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Us TOO[®]
PROSTATE CANCER
EDUCATION & SUPPORT

HOTSHEET

January 2009

DIAGNOSES OF CANCER DECLINE IN THE US

The pace at which Americans are getting cancer has started to decline, marking what could be a long-awaited turning point in the battle against the disease, according to an annual report that tracks progress in the war on cancer.

The drop in new cancer diagnoses has been driven largely by declines in many of the leading forms of cancer: lung, prostate and colorectal cancer in men, and breast and colorectal cancer in women. The analysis found that the overall incidence of cancer began inching down in 1999, but not until the data for 2005 were analyzed was it clear that a long-term decline was underway. The explanation for the drop in prostate cancer diagnoses remains less clear, but it may reflect a trend toward fewer men getting screened with the PSA test.

"It is a significant milestone," said Otis W. Brawley, chief medical officer at the American Cancer Society. "The take-home message is that many of the things we've been telling people to do to be healthy have finally reached the point where we can say that they are working," Brawley said.

The report analyzed data collected between 1975 and 2005 in ongoing

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CLEVELAND CLINIC UNVEILS 'TOP 10' MEDICAL INNOVATIONS FOR 2009

Imagine if a simple blood test could detect recurrent cancer earlier, while also predicting a patient's prognosis. Imagine if a device the size of two decks of cards could help a paraplegic breathe without a bulky ventilator. Or imagine if a machine could essentially keep harvested organs alive until they're transplanted in the recipient.

Now imagine that these innovations already exist, because they do, along with seven other emerging technologies that make up Cleveland Clinic's Top 10 Medical Innovations for 2009.

The list of breakthrough devices and therapies was selected by a panel of Cleveland Clinic physicians and scientists and was unveiled during Cleveland Clinic's 2008 Medical Innovation Summit, held November 10-12, 2008. The innovations touch on avian influenza, electronic medical records, and various minimally invasive surgeries.

"Once again, we are seeing a diverse list of technologies that have the potential to make an enormous medical impact in the near future," said Michael Roizen, M.D., who chaired the Top 10 Medical Innovations List.

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ANTIDIABETIC DRUGS LINKED TO LOWER PROSTATE CANCER RISK

Antidiabetic drugs are associated with a decreased risk of prostate cancer, investigators at the University of Tampere in Finland reported in the *American Journal of Epidemiology* (Vol. 168, pp. 925-31, 2008).

"Recent studies have reported a decreased prostate cancer risk for diabetic men, although the evidence is controversial," lead author Dr. Teemu J. Murtola and colleagues write. "It is currently unclear whether use of antidiabetic medication affects the association between diabetes and prostate cancer."

To better define this association, the researchers examined newly diagnosed cases of prostate cancer from the Finnish Cancer Registry between 1995 and 2002. The Population Register Center was used to randomly select matched controls, yielding a total of 24,723 case-control pairs. The authors also used a comprehensive prescription database to obtain information on medication use.

The subjects were a median of 68 years old. Oral antidiabetic drugs were used by 7.5% of men with prostate cancer and by 8.4% of controls. The

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5003 FAIRVIEW AVENUE
DOWNER'S GROVE, IL 60515
PHONE: (630) 795-1002 / FAX: (630) 795-1602
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'TOP 10' MEDICAL INNOVATIONS FOR 2009

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Top 10 Medical Innovations for 2009

1. Circulating Tumor Cells

A blood test that measures circulating tumor cells – cancer cells that have broken away from an existing tumor and entered the bloodstream – has the ability to detect recurrent cancer sooner, while also predicting how well treatment is working and the patient's probable outcome.

2. Warm Organ Perfusion Device

Once a heart becomes available for transplant, surgeons have just four hours before the organ begins to decay. This device recreates conditions within the body to keep the heart pumping for up to 12 hours.

3. Diaphragm Pacing System

Four electrodes are connected to the phrenic nerves on the diaphragm. When stimulated by current, the diaphragm contracts and air is sucked into the lungs. When not stimulated, the diaphragm relaxes and air moves out of the lungs.

4. Multi-Spectral Imaging Systems

The imaging system is attached to a standard microscope, where researchers can stain up to four proteins using different colors and look at tissue samples with 10 to 30 different wavelengths, allowing for the accumulation of more information than is currently available. This may lead to more personalized treatment for individual patients.

5. Percutaneous Mitral Valve Repair

Using a tiny barbed, wishbone-shaped device, the heart is fixed non-surgically from the inside out. Surgery is done more quickly and helps restore normal blood flow.

