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Cancer research news for clinicians

Prostate Cancer:

Finasteride Raises Odds Of Finding Fast-Growing Cancers Early, Study Says

For men at risk of prostate cancer, finasterine raises the odds that physicians will find fast-growing cancers early, according to a study from the Southwest Oncology Group.

"It appears that a man concerned about prostate-cancer risk, who is having a PSA test on a regular basis, will not only reduce his risk of prostate cancer if he takes finasteride, but will help find the cancers that pose the highest risk," said Ian Thompson, the study's senior author and a urologist at the University of Texas Health Science Center in San Antonio.

The new results appeared online earlier this month ahead of print

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Breast Cancer:

Breast Cancer Survivors Report More Severe Fatigue Than Healthy Women

A new study finds that, compared to healthy women, breast cancer survivors reported more days of fatigue and more severe fatigue symptoms.

The study, to be published in the Oct. 15, issue of CANCER, a peer-reviewed journal of the American Cancer Society, found women who received both chemotherapy and radiotherapy reported the most severe and prolonged fatigue.

Fatigue is a common complaint in the general population and, anecdotally, common among cancer patients. Comparative fatigue studies between the two populations, however, have been marred by methodological shortcomings, such as poorly matched controls and patient populations. The studies do not consistently agree whether or not fatigue is a more common complaint among cancer patients compared to the general population.

Paul Jacobsen from the Moffitt Cancer Center and co-investigators followed 221 women with non-metastatic breast cancer treated with either radiography (n=121) or a combination of chemotherapy and radiography (n=100) and 221 age- and geographically-matched healthy women at two, four, and six months after treatment.

The authors expected to find the greatest difference in fatigue scores just after treatment, diminishing with time. Surprisingly, they found that breast cancer patients had a significantly greater number of days with reported fatigue at each of the four assessments, and that even at the six-month follow-up assessment, a statistically significant and clinically meaningful group difference in fatigue duration was still evident. They studied further and

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Study Inteprets Confounding Results From Prevention Trial

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publication in the Journal of the National Cancer Institute.

"This report provides an important interpretation of results that confounded an overall favorable interpretation of the Prostate Cancer Prevention Trial initially, and should help lessen fears that finasteride somehow causes more aggressive prostate cancer," said Frank Meyskens, Jr., SWOG associate chairman for cancer control and prevention.

SWOG conducted the study to further analyze data from the NCI-sponsored 18,882-man, seven-year Prostate Cancer Prevention Trial, which found in 2003 that finasteride was an effective prevention agent. FDA has not approved finasteride for use in cancer prevention; the drug is approved for treating enlarged prostate.

Four years ago, SWOG researchers closed the PCPT early to report that finasteride could reduce the risk of prostate cancer by one-fourth. But that result, which potentially could keep around 50,000 men from developing prostate cancer each year, was clouded by a troubling finding: Men who took the drug but still developed prostate cancer by the end of the study had higher rates of detected high-grade tumors, an aggressive form of the disease, than did men in the placebo group.

The follow-up study, along with two others published recently, strongly suggests that finasteride makes it easier for physicians to detect high-grade cancers early by improving screening tests and prostate biopsy itself. The two previous studies show that finasteride improves the effectiveness of the two main measures of possible problems: digital rectal examination and the PSA blood test. In some men who have low PSA test results, cancer is present but not found in time.

"Our current study also shows that by shrinking the prostate gland, finasteride makes a biopsy more sensitive for any cancers that are present," Thompson said. "That increased accuracy is very important, because if a biopsy reveals a slow-growing cancer but fails to spot a fast-growing one, a doctor and patient may take a 'wait and see' approach when prompt treatment is actually needed."

In part because of concerns about possible drawbacks, most urologists, when asked about finasteride, say they seldom prescribe it as a prevention drug, despite the positive 2003 PCPT findings, Thompson said. Now, with several studies allaying concerns about the drug's possible drawbacks, including concerns about sexual dysfunction, Thompson believes men should be told routinely about the potential benefits of finasteride when they come to the doctor's office for a PSA test, in much the same way patients at risk of heart disease are told about the benefits of statin drugs.

