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◆ **Top Clinical Cancer Advances During 2013** ◆

Clinical cancer advances made during a year-long period are highlighted by the American Society of Clinical Oncology (ASCO) in its annual progress report, published online December 10 in the *Journal of Clinical Oncology*. The annual report is put together by a panel of prominent oncologists, who use a peer-reviewed process to highlight what they consider to be the most important advances in clinical cancer made during a 1-year period.

The panel highlighted 76 advances, the most clinically relevant of which are summarized here. This list includes the approval in the United States of 9 new drugs for cancer and the approval of extended cancer indications for another 7 drugs already on the market. (Editor's note: Only prostate cancer-related advances are shown here).

Patient Care Issues

- **Patients often do not understand goals of cancer treatment.** A study of more than 1000 cancer patients found that most believed that their treatment was curative. The researchers found that 70% of those with lung cancer and 80% of those with colorectal cancer did not understand that they had incurable disease and that the aim of treatment was palliation. ASCO says this finding "raises questions about how information is communicated and whether patients are adequately informed to make treatment decisions."
- **Hospice services are underused by Medicaid patients.** A study comparing rates of hospice use among patients with stage 4 lung cancer found substantially lower use among Medicare vs Medicaid patients (50% vs 25% patients used hospice) ASCO draws attention to its provisional clinical opinion that recommends extending palliative care services for all patients with advanced cancer and states: "Ensuring that people live their final days in comfort and dignity is a key responsibility of cancer care providers."
(Continued on page 17)

◆ **INSIDE THIS ISSUE** ◆

Cancer Advances Page 1
Next Speaker. Page 2

Prostate-Specific Issues Page 3
Counselors Listing Page 19

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◆ FROM THE EDITOR ◆

Our support group is a chapter of Us TOO, International, the largest prostate cancer advocacy organization. Have you visited the Us TOO website yet? Try it, you will like it! It contains a wealth of information such as current developments in prostate cancer therapies. And it's monthly *Hot Sheet* is a must-read publication. Go to www.ustoo.org to see what you have been missing.

◆ NOVEMBER 7, 2013, SPEAKER'S REMARKS ◆

Our program featured Dr. Edmond L. Paquette, Dominion Urological Consultants. The topic of his presentation was "The PSA Controversy-What Patients Should Understand." A summary of his presentation begins on page 14.

◆ MEETING SCHEDULE FOR FEBRUARY 6, 2014 ◆

Our speaker is Dr. Michele Ojemuyiwa, Department of Urology, Walter Reed National Military Medical Center. Her topic is "Hormone Therapy 101," a review of what every man affected by prostate cancer should know about hormone therapy. Hormone therapy is a major therapy for prostate cancer, either alone, or in combination with other therapies, so it is important that men with prostate cancer understand the role that hormone therapy plays in the treatment of the disease.

Join us at 7 PM, Thursday, February 6, 2014. Your family members and friends are always welcome. There is no charge and no registration. The presentation will be viewed live by video teleconference at the Fort Belvoir Community Hospital. Go to the Oaks Pavilion, 1st floor, Room 332.

**SEE THE BACK PAGE OF THIS NEWSLETTER FOR
IMPORTANT INFORMATION ABOUT THIS MEETING.**

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PROSTATE-SPECIFIC ISSUES

Credentialing for Robotic Surgery. In the United States, there are approximately 2 robots per robotic surgeon, and currently no standardized credentialing system exists to evaluate surgeon competency and safety with robotic urological surgery performance. Given the widespread and rapid utilization of robotic urologic surgery, guidelines for safe initiation of this technology are a necessity. Proctoring is a viable method to teach surgery, but credentialing guidelines are needed to ensure the requisite knowledge and technical skills needed to perform robotic surgery have been acquired.

The American Urological Association has guidelines for robotic surgery and recommendations for implementing structured curriculums throughout residency. Minimum standards have been proposed to include a required amount of bedside assistance (5 cases) and proctoring (20 cases). Implementation of robotic simulation curricula nation-wide was suggested.

However, there is currently no perfect robotic simulator. Some programs have already established simulation programs so residents have the minimal skill set required to operate the robot safely in a patient care setting. Implementation of preceptor protocols and proctoring guidelines is necessary to protect surgeons, institutions, and above all, patients. (Source: "Extraordinary Opportunities for Discovery." 14th Annual Meeting of the Society of Urologic Oncology: December 4-6, 2013; Bethesda, MD)

Robotic Surgery. Should You Go for It?

The reports of "adverse events" during various robotic procedures has led to new government scrutiny, as well as a cautionary

statement from the American College of Obstetricians and Gynecologists: "Robotic surgery is not the only or the best minimally invasive approach to hysterectomy...nor is it the most cost-effective."

Does any of this warrant rejecting robotic surgery? Many experts say no. Every patient profile is different, and a robot is just another surgical instrument. It's only as good as the surgeon using it. Before making a decision on what kind of procedure to elect, here are some things to consider:

Why the spike in robotic usage? Back in 2000, there were only 1,000 robotic surgeries world-wide. That number surged to 360,000 in 2011 and 450,000 last year. Boosters say the practice is on the rise because of its strong benefits. For the patient, there's usually less blood loss, a shorter hospital stay and less reliance on postoperative pain medication. There's also the cosmetic benefit of no big scars: As in laparoscopic surgery, the instruments enter the body through small incisions.

For surgeons, the procedures can be less tiring. They don't have to bend over an operating table—they can sit in front of a screen with a magnified, full-color 3-D view of the surgical field. For maneuvering in very tight spaces, like the back of the throat, the enhanced screen image makes it much easier to observe the treated area.

Other doctors cite a "wow" factor at work. One practitioner believes the technique is safe and useful for certain procedures, but it's spreading too fast. There is a propensity to embrace technological innovations without rigorous, standardized evaluation.

Some observers also say there's an arms race by hospitals eager to attract new patients and get a competitive edge, leading to highway billboards and websites sometimes suggesting that robots improve outcomes, a claim that many say isn't backed up by studies.

Government officials have shown concern about oversight. For example, responding to an increasing number of reports of patient complications from robotic surgery, Massachusetts health officials last March sent an advisory to the state's hospitals urging caution: "As with any new technology, care should be taken that protocols are in place to ensure appropriate patient selection and the full explanation of risks and benefits for all surgical options."