6. New Vaccines for Avian Flu

A newer vaccine approach that uses a mock version of the bird virus may offer a better solution to protect people against infection.

7. LESS and NOTES Applications

LESS (laparoendoscopic single-site surgery) reduces the process to a small cut in the belly button. NOTES (natural orifice translu-

minal endoscopic surgery) gets to the site of surgery by one of the body's natural cavities, such as the mouth, vagina, or colon.

8. Integration of Diffusion Tensor Imaging (Tractography)

Diffusion tensor imaging (DTI) is the new technology that allows neuroscientists to non-invasively probe the long-neglected half of the brain called white matter, with its densely packed collection of intertwining insulated projections of neurons.

9. Doppler-Guided Uterine Artery Occlusion

Fibroid tumors occur in upwards of 40% of women older than 35, triggering pelvic pain, pregnancy complications, and heavy bleeding. There is a new, non-invasive approach to treat fibroids called Doppler-guided uterine artery occlusion, or DUAO.

10. Private Sector National Health Information Exchange

A comprehensive system of electronic health records that link consumers, general practitioners, specialists, hospitals, pharmacies, nursing homes, and insurance companies is in the process of being established. Primarily a private-sector effort, this computerized system can potentially replace paper-based medical files with digitized records of patients' complete medical history.

Four major criteria served as the basis for qualifying and selecting the Top 10 Medical Innovations. Nominated innovations were required to:

- Have significant potential for short-term clinical impact (either a major improvement in patient benefit or an improved function that enhances healthcare delivery).
- Have a high probability of success.
- Be on the market or close to being introduced.
- Have sufficient data available to support its nomination.

PRNewswire, 12 November 2008

**DOC MOYAD'S WHAT WORKS & WHAT IS WORTHLESS
COLUMN ALSO KNOWN AS "NO BOGUS SCIENCE" COLUMN**

"It is now official in my opinion, statins or cholesterol-lowering medication is simply the greatest preventive pill of my lifetime and aspirin is overrated!!!"

Mark A. Moyad, MD, MPH
University of Michigan Medical Center, Department of Urology

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Bottom Line:

The envelope please...and the winner of the greatest pill ever invented award in my lifetime thus far goes to...."STATINS"!!! Thank you and I just want to say that "you like me, you really, really like me!!!"

Michigan lost to Ohio State in college football again, which simply means I do not have to buy beer for the entire staff at Us TOO, but I do have to spend more money on a therapist! However, we did just beat Duke and UCLA in basketball so perhaps I can reduce the dosage on my blood pressure medication?!

Anyhow, I said in the last issue that I would talk about selenium but that is boring compared to the breaking news that I have so lets talk selenium at a later time. In this issue we will talk briefly about the JUPITER Study that was done at 1315 clinical sites in 26 countries! A total of 17,802 healthy men and women with an LDL ("bad") cholesterol level of about 108 mg/dl and an hs-CRP blood test of about 4.2 mg/L took 20 mg per day of Crestor® (statin drug) compared to a placebo and it was expected that this study would go for 5 years.¹ However, after 1.9 years the study was stopped because the drug worked so well!!! The LDL after taking the drug was around 55 mg/dL and the hs-CRP was 1.8 mg/L. The statin reduced the risk of heart attack by 54%, stroke by 48%, dying early for any reason by 20% and dying from cancer by 43% (all statistically significant findings)!!!

So, what do you do with this incredible new information?! Well, you do NOT run out and get a prescription of Crestor just yet or another statin drug but you ask yourself if you have an LDL that is above 100 and a high hs-CRP blood test despite regular exer-

cise and a good diet than perhaps you should talk to your doctor about a statin drug.

The bottom line is that I find it interesting that someone might simply recommend or take a multivitamin, selenium, vitamin E, or another pill without thinking twice, but along comes a drug that at a lower dose has a side effect rate similar to a placebo, but people get nervous about recommending it or taking it?! Also, I find it amazing that so many so called "preventive medicine full of BS experts" will tell patients and the public to take a daily aspirin or two even if your healthy, which is so dangerous unless someone really needs it, but will be nervous themselves about recommending a statin drug!? What?! It is time for all of us to realize that an LDL cholesterol level greater than 100 and a high hs-CRP level is not good enough anymore and we should work harder on bringing those numbers down, down, down!!!

This study was outstanding and ground-breaking and hopefully eye opening for all of us!