When the PCPT trial results were announced in 2003, it was unclear whether finasteride produced biological changes that could lead to more high-grade cancers. Researchers in the follow-up study analyzed tissue from biopsies and in men in the finasteride and placebo groups to compare hormonal levels and disease extent. They compared prostate size at the time of biopsy in the two groups. They also examined tumor grade and extent in men in the study who went on to have their prostates removed.

They found no significant differences in degenerative hormone changes when they examined high-grade tumor biopsies in men in both groups. However, the men taking finasteride had smaller prostates. Their biopsies correctly identified a higher proportion of high-grade tumors found later when their prostates were removed, compared to men in the placebo group.

In the study, the researchers conclude that finasteride may have contributed to the increased rate of high-grade cancers detected in the PCPT by making the prostate smaller, helping the biopsy find the cancer.

They did not find evidence that the drug caused

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changes in tumor composition that might contribute to aggressive cancer, though they don't entirely rule out the possibility that finasteride may have led to high-grade prostate cancer in some men in the study.

"The results suggest that high-grade cancer was detected earlier and was less extensive in the finasteride group than in the placebo group," the researchers write.

Breast Cancer:

Breast Cancer Patients At Risk Of Fatigue From Therapy

(Continued from page 1)

found that the difference was attributable primarily to heightened fatigue in those women who received both chemotherapy and radiotherapy.

These findings provide strong evidence that women with non-metastatic breast cancer treated with adjuvant chemotherapy are at significantly greater risk for severe fatigue. The next step is to "explore whether interventions administered during or at the end of treatment are effective in preventing or limiting fatigue in the post-treatment period." They point in particular to the role of exercise, which has been shown to reduce fatigue in breast cancer survivors.

Breast Cancer:

Black Women More Likely To Have Aggressive, Less Treatable Breast Cancer

A large analysis of racial differences in rates of estrogen receptor (ER)-negative breast cancer finds that black women in the U.S. are more likely than white women to have breast tumors that are ER-negative.

ER-negative tumors are associated with less favorable outcomes than those that are ER-positive, in part because anti-estrogen therapies—effective with ER-positive tumors—do not affect ER-negative tumors.

The study was presented at the first annual Breast Cancer Symposium, co-sponsored by the American Society of Breast Disease, the American Society of Breast Surgeons, the American Society of Clinical Oncology, the American Society for Therapeutic Radiology and Oncology, the National Consortium of Breast Centers, and the Society of Surgical Oncology. The inaugural symposium was held earlier this month in San Francisco.

The overall incidence of breast cancer in black women is lower than in white women, but survival rates are significantly lower in black women than in their white counterparts. Black women have a higher incidence of breast cancer at younger ages and also are diagnosed at later stages of disease. Much of this discrepancy has been attributed to socioeconomic factors such as access to screening and adequate cancer care. But this study suggests that there is also a biological basis for differences in survival rates.

The investigators analyzed data on 170,079 cases of breast cancer included in the National Cancer Data Base (NCDB), a multi-institutional tumor registry that collects cancer data from 1,600 hospitals in all 50 states. White women comprised 90.3 percent of cases; black women accounted for 9.7 percent of cases. For women with invasive cancers, ER-negative tumors were significantly more frequent in black women at every stage of disease and in all age categories: 39 percent of black women had ER-negative tumors, compared with 22 percent of white women. The data also showed that black women were diagnosed at a younger average age (57 for black women vs. 62 for white women) and at a later stage (29 percent were stage 1 vs. 42 percent for white women). They also had larger tumors at diagnosis and cells that were more poorly differentiated, which is associated with less favorable outcomes.