What about risks? Reports of adverse robotic events to the Food and Drug Administration are on the rise. Based on a draft analysis of these reports by physicians at Rush University Medical Center, the University of Illinois and the Massachusetts Institute of Technology, there has been a sharp increase in the injury and death rate from robotic surgery to about 50 reports per 100,000 procedures last year from only 13.3 in 2004. A manufacturers' spokesman disputes this analysis, claiming there isn't any "statistically significant trend."

How should patients weigh all of this? The wisest approach is to have your surgeon explain the alternative procedures, including typical postoperative scenarios and why the suggested approach is the best option in your particular case. No single approach is a one-size-fits-all answer for all conditions requiring surgery.

How much training is required to perform robotic surgery? One expert believes that overall, robotic surgery is safe, but problems can get magnified if a surgeon doesn't have advanced laparoscopic surgical skills to begin with and doesn't have full com-

mand of the device. That means it's easier to cause inadvertent injury.

Training protocols vary by hospital. There's no magic number of supervised procedures that must be performed before a surgeon is deemed ready. A sign-off usually comes after a more experienced colleague or a committee is satisfied with a surgeon's skill set on the machine. Obviously, ask your surgeon how experienced he or she is in the procedure and whether there have ever been any complications.

What about the cost? Generally, robotic procedures cost more than other comparable types of surgery. A study published last year by surgeons at Brigham and Women's Hospital in Boston showed these average total patient costs for different types of hysterectomies: \$49,526 for a robotic procedure, \$43,622 for abdominal, \$28,312 for laparoscopic and \$31,934 for vaginal. But bear in mind that patients may end up saving on their overall costs. A robotic procedure may mean less need for blood transfusions and post-op pain medications. Patients may also spend less time in the hospital and have a lower chance of readmission for complications. (Source: *Wall Street Journal Reports*; November 17, 2013)

Inherited Risk for Prostate Cancer. One legacy that most men could do without is an inherited risk for prostate cancer, but a massive cohort study shows that for some men, genetic history hints at oncologic destiny.

Data on both identical (monozygotic) and fraternal (dizygotic) twins from the comprehensive birth-to-death registries in Denmark, Finland, Norway, and Sweden show that a man whose identical twin has prostate cancer has a 32% risk for the disease himself, whereas a fraternal twin whose brother has prostate cancer has only a 16% risk.

The estimated heritability of prostate cancer — the degree to which genes contribute to risk — was 58%, which is the highest for any malignancy studied, according to the researchers. These estimates for common cancers are greater than previously estimated. For rare cancers, such as testicular cancer, the concordance risk was substantial so it provides an accurate estimate of familial risk prediction.

Table. Cancers With Significant Heritability

Cancer Type	Heritability Estimate, %	95% Confidence Interval
Prostate	58	52–63
Testicular	36	2–95
Breast	28	12–52
Kidney	23	11–42
Lung	25	12–44
Melanoma	39	8–81
Ovarian	28	15–47
Stomach	24	5–65
Uterine	24	14–87
Colon	16	2–63

The magnitude of the genetic contribution to prostate cancer found in this study is higher than the estimated 42% seen in a previous study of Nordic twins. This difference can be attributed to the fact that the researchers expanded the original cohort to include data from Norway, had 10 additional years of follow-up data, and had an aging cohort, with a resultant increase in incident cancers.

What's Going On? This study raises important questions about the interplay between genetics and environment in cancer. An ob-

server said that it's a very strong study. The exciting thing about this study with prostate cancer is that it's certainly saying something about mechanisms that we don't yet understand.

The study supports the presence of genetic polymorphisms in prostate cancer, and to a lesser degree breast cancer, that can cumulatively contribute to risk, he said.

"The specific polymorphisms we're aware of — familial syndromes — account for very little breast cancer or prostate cancer. There are other genes where allelic variation and risk is moderate. There must be a lot of those genes with moderate risk; you put them together and it makes you more susceptible," said one researcher. (Source: American Society of Human Genetics 63rd Annual Meeting: Abstract 43. Presented October 23, 2013)

Prostate Cancer Death Risk and Diabetics. Men with type 2 diabetes are at increased risk for death from prostate cancer (PCa) or from any cause, Canadian researchers reported online ahead of print in *Cancer Causes & Control*.

Azoulay et al., McGill University, Montreal, studied 11,920 men newly diagnosed with non-metastatic PCa. The cohort included 1,132 men (9.5%) with pre-existing type 2 diabetes. A total of 3,605 deaths, including 1,792 from PCa, occurred during a mean 4.7 years of follow-up. Compared with non-diabetics, men with type 2 diabetes had a 23% increased risk of PCa mortality and 25% increased risk of all-cause mortality, after adjusting for potential confounders, including smoking, excessive alcohol use, comorbidities, and PCa-related variables.

According to the authors, the findings may signal an association between hyperinsulinemia or other diabetes-associated metabolic derangements and cancer aggressivity. (Source: Renal & Urology News. January 7, 2014)

Low Fat Diet, Omega-3 and Prostate Cancer.

A recent study reveals that men suffering from prostate cancer who took fish oil supplements with a low-fat diet demonstrated changes in their cancer tissue that may indicate reduced cancer aggression. Researchers from the University of California-Los Angeles have looked to changes in diet as a potential intervention. This most recent study follows on from previous research conducted by the team in 2011.

The previous study required two groups of men with prostate cancer to follow two separate diets for a period of 4 to 6 weeks. The first group followed a low-fat diet consisting of 15% of calories from fat, and they also took 5 g of fish oil a day through five fish oil supplements in order to have a regular intake of omega-3 fatty acids.

Omega-3 fatty acids are types of fat that are commonly found in plant and marine life oils. Omega-3 is known to reduce inflammation and has been linked to many health benefits, such as the prevention of oral and skin cancers.

The second group followed a high-fat Western diet. This diet consists of around 40% of calories from fat - the equivalent to what many Americans consume each day, the researchers say. The Western diet also includes high levels of omega-6 fatty acids from corn oil, but low levels of fish oil that provides omega-3.

The men who adopted the low-fat diet showed slowed growth of cancer cells, compared with the men who followed the high-fat diet. Furthermore, the research found that men following the low-fat diet showed changes in the composition of their cell membranes in both healthy cells and cancer cells in the prostate.