Reference:

1 N Engl J Med 359:2195-2207, 2008.



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See our appeal letter and/or make an online donation at:
www.ustoo.org/HolidayAppeal

**PSA DOUBLING TIME AND
TIME TO BIOCHEMICAL
FAILURE MAY PREDICT
PROSTATE CANCER-
SPECIFIC MORTALITY**

Time to biochemical failure and PSA doubling time may be useful surrogate markers for prostate cancer-specific mortality among patients who fail curative treatment according to an article published in the journal *Lancet Oncology* (Vol. 9, pp. 1058-1068, 2008).

Researchers from the School of Medicine and Public Health in Newcastle, Australia and the Wellington Cancer Centre in New Zealand conducted a surrogacy study to determine the efficacy of time to biochemical failure and PSA doubling time as surrogate markers using data from the Trans-Tasman Radiation Oncology Group 96.01 trial. The trial included 802 men with locally advanced prostate cancer. From 1996 to 2000, participants were randomly assigned to prostate irradiation or to three or six months of maximum short-term androgen deprivation therapy (ADT) before and during radiation, according to the researchers.

Compared with radiation alone, short-term ADT for six months decreased prostate cancer-specific mortality (HR=0.56; P=0.01); however, ADT for three months did not (HR=0.95; P=0.79, non-significant difference).

PSA doubling time successfully predicted the time from randomization to death from prostate cancer and satisfied four Prentice criteria at cut points of <12 months and <15 months. Proportion of treatment effect ratios was between 0.36 and 0.56. However, time to biochemical failure was superior at predicting the trial finding and satisfying Prentice criteria at cut points <1.5 years, <2 years and <2.5 years. The proportion of treatment effect ratios was between 0.45 and 0.64.

According to the researchers, PSA doubling time and time to biochemical failure may have the potential to reduce follow-up in clinical trials.

HemOnco Today, 5 November 2008

REPORT ON US TOO UNIVERSITY—TEMPE

Vital information - Connection & Friendship - Warm sunshine

Us TOO Chapter members and leaders from around the country gathered in Tempe, AZ on November 7th and 8th for Us TOO University. This was the fourth “Us TOO U” program of this kind and, like its predecessors, it received rave reviews! Not only were the speakers and sessions well received but the location and warm sunshine of Arizona made for a terrific setting and enjoyable weekend.

Us TOO U began Friday evening with the Arizona Update, a prostate cancer

- Anti-cancer Agents, Michael Gordon, MD
- Incontinence Solutions, Melissa Morrison, RN, CURN

We know that prostate cancer is a disease of the patient, as well as the partner or spouse, and the family. This was readily evident at the Arizona Update Symposium. Many prostate cancer patients and survivors attended the event with a partner, spouse or loved one. Some loved ones came to this Us TOO U Symposium for infor-

mation, while others were actively seeking connection with other couples, spouses or family members. Still others were doing what they always do, providing logistical support and standing strong beside their loved one.

On Saturday, 79 current and future chapter leaders participated in a full-day Us TOO U program designed to:

- Provide information, tools and interactive discussions about the larger prostate cancer community
- Clarify the structure, vision, and challenges of Us TOO International, and
- Further strengthen the global network of chapters.

The day included an opening presentation by Tom Kirk, Us TOO CEO and President, a panel discussion and small group sessions about issues chapter leaders face in their local chapters. In keeping with Us TOO U’s motto “Learn. Laugh. Lead.” participants were provided with timely and useful information, they had a terrific time, and returned home better prepared to confidently lead.

Recipients of Us TOO’s First Annual Edward C. Kaps Hope Award were acknowledged at Us TOO University’s Gala Celebration Dinner on Saturday evening. Not only did those present



Tom Kirk, Us TOO President and CEO, opens the Arizona Update Symposium

educational symposium featuring excellent speakers, abundant pertinent exhibitors, excellent food, music and FUN. Participants included nearly 200 patients, survivors, loved ones, curious community members, exhibitors and Us TOO chapter leaders.

Attendees heard from well recognized speakers in a variety of fields of prostate cancer expertise. In addition to our two keynote speakers, Larry Bans, MD, and Russ Gould, the program offered four concurrent sessions from which attendees could choose:

- Reclaiming Intimacy - Solutions that Work, James Daitch, MD, Jerry & Jo Ann Hardy
- Radiation Update, Scott Tropper, MD



Jim Kiefert, Us TOO Chairman of the Board, opens Saturday’s Us TOO University Chapter Leader workshop as Tom Kirk looks on



Jo Ann Hardy, Vice Chair for the Us TOO Board, facilitates small group discussion



An attendee talks to Enlight exhibitor and presenter, Mellissa A. Shepherd

receive a lovely plaque, but Ed Kaps, the award's namesake and one of the organizing and founding Board Members, was there to address the crowd and witness the event!