"Differences in tumor biology have a significant impact on survival," said M. Catherine Lee, a clinical lecturer in the department of surgery at the University of Michigan Comprehensive Cancer Center and the study's lead author. "The fact that breast cancers in black women are more aggressive biologically suggests that we need to focus more of our research energy on developing better treatments targeting ER-negative tumors. These findings also point to a need for improved cancer education and screening in black women, particularly those in younger age groups."

Following are other highlights from the conference:

Low Adherence to Tamoxifen Therapy Associated with Increased Risk of Death

Results of a large retrospective study have found that although adherence to tamoxifen therapy is generally high, a significant proportion of women do not fill a substantial proportion of their tamoxifen prescriptions, and those women are at greater risk of death.

When used as an adjuvant therapy for five years after primary treatment for breast cancer, tamoxifen has been shown to reduce the recurrence of breast cancer that is estrogen-receptor positive. However, for some patients it is associated with side effects similar to the symptoms of menopause, especially hot flashes, which can cause

some women to stop taking their medication.

In this study, the research team reviewed the records of 2,080 women treated for breast cancer between 1993 and 2002 in Scotland. The majority of women (79 percent) were prescribed tamoxifen as an adjuvant treatment after surgery. Clinical and cancer registry records were used to find out the stage of cancer each patient had, and pharmacy records were used to determine the proportion of tamoxifen prescriptions that had been filled.

Although the recommended duration for tamoxifen therapy is five years, the average length of time women in the study took tamoxifen was 2.42 years, in part because when the study started there was not yet consensus about the duration of treatment needed to maximize the drug's benefit. The investigators found that 10 percent of women collected 70 percent or fewer of their tamoxifen prescriptions over the duration of time that their physicians prescribed the drug. These women had a 16 percent increase in the risk of death compared with those women who collected all of their tamoxifen prescriptions.

"While an occasional missed tablet is not a great worry, once you take tamoxifen less than 70 percent of the time your survival significantly decreases," said Alastair Thompson, professor of surgical oncology at the University of Dundee in Scotland and the study's lead author. "Problems associated with adhering to therapy may become increasingly important as more women are taking aromatase inhibitors in place of tamoxifen, because AIs do not stay in the body as long and therefore missing doses may be more worrisome."

Musculoskeletal Side Effects Cause Women To Discontinue Aromatase Inhibitors

An analysis of a multicenter study has found that although a class of drugs called aromatase inhibitors are important medications for treating breast cancer, they are associated with musculoskeletal side effects that result in a substantial number of women—13 percent in this trial—discontinuing their therapy. The rate of occurrence of musculoskeletal side effects in the trial was 42 percent.

One hundred patients were enrolled in the study, which was part of the National Institutes of Health-funded Consortium on Breast Cancer Pharmacogenomics (COBRA). The study included women who had estrogen receptor-positive, early stage (I-III) breast cancer who were starting treatment with an AI to prevent cancer recurrence following primary treatment. About half had previously taken tamoxifen for the same purpose. Some women took the AI exemestane and some took letrozole (the study did not compare the rate of side effects between the two).

The study, which used questionnaires asking about pain and difficulty with daily activities, found that 42 percent of the women (42 women) had musculoskeletal side effects. Of the 38 women for whom more detailed data are available, the most common side effects were rotator cuff tendonitis (eight women), carpal tunnel syndrome (nine), and osteoarthritis (12). Of the women who discontinued participation in the study, 13 did so because of musculoskeletal side effects. Other studies have indicated that musculoskeletal aches and pains occur in about one-third of patients who take AIs, a slightly higher incidence than in women who take tamoxifen, but they have not examined the musculoskeletal side effects in the same level of detail.

The mechanism of action for causing the side effects found in this study is not known. Previous data suggested that the symptoms may be caused by inflammation, but clinical evaluation and laboratory studies in this trial indicated that the side effects were not due to inflammatory or autoimmune processes. In addition, most women in the study took some form of anti-inflammatory pain medicine (such as aspirin or ibuprofen), but only a small subset of women benefitted from it.