These men showed increased levels of omega-3 fatty acids as a result of the fish oil supplements but showed reduced levels of omega-6 fatty acids in the cell mem-

branes, which could directly affect the cell's biology.

Men with prostate cancer "really are what they eat." For this most recent study, the investigators wanted to determine exactly how the low-fat fish oil diet works to produce the effects found in their previous research.

Therefore, they measured the levels of pro-inflammatory substances in the blood and analyzed the men's prostate cancer tissue in order to find out their cell cycle progression (CCP) scores - a measure of aggression within prostate cancer cells used to determine a patient's likelihood of recurrence.

On analyzing one particular pro-inflammatory substance called leukotriene B4 (LTB4), it was found that men with lower levels of this substance after following the low-fat diet also had lower CCP scores. Further analysis revealed that one of the receptors of LTB4 is present on the surface of prostate cancer cells, which the researchers say is a "completely novel finding."

The investigators note that their findings are significantly important, since the ability to lower a patient's CCP scores could be a way of preventing prostate cancers from becoming more aggressive.

Commenting on their findings, William Aronson, a clinical professor of urology at UCLA and lead study author, says: "These studies are showing that, in men with prostate cancer, you really are what you eat. The studies suggest that by altering the diet, we may favorably affect the biology of prostate cancer." Further studies are planned at UCLA next year to investigate the importance of the LTB4 receptor in prostate cancer progression. (Source: *Medical News Today*, November 20, 2013) based on research published in the journal *Cancer Prevention Research*.)

Inflammation at Biopsy and Prostate Cancer Risk.

Researchers say that men who show signs of inflammation in their initial prostate biopsies may have a reduced risk of being diagnosed with prostate cancer from future biopsies. This is according to a study published in the journal *Cancer*.

Morreira, et al., North Shore-Long Island Jewish Health System, New Hyde Park, NY, say their findings suggest that since inflammation has a "predictive value," it should be regularly reported from prostate biopsies.

The link between inflammation and prostate cancer has been controversial. Previous studies have also suggested that inflammation of the prostate is associated with a lower risk of cancer, but other research has suggested that therapies to combat prostate inflammation reduce cancer risk. To further examine the issue, the research team looked at data of 6,238 men aged between 50 and 75 years.

All men had previously undergone prostate biopsies that were negative, suggesting no sign of prostate cancer. Additional biopsies were conducted 2 and 4 years later.

On prostate-specific antigen (PSA) tests (a blood test determining the risk of prostate cancer), all men showed PSA levels between 2.5 to 10 ng/mL.

From the analysis, it was found that acute inflammation was common from biopsies at the beginning of the study in men of younger ages who had lower PSA levels and smaller prostates. Men who were older with larger prostates were more likely to have chronic inflammation. From the biopsies taken 2 years later, prostate cancer was detected in 900 men (14%).

The researchers found that men who had acute inflammation at baseline had a 25% lower risk of developing prostate cancer, while men with chronic inflammation had a

35% lower risk. The biopsies taken 4 years later revealed that only acute inflammation was linked to a lower risk of prostate cancer.

The researchers hypothesize that inflammation may be linked to a lower risk of prostate cancer because inflammation occurs as part of an immune response when the body observes "malignant cells as foreign agents." The body may eliminate the cells before they turn into a tumor. If this is the case, it is possible that monitoring and balancing inflammation and the body's immune response could assist the prevention and treatment of prostate cancer.

The researchers say that given its predictive value, inflammation - and its type and severity - should be routinely reported in prostate biopsies. Also, it is possible that patients with inflammation at baseline biopsy may be followed differently compared with patients without inflammation at baseline biopsy, given their risk of subsequent cancer detection is lower. (Source: *Medical News Today*, December 9, 2013)

Surgical Anesthesia and Prostate Cancer Recurrence.

For men having prostate cancer surgery, the type of anesthesia doctors use might make a difference in the odds of the cancer returning, a new study suggests. Researchers found that of nearly 3,300 men who underwent prostate cancer surgery, those who were given both general and regional anesthesia had a lower risk of seeing their cancer progress than men who received only general anesthesia.

Over a period of 15 years, about 5 percent of men given only general anesthesia had their cancer recur in their bones or other sites, the researchers said. That compared with 3 percent of men who also received regional anesthesia, which typically meant a spinal injection of the painkiller morphine, plus a numbing agent.

None of that, however, proves that anesthesia choices directly affect a prostate cancer patient's prognosis. "We can't conclude from this that it's cause-and-effect," said senior researcher Dr. Juraj Sprung, an anesthesiologist at the Mayo Clinic in Rochester, Minn. But, he said, one theory is that spinal painkillers -- like the opioid morphine -- can make a difference because they curb patients' need for opioid drugs after surgery. Those post-surgery opioids, which affect the whole body, may decrease the immune system's effectiveness. This is potentially important because during prostate cancer surgery, some cancer cells usually escape into the bloodstream.

The study, reported online December 17 in the *British Journal of Anaesthesia*, is not the first to see a link between regional anesthesia and a lower risk of cancer recurrence or progression. Some past studies have seen a similar pattern in patients having surgery for breast, ovarian or colon cancer. But those studies, like the current one, point only to a correlation, not a cause-and-effect link.

Dr. David Samadi, chief of urology at Lenox Hill Hospital in New York City, agreed. "We have to be very careful about how we interpret these results," said Samadi, who was not involved in the new study.

One important issue, he said, is that the men in this study all had open surgery to remove their prostate gland. But these days, the surgery is almost always done laparoscopically -- a minimally invasive approach in which surgeons make a few small incisions. In the United States, most of these procedures are done with the aid of robotic "arms." Compared with traditional open surgery, laparoscopic surgery is quicker and causes less stress, blood loss and post-surgery pain, so patients' need for opioids after surgery is low.

The findings are based on the records of nearly 3,300 men who had prostate cancer

surgery between 1991 and 2005 at the Mayo Clinic. Half had been given only general anesthesia, while the other half had received regional anesthesia as well. In 83 percent of the cases, that meant a spinal block containing morphine.

The researchers weighed other factors, such as the stage of the cancer and whether a man received radiation or hormone therapy after surgery. In the end, having general anesthesia alone was linked to a nearly threefold higher risk of a cancer turning up in distant sites in the body over the next 15 years.