Some of the winners, such as Shirley Grey, Stan Rosenfeld, and Ralph Valle were on hand to receive their awards. Larry Hollis accepted the award on Chuck Maack's behalf and Bill Blair will receive his award via personal visit from Us TOO staff.



(L to R) Ed Kaps Hope Award recipients: Larry Hollis (accepting for Chuck Maack); Shirley Grey, Ralph Valle, Stan Rosenfeld; Ed Kaps, the award's namesake and one of the organizing and founding Board Members of Us TOO (not pictured: Bill Blair)

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Exhibitors

- Arizona Department of Health Services
- Arizona State University
- La Loma Village/La Loma Care Center
- The University of Arizona College of Nursing

Many thanks to all who made this program possible, and for those who will take lessons learned back home!



(R to L) Australian support group leaders Bill McHugh and Peter Gebert present Tom Kirk



George Lloyd & Johnny Payne, chapter leaders from South Carolina, enjoy networking

THE DOCTORS NOTE

Dr. Gerald Chodak

One of the most important articles in this month's *HotSheet* cites a report looking at PSA doubling time which found that it was a good predictor of dying from prostate cancer following radiation/hormone therapy. This also is potentially a very important finding. It is based on a prospective, randomized study and could mean that future studies might generate results in less time than currently required. Until now, the most important and acceptable end-point for a study to determine if a treatment is beneficial is the survival rate, which can take many years. If this finding is correct, studies could yield interpretable results earlier and bring potentially beneficial therapies to patients much sooner.

An interesting study from Finland is also cited, which found that men taking any of medication to treat diabetes were less likely to be diagnosed with prostate cancer and less likely to have advanced disease. Because of the study design, however, this one does not prove cause and effect. The authors suggest that it is the disease that is the reason for the lower detection rather than the medications. If valid, it would mean a side benefit of having diabetes is perhaps a reduced risk of prostate cancer. Is there any practical take home message from this study at this time? Probably not. Certainly, without a prospective study, there is no way to suggest that any of these medications be taken by men as a preventive agent. Also, no one is likely to suggest that you find a way to cause diabetes because it might lower your prostate cancer risk! But, potentially, there is an opportunity with further study to find out what effect diabetes or the medications produce that might be impacting on the disease. Follow-up studies will be interesting to watch.

Another article raises some important issues regarding seed implantation. Patients at several VA hospitals were found to have received a lower radiation dose than prescribed to treat their prostate cancer. Investigations are underway to determine why this happened. Is it technical, meaning that not enough seeds were used, or the seeds were not placed in the right location or could the seeds have migrated? Interestingly, the analysis has suggested no

harm has come from it yet, but of course it is far too early to know if that is true and it does leave these patients with a dilemma. Do they get additional treatment now or just wait to see what happens? It is interesting that some of the comments from officials have said that the patients had low risk disease. Does that mean that men with low risk disease do not need a full course of treatment, or perhaps any treatment at all? A message for prospective new seed implant patients is to make sure you are treated by clinicians with significant experience and ask your doctor how they insure that you are getting the right dose.

The Cleveland clinic has published its top ten medical innovations it expects to reshape health care in 2009. In that list is the ability to detect circulating tumor cells including prostate cancer and potentially identify men with advanced prostate cancer. At this time, extreme caution is advised. In other words, there is no evidence that men should run out and get this test performed. The reason is that it is unclear how to interpret the result. If a man with an undetectable PSA does have some of these cells, there is no evidence what it means; does it predict a future recurrence in all cases, how long will that recurrence take to develop and what should be done about it are all critical questions that need answers before clinical use. Some years back there was great excitement over using RT-PCR because it also could identify circulating tumor cells before a man was treated for prostate cancer. Some investigators suggested that the information could determine who was not a good candidate for local treatment thinking that if there were already cells outside the bother then the 'cat was out of the bag.' Subsequently, however, it was found NOT to be a useful predictor. Clearly, more research is needed, but at this time it must be considered strictly a research tool needing much more investigation.

Lastly, I want to announce several new videos to the prostate video website, <www.prostatevideos.com>. These include Proton Beam radiation, immediate radiation after radical prostatectomy and managing impotence after cancer therapy.

