out of the body), cystitis (an infection of the bladder), and pyelonephritis (a bacterial infection of one or both of the kidneys). Complete story at: http://www.brooklyneagle.com/categories/category.php?category_id=27&sid=14089

Simple addition of foods with high nutritional value can increase the overall health benefit. Read the full story at: http://www.cnn.com/2007/HEALTH/diet.fitness/06/26/cl.boost.nutrition/
In June of this year, a committed group of cancer survivors and medical providers gathered together to stomp out their foe: prostate cancer. The scene was the American Cancer Society’s Relay for Life at Maryville College, Tennessee. The ‘Men Against Cancer’ team, led by co-captains cancer survivor, Bill Orr, and nurse extraordinaire, Jeanie Knapp, was composed of the dedicated people from the Tennessee Urology Associates, members of the support group Man to Man, and their families and friends. They not only took pledges for the miles they collectively walked in the race, they sold delicious baked goods there too. Their weeks of hard work paid off. They raised almost twice what they had hoped to, for a grand total of $9000!

WHEN YOU NEED A HELPING HAND....

IMERMAN ANGELS  312.643.5560  (www.imermanangels.org)

Some of the best support groups are created by those who once needed support themselves. ‘Imerman Angels’ is no exception. Their mission is to match a person who is fighting cancer with someone who has won a battle with that same kind of cancer. It’s a one-on-one relationship that not only encourages and strengthens the cancer fighter, but also allows the cancer survivor to give back in a very real and specific way.

Jonny Imerman is the survivor behind this organization. When he was 26 years old, he was diagnosed with testicular cancer that had already begun to metastasize. After they operated, he endured five brutal months of chemotherapy that produced overwhelming side effects. But he persevered and finally began to focus on getting healthy again. But it was not over yet. One year later tumors along his spine were found. Once they were surgically removed, he was on the road to a permanent recovery.

While Jonny was going through this fight, he was surrounded by family and friends who wouldn’t let him give up. As he walked the halls of the hospital, he saw others who weren’t as fortunate. They were fighting their battle alone. Even in the midst of his pain and fear, he made a promise: if he survived, he would try to change that.

Now Imerman Angels exists to connect cancer fighters and survivors. After the initial contact, a representative (all are also survivors) searches the database to find the most appropriate match—same cancer type, treatments, age, gender, family, etc.

After the introduction is made, the relationship is in the hands of the newly matched team, but Imerman Angels is always available for advice or guidance. They can also match up caregivers with others who are in similar situations supporting someone who is fighting cancer. Matches have been made for people of all ages and cancer types all across the country and the world.

If you find yourself alone and fighting cancer, please contact Imerman Angels. As Jonny says, “…cancer survivors are angels—walking, living proof that the fighter can win too. No one should have to fight this disease alone.”
Women play many important roles throughout their lives—daughter, mother, and friend—but no relationship is as unique as the one between two sisters. Sister Study researchers hope the sisters of women with breast cancer can play another important role by helping discover how our environment and genes affect our chances of developing breast cancer.

The Sister Study is a nationwide effort, conducted by the National Institute of Environmental Health Sciences, to learn about environmental and genetic causes of breast cancer. Women ages 35 to 74 are eligible to join if their sister (living or deceased), related to them by blood, had breast cancer; they have never had breast cancer themselves; and they live in the United States or Puerto Rico.

The Sister Study is particularly committed to enrolling women in every state, and from all backgrounds, occupations, races and ethnicities, so the study results represent and benefit all women. The women enrolled in the Sister Study look like many of our relatives, friends, and co-workers. They may even look like you. The study needs to enroll 50,000 women by the end of 2007, and with your help, it can.

“Many women have heard about the Sister Study, but they haven’t signed up yet, and we really need them now,” said Dale Sandler, Ph.D., Chief of the Epidemiology Branch at NIEHS and Principal Investigator of the Sister Study. “Doctors know very little about how the environment may affect breast cancer, that is why the Sister Study is so important. We hope women will make that call today,” she added.

The Sister Study is available in English and Spanish and can be done from home when it is convenient for women. To learn more about the Sister Study, visit the web site www.sisterstudy.org, or for Spanish www.estudiodehermanas.org. A toll free number is also available 1-877-4SISTER (877-474-7837). Deaf/Hard of Hearing call 1-866-TTY-4SIS (866-889-4747).

Woman by woman….Sister by sister…We can make a difference.

Queens Barbers Join Fight Against Prostate Cancer
By Kafi Drexel – NY1

A great fade and medical advice for the price of a single haircut? a new public health information campaign in Queens has the neighborhood barber wearing more than one hat.

In addition to figuring out just how much hair you should take off, health professionals are turning to barber shops like Toram’s on Merrick Boulevard in Springfield Gardens to get the conversation started about the importance of getting checked early for prostate cancer.

“Prostate cancer is the second most common cancer killer in men and men in this particularly community of Queens have a higher burden of disease and mortality due to their cancer,” says Dr. Elliott Goytia of Queens Hospital Center. “So, it’s very important for them to get screened early and come in for regular check-ups.”

But Goytia says, unfortunately, that’s not happening as much as doctors would like to see. That’s why Queens Hospital Center, the American Cancer Society, and The Prostate Net are enlisting local barbers to spread the word to men about a topic they’re often too stubborn to discuss on their own.

“Over the time, the years, we’ve had quite a few conversations about men who got prostate [cancer]… I got friends that died from prostate [cancer] and men who are afraid of it. So I said, it’s better for me to go and get some information, learn about it, and then I can probably try to ease some of their fears or encourage them,” says barber Brian Questelle.

“The barbershop is a great place, because we have a captive audience,” says Daphne Dominique of the American Cancer Society. “We have men talking to men, encouraging them about the importance of getting screened for prostate cancer.”

Barbers get trained with talking points. If men have more questions, they give them numbers to local doctors for screening referrals. And barbers aren’t the only ones giving the advice. Some clients help keep the conversation going, too, like 58-year-old Erskine Lynch who’s a prostate cancer survivor himself.

(continued on back cover)
At least as important, or more important, than actual PSA levels in assessing the risk of prostate cancer progression.” They suggest tracking PSA changes during the entire course of the disease: before diagnosis, after treatment, and if the cancer returns.

The Future:

When it comes to the PSA, there is consensus on one thing—we need a better test. Below is a recipe for an ideal prostate cancer biomarker (Getzenberg, Chodak):

--Distinguishes between benign and malignant disease
--Identifies potentially life-threatening disease and progression early
--Tissue and tumor sensitivity and specificity
--Few false positives and negatives
--Stable (easily collected and stored); highly reproducible
--Simple, low cost

In the meantime, while many promising prostate cancer markers are being developed and studied, the PSA remains a proven and valuable tool in the management of prostate cancer. For millions of men, their health and well-being, indeed, their lives, depend on it.

Send us your photos!
If you have pictures of prostate cancer related activities or events, please send them to us with a description.

Barbers Join Fight

“At least once a year, get yourself checked, because prostate cancer can be a very deadly disease,” says Lynch. “If you catch it early, it’s better for you. If you wait too late there’s nothing they can do with it. So check yourself.”

Besides Toram’s there are about nine other barbershops in the neighborhood participating in the initiative. With dozens of other barbershops in the neighborhood, they are hoping to expand this and create somewhat of a movement, educating men all around the community.

(continued from pg 11)