One expert noted that since only 3 percent to 5 percent of the men had a cancer recurrence, the risk is generally low with a skilled surgeon. He suggested that patients be more concerned about their surgeon's experience than the type of anesthesia. Studies have found that prostate cancer patients treated by more experienced surgeons tend to have a lower risk of recurrence. They also have lower rates of lasting side effects, such as erectile dysfunction and incontinence.

To prove that regional anesthesia directly affects cancer patients' prognosis, "controlled" studies are needed. That means randomly assigning some surgery patients to have general anesthesia only, while others get regional anesthesia as well.

For now, Dr. Sprung said, the decision about whether to use a spinal painkiller during surgery should be based on other factors, such as its potential to limit post-surgery pain. (Source: *British Journal of Anaesthesia*, online, December 17, 2013, via HealthDay News)

Metastatic Prostate Cancer and Chemotherapy. Men with hormone-sensitive metastatic prostate cancer who received the chemotherapy drug docetaxel given at the start of standard hormone therapy lived longer than patients who received hormone

therapy alone, according to early results from a National Institutes of Health-supported randomized controlled clinical trial.

The study results were made public because a recent planned interim analysis showed the prolongation in overall survival. Full details from this early analysis will be presented at a scientific meeting in 2014 and in a peer-reviewed publication.

The study enrolled 790 men with metastatic prostate cancer between July 2006 and November 2010. All patients started treatment by receiving a form of hormone therapy known as ADT (androgen deprivation therapy). Androgens regulate male sex characteristics and can stimulate prostate cancer cells.

Men received either ADT alone or ADT with the chemotherapy drug docetaxel every three weeks over a period of 18 weeks. In addition to examining whether the study participants lived longer with the addition of chemotherapy, investigators looked at whether the extent of a patient's metastatic disease was high or low at the start of treatment. Approximately two thirds of patients had a high extent of disease which, according to the study, meant the disease had spread to major organs such as the liver, had a spread resulting in four or more bone lesions, or both.

A significant improvement in the overall survival was noted favoring the participants who had received docetaxel chemotherapy in addition to the ADT compared to the ADT alone (three-year survival rates of 69.0 percent vs. 52.5 percent respectively). Further analysis showed that patients with a high extent of metastatic disease accounted for most of the benefit in the overall survival from docetaxel plus ADT (three-year survival rates of 63.4 percent vs. 43.9 percent for ADT alone). Median follow-up to date is two years.

Since docetaxel has been shown in previous clinical trials to be beneficial in ADT-resistant disease and is approved by the U.S. Food and Drug Administration for treatment of late-stage prostate cancer, it is available for use now. However, because it is a chemotherapy drug, its use in combination with ADT at this time should be restricted to patients with high-extent metastatic prostate cancer who are candidates for treatment with docetaxel, according to the trial investigators. This is the group of patients who experienced the most benefit in the current analysis. Further follow-up will be performed on patients with less extensive metastatic disease in order to define the effect of this treatment combination on these patients.

"The results of this study are practice-changing," said lead investigator Christopher Sweeney, Dana Farber Cancer Institute, Boston. "We have strong scientific evidence that patients with the most advanced metastatic prostate cancer benefit from the early addition of docetaxel to ADT and not waiting until the cancer has progressed on hormonal therapy. The findings of this study are important both for improving the clinical care we deliver now and in designing new clinical trials as we strive to further improve the lives of men with metastatic prostate cancer." (Source: National Institutes of Health: *News & Events*; December 5, 2013)

Evidence for Supplement Use Lacking.

There still is not enough evidence to recommend for or against using vitamin and mineral supplementation for the primary prevention of cardiovascular disease or cancer, a draft of updated recommendations from the U.S. Preventive Services Task Force (USPSTF) stated.

The task force also reaffirmed a recommendation against the use of beta-carotene supplements for preventing cardiovascular disease or cancer because of clear evidence of a lack of benefit, accompanied by

an increased risk of lung cancer in those already at risk for the disease.

In a change from the previous iteration of the recommendations issued in 2003, the task force found enough evidence to advise against the use of vitamin E to protect against cardiovascular disease or cancer because of a lack of benefit.

The guidance applies to primary prevention in healthy adults without nutrient deficiencies, with the exception of women who are pregnant or may become pregnant, a group that "should take a daily supplement containing folic acid to help prevent neural tube defects."

Sidney Smith Jr., MD, University of North Carolina at Chapel Hill, told *MedPage Today* that "information like this is very helpful in terms of informing us about the value of nutritional supplements."

"I think we have to remember this deals with primary prevention, and my advice based on this and everything I'm seeing coming out is choose your diet wisely," he said. "That's the best thing you can do for cardiovascular health and cancer. And also be sure that if you have risk factors, you take medications that will deal with them effectively."

The new proposed guidance is consistent with that from other organizations, including the National Institutes of Health and the Academy of Nutrition and Dietetics, which also found insufficient evidence to recommend the use of multivitamins to prevent chronic disease. The American Heart Association recommends "that healthy people get adequate nutrients by eating a variety of foods in moderation, rather than by taking supplements."

The use of vitamins and minerals to prevent chronic disease has some biological plausibility based on the ability of certain supplements to counteract the oxidative stress

and inflammation believed to be involved in the development of cardiovascular disease and cancer. And the general public appears to support the benefits of dietary supplements, with Americans spending \$28.1 billion on them in 2010, according to the task force.

In 2003, the task force reviewed the evidence for use of vitamins A, C, and E, multivitamins with folic acid, and antioxidant combinations to prevent cardiovascular disease or cancer and determined that it was insufficient to recommend for or against their use for that purpose.

For the updated guidance, the task force considered an evidence review conducted by Stephen Fortmann, MD, of the Kaiser Permanente Center for Health Research in Portland, Ore., and colleagues and published online in *Annals of Internal Medicine*. In the new review, the researchers included a wider range of supplements, including vitamin D, calcium, selenium, and folic acid.

The findings led the task force to conclude that, overall, there was not enough evidence to make a determination on the relative risks and benefits of using multivitamins, single-nutrient supplements, or paired-nutrient supplements for the prevention of cardiovascular disease or cancer.