VA CLEARS MOST FACILITIES IN PROSTATE CANCER PROBE

Veterans Health Administration doctors investigating radiation underdosing of prostate cancer patients said they have found no problems at nine of 13 medical facilities that perform the treatment known as brachytherapy. In May, a physicist at the Philadelphia VA Medical Center discovered that a patient had received a lower-than-prescribed dose of radiation, prompting a probe that uncovered more than 90 additional cases of incorrect dosages at the facility since the cancer treatment program's inception there in 2002.

The problems in Philadelphia prompted VA to investigate its 12 other medical facilities that perform brachytherapy. In reviewing the 10 most recent procedures performed at each of the facilities, VA found several additional potential cases of underdosing at centers in Washington, DC; Jackson, MS; and Cincinnati, OH. So far, VA has found no evidence that any patients have suffered adverse outcomes as a result of the underdosing, said Dr. Madhulika Agarwal, VA's chief patient care services officer.

"We have some limited data that show the [cancer] recurrence rate is no different from the national average," said Dr. Charles Anderson, a radiologist and chief consultant of diagnostic services. "Understand that prostate cancer is a very slow-growing tumor and you may not know for 10 or more years. Most people with prostate cancer die of something else."

According to reports VA filed with the Nuclear Regulatory Commission, which licenses VA's radiation programs and has initiated its own review of operations at the medical centers, nine cases of underdosing were identified at Jackson, six at Cincinnati, and three at Washington. VA has convened a multidisciplinary team of medical specialists to examine the findings at the three additional medical centers with cases of potential underdosing. The team will determine if the investigation should be expanded beyond the initial 10 cases examined at those hospitals, Anderson said.

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CANCER CASES DECLINE

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surveys and cancer registries that federal officials use to track cancer trends. The analysis, published in the October 15th issue of the *Journal of the National Cancer Institute*, found that a drop in the rate at which Americans are dying from cancer, which began in the early 1990s, fell about 2% per year for men since 2001 and 1.6% per year for women since 2002.

The analysis found that since 1999 the overall incidence of cancer was also falling, retreating 0.8 percent per year. Notably, the drop occurred for both men and women, although it fell much more sharply for men -- down 1.8 percent per year from 2001 to 2005, compared with 0.6 percent per year for women from 1998 through 2005.

Brawley and others cautioned, however, that part of the reduction could be the result of fewer people getting screened for prostate and breast cancers. In addition, the rates at which many other types of cancer are being diagnosed are still increasing, he said, and overall far too many Americans are still getting and dying from cancer.

Washington Post, 26 November 2008

ANTIDIABETIC DRUGS

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prevalence of insulin use was 2.5% in the cases and 3.0% in the controls, according to the investigators. An association was observed between ever using any antidiabetic medication and a decreased risk of prostate cancer (adjusted OR = 0.84).

Decreased risk was comparable for all antidiabetic drugs, including metformin, sulfonylureas and insulin. They found that the overall risk, as well as the risk of advanced prostate cancer, decreased with the amount and duration of medication use.

“The potential mechanism behind decreased prostate cancer risk for diabetic men is currently unclear,” Dr. Murtola’s group notes. “Most likely, the changes in endogenous hormone metabolism occurring in diabetes have an important role.”

Reuters Health, 18 November 2008

Editor’s note: *This is another uncontrolled study suggesting a risk association between prostate cancer and disorders of insulin metabolism. Other studies have suggested increased risk from hyperinsulinemia and elevated blood levels of IGF-1 (insulin-like growth factor 1) although a direct association has not yet been proven.*

VA HOSPITAL PROBE

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Agarwal said one reason the numbers likely will change is that some initial findings were based on CAT scans taken very soon after the procedure was conducted. Because the radioactive seeds are metal and show up on the scans, specialists can determine the dosage based on the scans and seed placement. In a couple of cases subsequent CAT scans have shown the dosing to be correct, she said.

A significant number of the underdosing cases discovered in Philadelphia resulted from radioactive seeds being inadvertently placed in other organs, said Anderson. Two of the 57 patients found to have received lower-than-prescribed doses have since died of unrelated causes, according to VA.

The problems encountered in the three additional hospitals were of a lower magnitude than those in Philadelphia. VA has a conference in early January to bring all of the agency’s radiation oncologists together to discuss the probe’s findings and develop stricter guidelines for giving brachytherapy.

*<www.GovernmentExecutive.com>
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