"However, there are only a limited number of studies for most individual nutrients, and differences in study designs make it difficult to pool effects across supplements," according to the draft recommendations. "Therefore, the USPSTF is not able to conclude with certainty that there is no effect."

The two exceptions were beta-carotene and vitamin E. With "moderate certainty," the task force concluded that solid evidence indicated that neither supplement is effective at preventing cardiovascular disease and cancer, and that beta-carotene increases the risk of lung cancer in susceptible individuals.

Although pooled results from two trials -- the Physicians' Health Study II and the Supplementation in Vitamins and Mineral Antioxidants Study -- did show a lower incidence of cancer among men taking multivitamins (pooled RR 0.94, 95% CI 0.89-1.00), there was no such benefit among women in the one study that included them. That evidence was not strong enough to support a recommendation for using multivitamins to prevent cancer, however.

"Future trials should be more representative of the general population, including women and minority groups, and have enough power to demonstrate whether there are true subgroup differences," the task force stated. (Source: MEDPAGE Today, November 12, 2013)

Shared Decision-making Uncommon for PSA Tests. Most men have not discussed the potential advantages and disadvantages of prostate cancer screening with their doctor, according to a new study. Guidelines from groups including the American Urological Association and American College of Physicians call for shared decision-making when it comes to prostate specific antigen (PSA) testing, taking into account each man's values regarding screening.

"There's a lot of scientific uncertainty about its benefits and harms for any one person," said Dr. Paul Han, Maine Medical Center, who led the new study. The concern with screening is that PSA tests catch some cancers that never would have affected a man's life because they are so small and slow-growing - yet treatment can cause side effects such as incontinence and impotence. And there's still controversy about whether regular screening saves a significant number of lives.

The U.S. Preventive Services Task Force (USPSTF), a government-backed panel, recommends against prostate cancer screening.

Han and his colleagues analyzed questionnaires completed by about 3,400 men in their 50s, 60s and early 70s as part of a 2010 national health survey. They found 64 percent of those men had not discussed the pluses and minuses of PSA tests with their doctors, or the scientific uncertainty of their effect. Of the rest, about half had talked only about the advantages of screening.

About 44 percent of study participants hadn't been screened for prostate cancer in the past five years. The majority of those - 88 percent - reported no discussions regarding that choice, according to findings published in the *Annals of Family Medicine*. Prior studies have focused on men who were screened without a discussion of the potential benefits and harms - sometimes without their knowledge.

Beyond weighing the risks and benefits of screening for any individual man, the PSA test itself may not be that accurate or reliable an indicator of cancer. But if the evidence on PSA tests is "truly uncertain," Han told Reuters Health, failing to talk about the decision to not get screened could be concerning as well.

The PSA test is the "poster child for uncertainty," said Dr. Michael Wilkes, from the University of California, Davis. "The test is horrible, yet there are still reasonable men who still might opt to have the test because they feel that knowing the information, even though it's not perfect, is better than not knowing it," he told Reuters Health. "In this situation, reasonable people can look at the data and because of their own values and their own preferences decide, 'I want the test' or, 'I don't want the test.'"

Having the Conversation. In two studies published in the same journal, Wilkes and his colleagues looked at whether educating doctors about prostate cancer screening and prompting patients to ask about it

boosted rates of shared decision-making. Their studies included about 120 doctors who either were given typical brochures about PSA tests or completed an interactive program that included video vignettes showing the possible benefits and harms of screening.

When faced with a test patient a few months later, doctors in the intervention group were a little better at leading shared decision-making discussions - but not much. Audio recordings of the appointments showed those doctors incorporated an average of 14 out of 32 decision-making elements into the visit, versus 11 by doctors in the comparison group. Those elements included sharing information about different screening and treatment options and asking about the patient's values in relation to screening.

In another analysis, doctors were more neutral about their screening recommendations when they'd completed the computer program and some of their patients had been educated and primed to ask about screening. "What we found was, educating the doctor is necessary but not sufficient," Wilkes told Reuters Health.

He recommends men do their homework on prostate cancer screening - by looking at the U.S. Centers for Disease Control and Prevention and USPSTF websites, for example - before going in to see their doctor. Better training and resources for doctors might also help, according to Han.

"Studies are converging to the same conclusion, that (shared decision-making) really doesn't happen very often in PSA screening," he said. "It's one of these things like world peace. Everyone agrees with it as an ideal, but how to actually achieve it, we don't know." (Source: Medline Plus, Reuters Health Information; July 11, 2013) (Editor: See comments on legal issues - Merenstein, et al, below)

New Radiation Therapy Prolongs Prostate Cancer Survival of men with the most advanced form of prostate cancer.

A new radiation therapy can extend the lives of men with the most advanced form of prostate cancer, a large new study has found.

The treatment is an isotope of radium that zeroes in on cancer cells that have spread to bones. The radium, which mimics calcium, binds with minerals in a patient's bones, where it delivers radiation that destroys cancer cells without inflicting as much damage to surrounding tissues as older radiation therapies.

The study, published in The New England Journal of Medicine, involved a large group of men with late-stage prostate cancer who were expected to live less than a year. Those who were given the drug, however, saw their median survival time increase to nearly 15 months, a "substantial 30 percent improvement," said Dr. Chris Parker, the lead author of the new study and a consultant clinical oncologist at the Royal Marsden Hospital and the Institute of Cancer Research, both in London. Men given the drug also experienced fewer adverse effects, like bone pain and muscle weakness.

The drug was approved by the Food and Drug Administration in May and is sold under the brand name Xofigo. The agency reviewed the drug under a fast-track priority program, approving it three months ahead of schedule.

The drug's mechanism is not specific to prostate cancers. In clinical trials it has also shown promise in treating bone metastases resulting from breast cancer. And it is likely to help in treating bone metastases caused by other cancers as well, said Dr. Robert Dreicer, a prostate cancer specialist and the chairman of the Cleveland Clinic's

department of solid tumor oncology, who was not involved in the new research.

“I think this is a big deal,” said Dr. Dreicer said. “It’s not a home run, but it’s a nice advance.”

Prostate cancer is the second leading cause of cancer deaths among men in the United States. Every year, nearly 30,000 men die from the disease, and almost a quarter of a million new cases are diagnosed.

The cancer is usually treated with radiation or an operation that removes the prostate gland, followed by drugs that suppress the hormone testosterone, which can stimulate the growth of prostate tumors.

In many men, however, the disease eventually spreads and reaches a point where hormone therapy no longer keeps it in check. Most of the deaths from prostate cancer occur when the disease has spread to the bone.

“About 90 percent of men with advanced prostate cancer have bone metastases, and there has certainly been an unmet need for an effective treatment,” Dr. Parker said.

The new drug contains radium 223, which targets bone and emits alpha particles that are far more massive and energetic than the beta particles emitted by older radioimmunotherapies like strontium. Once in the bone, the heavier alpha particles do not stray as far as the lighter beta particles, which makes them less toxic to bone marrow, Dr. Parker said.

In the new study, Dr. Parker and his colleagues recruited more than 900 men in 19 countries who had hormone-resistant prostate cancer that had spread to their bones but not to other organs. Such men typically live for two or three years, but by the time they entered the study their

disease had already progressed for some time.

The men were randomly assigned to receive either placebo or a monthly injection of Xofigo. In those who received it, the drug increased the median survival time from about 11 months to nearly 15. Dr. Parker said that in the real world, the drug could be used even earlier.

“If the drug were used earlier and the 30 percent benefit maintained,” he said, “it would give a longer absolute benefit.”

Drugs for advanced prostate cancer are typically expensive, costing tens of thousands of dollars for a single course of treatment. Xofigo is no different. A course of treatment, administered over roughly six months, costs \$69,000. A spokeswoman for the drug’s developers, Bayer and its partner Algeta, said Medicare and most commercial insurers were likely to cover the drug.

In an editorial that accompanied the study, two leading radiation oncologists at the University of Pennsylvania noted that Xofigo could be used to complement other fairly new drugs that prolong survival in the late stages of the disease.

“As newer targeting molecules emerge,” they wrote, “we can envision alpha emitters as a potent partner to further enhance radioimmunotherapy and create the ultimate ‘smart bomb.’” (Source: Bayer Healthcare Pharmaceuticals, via PR Newswire)

"The Prostate Cancer Controversy: What Patients Should Understand"

by

Edmond L. Paquette, MD FACS

Assistant Professor, Surgery

Virginia Commonwealth University School of Medicine

(Summary of a presentation to the WRNMMC Prostate Cancer Support Group, November 7, 2013)

(Editor's Note: The issue is clear: Should the PSA test be used as a routine screening device to detect prostate cancer in the hope of effecting a cure for asymptomatic men by early diagnosis, given the healthcare cost and the potential for side effects associated with quality of life? Dr. Paquette, a practicing urologist, discusses issues affecting the patient's decision to undergo a PSA test. Audio-visual problems do not allow us to present a verbatim transcript, so this summary relies on the slides Dr. Paquette used in his presentation.

Introduction. At the outset, Dr. Paquette discussed the prevalence of prostate cancer, noting that 1/3 of all men between the ages 45-60 will have prostate cancer at autopsy, as will 2/3 of all men between the ages 60-85. He also reviewed the age-adjusted U.S. mortality rates for selected cancers affecting males (lung, colorectal, oral, prostate) during 1975-2008. Lung cancer is clearly the greatest threat, followed by prostate cancer. The mortality rate for prostate cancer declined from about 31 deaths per thousand men in 1975 to about 21 deaths per 10,000 men by 2008. The decline has been attributed by many to early detection due to PSA screening. It was noteworthy that the prostate cancer death rate for black men during 2004-2008 was more than twice as high as the rate for white men.

Screen-detected Prostate Cancer. Screen-detected prostate cancer can fall into one of three categories: **(1)** Cancer that results in death despite early detection and diagnosis. For example, a 56-year-old man with a PSA of 4, a slight ridge on the right lobe, and a Gleason 9 cancer in every core, and bone metastasis. **(2)** Cancer in which early detection and diagnosis improves survivability. For example, a 56-year-old man with a PSA of 4, a Gleason 7, stage T3a. This individual is the one who can be helped by screening **(3)** Cancer in which the outcome would be good without screening because the cancer was indolent. For example, a 56-year-old man with a PSA of 4, Gleason 6 in one of 12 cores, and a PSA of 6 after 10 years.

The Prostate Cancer Prevention Trial. The well-known Prostate Cancer Prevention Trial (PCPT) was a study designed to see whether the drug finasteride (trade name Proscar) can prevent prostate cancer in men ages 55 and older. The study enrolled 18,882 men: 92 percent white, 4 percent African American, 4 percent other races/ethnicities. The men were age 55 and older; in general good health; no evidence of prostate cancer at beginning of trial; PSA 3 ng/ml or lower; and willing to have a prostate biopsy at the end of the study. The men were randomly assigned to take either 5 milligrams of finasteride or a placebo once daily for seven years. All men had an annual digital rectal exam and a PSA test. At the end of the seven years, men who had not been diagnosed with prostate cancer were asked to have a prostate biopsy to see if they were truly cancer free.

In June 2003, the PCPT was stopped early because of a clear finding that finasteride reduced the incidence of prostate cancer. However, those trial participants who did develop prostate cancer while taking finasteride experienced a slightly higher incidence of high-grade tumors. Researchers analyzing the data have shown that because men taking finasteride have a reduced prostate size, this contributes to finding more high-grade tumors on biopsy. Additionally, researchers also found that high-grade cancer was detected earlier and in a less extensive stage in the finasteride group than in the placebo group.

The Case Against Screening. The U.S. Preventive Services Task Force (USPSTF), an advisory group, reviewed the screening issue. Its 2011 finding recommended against prostate cancer screening with PSA testing because there is moderate or high certainty that the service has no net benefit, or that harms outweigh the benefits. Its study of the mortality benefits of PSA-based prostate cancer screening through ten years showed that benefits are small to none, while harms are moderate to substantial (e.g., unnecessary biopsies, risk of incontinence and impotence). In short, the USPSTF concluded that PSA-based screening for prostate cancer, as currently utilized and studied in randomized, controlled trials, has no net benefit. Its recommendation does not apply to men that have highly suspicious symptoms of the disease, nor for surveillance in men already diagnosed with prostate cancer.

In a related study, the 2009 European Randomized Study of Screening for Prostate Cancer involved 182,000 men in seven countries randomized to a screened group or a control group without screening. Ages ranged from 50 to 74 and treatment was performed according to local policies and guidelines. The study found that 1,068 men had to be screened and 48 of them treated in order to prevent one death from prostate cancer. One-third to 1/2 of the detected cancers may be indolent, indicating a significant over-diagnosis and potential overtreatment. Although the study concluded that there was no benefit in overall mortality in the screened versus unscreened group, there was a 20% reduction in prostate cancer mortality in the screened group.

In another major trial, the Prostate, Lung, Colorectal and Ovarian Screening Protocol (PLCO) trial, 76,693 men were randomized to annual screening or "usual care" during 1993-2001. The screening arm of the study had 2,820 incidences of prostate cancer, 50 men died from the disease, and the incidence of death was 2.0 deaths per 10,000 person years. The control arm had a remarkably similar experience - 2,322 incidences of cancer, 44 deaths, and incidence of death was 1.7 deaths per 10,000 person years. It should be noted that the PLCO test had significant contamination issues that may cause some to find it dubious.

The Harms of Early Detection. The cost of routine screening is high and the net benefits low, making screening non-cost effective in economic terms. Men have substantial worry throughout the process.. The transrectal ultrasound and biopsy can cause problems. For example, 68 cases per 10,000 biopsies will have excessive bleeding or infection requiring hospital admission and 2-4% of patients will get a urinary tract infection. Five in 1,000 men will die within one month of prostate cancer surgery. Finally, screen-detected cancers may be indolent (non-aggressive) posing no threat to mortality.

The Case for Screening. The 2009 European Randomized Study cited above was updated (11 year follow-up compared to 9 years in the original study). It confirmed the previous finding that although death from all causes within both the screened and unscreened groups was unchanged, PSA-based screening significantly reduced mortality from prostate cancer. The relative reduction in risk of death from prostate cancer was 21%.

The Goteborg (Sweden) Trial was part of the larger European Trial. The screened and the unscreened groups both had 9,952 patients. The unscreened group had 718 prostate cancers and 78 deaths. The screened group had 1,138 prostate cancers, but only 44 deaths. This amounted to a relative risk reduction of prostate cancer deaths of nearly 50% in the screened group. The Goteborg Trial received much less attention despite its better methodology and more favorable results. Certain technical issues accounted for the favorable screening outcome compared to other studies. Among them: a longer median follow-up of 14 years; the patients were generally younger; the PSA threshold was 3.4, then 2.5 compared with other studies; and the biopsy rate for those with an increased PSA was higher than other studies.

The Prostate Cancer Intervention Versus Observation Trial (Pivot Trial) and the Scandinavian Trial Regarding Radical Prostatectomy Versus Watchful Waiting in Early Prostate Cancer. The PIVOT study randomly assigned 731 men with localized prostate cancer (mean age, 67 years; median PSA value, 7.8 ng per milliliter) to radical prostatectomy or observation and followed them through January 2010.

The primary outcome was all-cause mortality; the secondary outcome was prostate-cancer mortality. Among men with localized prostate cancer detected during the early era of PSA testing, radical prostatectomy did not significantly reduce all-cause or prostate-cancer mortality, as compared with observation, through at least 12 years of follow-up. In the intermediate and high risk group, there was a significant reduction in prostate cancer mortality in the radical prostatectomy arm.

The Scandinavian study randomly assigned 695 men to radical prostatectomy or observation. 88% were diagnosed by abnormal digital rectal examination, not PSA. The updated Scandinavian randomized trial comparing radical prostatectomy with watchful waiting found a benefit in favor of radical prostatectomy among men younger than 65 years and no difference among older men. In summary of the two studies, there was significant reduction in prostate cancer mortality in the radical prostatectomy group compared to the observation group if the patients had moderate risk to high risk disease. There was probably little benefit in aggressive treatment (i.e., radical prostatectomy) in men with low risk disease, defined as Gleason 6 or less, PSA less than 10, less than three positive cores, and less than 50% in any one particular core.

Legal Considerations. Given the potential for overtreatment associated with PSA screening, the several national urological associations encouraged urologists to practice "shared decision-making" regarding PSA testing in asymptomatic men. Doctors would engage the patient in discussion regarding prostate disease, its treatment, and the risks associated with it, resulting in an shared agreement about whether to perform the PSA test.

A Dr. Merenstein, a resident at the time, and his patient shared a well-documented decision not to have a PSA test. The patient later saw another doctor who routinely ordered a PSA test for him without any consultation. The test revealed advanced, aggressive prostate cancer and the patient succumbed to it. Dr. Merenstein was sued for malpractice, and although he was personally exonerated, his medical program had to pay \$1 million dollars in damages.

This landmark case was one factor in the "defensive medicine phenomenon" wherein doctors are inclined to order testing beyond the standard of care in order to avoid malpractice law suits. This results in excessive, unnecessary cost to healthcare programs. Now most physicians order PSA tests without consultation with the patient.

WHAT TO DO? Studies now show a reduction in risk of death prostate cancer due to PSA testing, especially in younger, healthy men detected with aggressive disease. Nevertheless, there is still concern about the cost of screening, biopsies, treatment of indolent cancer, potential side effects and the possibility of death from non-prostate cancer related causes.

To address the costs and risk of PSA screening, the American Urological Association convened a panel to provide guidelines for dealing with the PSA screening issue. The panel:

1. Recommends against PSA screening in men under 40 years of age because there is a low prevalence of clinically detectable prostate cancer; no evidence of benefit from screening; and the same harms of screening as in other age groups.
2. Recommends against routine screening in men between ages 40 to 54 years at average risk. For men younger than age 55 years who are at higher risk (e.g., men with family history of the disease or African Americans) screening decisions should be individualized.
3. Recognizes that for men between ages 55-69, the decision to undergo screening must weigh the benefits of preventing prostate cancer mortality in one of every 1,000 men over a decade against the known potential harms associated with screening and treatment. Accordingly, the panel strongly rec-

ommends shared decision-making for men ages 55 to 69 and proceeding based on the man's values and preferences. (The greatest benefit of screening appears to be in men ages 55 to 69.)

4. To reduce the harms of screening, a routine screening interval of two years may be preferable over annual screening in those men who have participated in shared decision-making and decided on screening. It is expected that a two year screening interval preserves the majority of the benefits and reduces overdiagnosis and false positives. Also, intervals for rescreening can be individualized by a baseline PSA level.

5. Does not recommend routine PSA screening in men age 70+ or any man with a life expectancy of less than 10 to 15 years. But some men over age 70+ who are in excellent health may benefit from prostate cancer screening.

SUMMARY. There is a decrease in prostate cancer mortality by screening younger men and if high grade cancers are detected. Yet, the question will continue to be asked: Is it worth the risks of screening and biopsying thousands of men to find the 56 year old man with Gleason 7 that would have died at age 70? The PSA test is a useful tool when used wisely.

(ASCO 2013 Summary - Continued)

- **Off-label use of chemotherapy is often not supported by guidelines.** A study of chemotherapy use in community oncology practice found that about 30% of chemotherapy is used off-label and that only about half of this off-label use adheres to guidelines from the National Comprehensive Cancer Network (NCCN). ASCO comments that more work is needed to see how much of this non-NCCN-recommended off-label use is inappropriate or potentially harmful.

Prostate Cancer Developments

- **Cabozantinib shows impressive activity in prostate cancer.** This includes the disappearance of bone metastases on scans described as unprecedented. However, there were also adverse events seen at higher doses, and more research is needed, ASCO comments; larger phase 3 trials that will collect survival data are in progress. Cabozantinib (*Cometriq*), a multireceptor tyrosine kinase inhibitor, is approved for use in medullary thyroid cancer.
- **Radium223 (*Xofigo*) was approved for advanced prostate cancer.** This novel alpha-emitting radiopharmaceutical was approved by the FDA for patients with advanced prostate cancer and symptomatic painful bone metastases.
- **Abiraterone (*Zytiga*) was approved for first-line use in prostate cancer.** This approval expands the drug's indication in the treatment of this disease; it was already approved for use after chemotherapy.
- **Chemoprevention of prostate cancer with finasteride not approved.** This issue has run on for years: the data to support this use come from the Prostate Cancer Prevention Trial, which showed a 25% reduction in prostate cancer in men taking finasteride compared with those receiving placebo, but at the same time, it found an increase in high-grade cancers in the finasteride group. As a result, the chemoprevention indication for finasteride (and a related drug, dutasteride) was not approved. Now, long-term follow-up during a median of 18 years has found that overall survival was identical in the finasteride and placebo groups (*N Engl J Med.* 2013;369:603-610). (Source: Top Clinical Cancer Advances: ASCO 2013 Report. *Medscape.* Dec 26, 2013)

◆ **WRAMC US TOO COUNSELORS** ◆

(As of February 1, 2014)

(THESE PERSONS ARE WILLING TO SHARE THEIR EXPERIENCES WITH YOU. FEEL FREE TO CALL THEM.)

SURGERY

Tom Assenmacher	Kinsvale, VA	(804) 472-3853	
Jack Beaver	Falls Church, VA	(703) 533-0274	1998 (Open RP)
Gil Cohen	Baltimore, MD	(410) 367-9141	
Richard Dorwaldt	San Antonio, TX	(210) 310-3250	(Robotic Surgery)
Michael Gelb	Hyattsville, MD	(240) 475-2825	(Robotic Surgery)
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Tony Giancola	Washington, DC	(202) 723-1859	2013 (Radical Prostatectomy)
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Bill Johnston	Berryville, VA	(540) 955-4169	
Dennis Kern	San Francisco, CA	(415) 876-0524	
Sergio Nino	Dale City, VA	(703) 590-7452	
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George Savitske	Hellertown, PA	(703) 304-3081	2000 (Open RP)
Artie Shelton, MD	Olney, MD	(301) 523-4312	
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Don Williford	Laurel, MD	(301) 317-6212	2000 (Open RP)

PROSTATE CANCER AND SEXUAL FUNCTION

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RADIATION

Leroy Beimel	Glen Burnie, MD	(410) 761-4476	1987 (External Beam Radiation)
Bob Bubel	Grand Junction, CO	(970) 263-4974	2010 (Proton Beam Radiation)
Harvey Kramer	Silver Spring, MD	(301) 585-8080	1998 ((Brachytherapy)
Bill Melton	Rockville, MD	(301) 460-4677	2001 ((External Beam Radiation)
Joseph Rosenberg	Kensington, MD	(301) 495-9821	2009 (Brachytherapy)
Barry Walrath	McLean, VA	(571) 969-8269	2001 (Brachytherapy)

INCONTINENCE

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WATCHFUL WAITING

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OTHER THERAPIES/MULTIPLE THERAPIES

Howard Bubel	Fairfax, VA	(703) 280-5765	1995,1996 (Hormonal, Cryosurgery, Sexual Function)
Arthur E. Clough	Kerryville, TX	(830) 896-8826	1993 (Surgery and Radiation)
Pete Collins	Mechanicsburg, PA	(717) 766-6464	2007, 2009 (Surgery, Radiation, Hormonal)
Charles Preble	Annandale, VA	(703) 560-8852	(Cryosurgery, Hormonal)
Ray Walsh	Annandale, VA	(703) 425-1474	1999, 2001 ((Surgery and Hormonal)

◆ MEETING ANNOUNCEMENT ◆

THURSDAY, FEBRUARY 6, 2014
7 PM

RIVER CONFERENCE ROOM
AMERICA BUILDING (3D FLOOR)
WALTER REED NATIONAL MILITARY MEDICAL CENTER

◆ SPEAKER ◆

MICHELE OJEMUYIWA, MD

UROLOGY DEPARTMENT
WALTER REED NATIONAL MILITARY MEDICAL CENTER

◆ TOPIC ◆

"HORMONE THERAPY 101"

We meet this month in River Conference Room (3d floor), America Building, at the Walter Reed National Military Medical Center located at 8901 Wisconsin Avenue, Bethesda, MD 20889.

Gate/Parking: If you enter the base through South Gate (Gate 2) off Rockville Pike/Wisconsin Ave, take the first right (Palmer Road South). On your left you will see the Emergency Room. Continue to follow signs to the America Building and the America parking garage.

Security: A military ID is required to get on base. Persons without a military-related ID card who are attending the meeting are required to register in advance in order to gain entry. To register, contact the CPDR front desk at 301-319-2900 **no later than noon on Wednesday, February 5, 2014, to arrange for entry.** Have a photo ID card ready when arriving at the gate.