"Patients who have these symptoms should tell their oncologists rather than stopping the drugs on their own," said N. Lynn Henry, a clinical lecturer at the University of Michigan Comprehensive Cancer Center and the study's lead author. "Pain medication may help alleviate symptoms in some women, but in those with severe symptoms, physicians should consider discontinuing their therapy temporarily until symptoms improve and then switching them to a different medication, such as tamoxifen."

Lung Cancer:

Pfizer Begins Phase III Trial Of Sunitinib In NSCLC

Pfizer Oncology has begun a large, global phase III clinical trial to evaluate the efficacy and safety of sunitinib malate, in combination with erlotinib, in previously treated patients with advanced non-small cell lung cancer.

The phase III trial plans to enroll 956 patients to compare the overall survival of patients taking sunitinib combined with erlotinib with those taking erlotinib plus placebo. Secondary endpoints of the study include

progression-free survival, objective response rate, 1-year survival, duration of response, adverse events and patient-reported outcomes.

Also, preliminary results from a phase II study, presented earlier this month at the International Association for the Study of Lung Cancer World Conference in Seoul, Korea, provided information on the safety and tolerability of sunitinib in combination with erlotinib in patients with advanced NSCLC.

The early results indicated that adverse events from 12 patients receiving sunitinib 37.5 mg/day given continuously with erlotinib 150 mg/day were mild to moderate in severity (grade 1 or 2) at the tested doses and schedule. The most frequent AEs (n=7) were diarrhea and fatigue. Other AEs(Grade 3) included acne, nausea, anemia, dehydration, gastroesophageal reflux disease, paronychial inflammation, purities, rash and vomiting(each n=1).

As of August, two patients had experienced a partial response: One patient demonstrated a PR after two cycles of therapy, which was maintained for >3 months, and the second patient has a documented durable PR and continues on the study. Also, stable disease for ≥16 weeks has been observed in two patients. The tolerability and activity observed in this lead-in cohort supports the randomized phase II portion of this study, which is now enrolling to further evaluate this combination in NSCLC.

Colon Cancer:

Xeloda As Effective As 5-FU/LV, Five-Year Survival Data Show

Five-year follow-up overall survival data from the X-ACT (Xeloda in Adjuvant Colon Cancer Trial) study show that oral chemotherapy Xeloda (capecitabine) is as effective as the current standard treatment—intravenous bolus 5-FU/LV (5-fluorouracil/ leucovorin)—in the adjuvant treatment of Dukes' C colon cancer. These data were presented earlier this month at the 14th European Cancer Conference in Barcelona, Spain.

Results show five-year overall survival rates for Xeloda at 71.4 percent compared to 68.4 percent in the 5-FU/LV arm. Additional data presented at the meeting from a previous analysis show that Xeloda is also comparable to 5-FU/LV with respect to disease-free survival and relapse-free survival.

"These updated five-year overall survival data provide further proof that Xeloda can be a safe and effective alternative to the current standard of care for adjuvant colorectal cancer, which can require upwards of 30 clinic visits over the 24-week treatment course," said Howard Burris of the Sarah Cannon Research Institute, Nashville, Tenn., and lead U.S. investigator in the study. "Based on this evidence, physicians—especially those who have relied on 5-FU/LV—should feel confident about exploring Xeloda as a treatment option with their patients who could benefit from the flexibility of oral chemotherapy."

Previous results from the X-ACT study also show that Xeloda is more cost-effective than the Mayo Clinic regimen (the current standard treatment) and is associated with fewer side effects. Also, many of the side effects can be easily managed by altering the dose without compromising efficacy. In the same analysis, costs for medicines to treat side effects, such as nausea and diarrhea, were cut by nearly 75 percent in the Xeloda arm compared to use of intravenous 5-FU/LV.

The international, phase III X-ACT trial enrolled 1,987 patients (1,004 patients were randomly assigned to Xeloda; 983 patients were assigned to intravenous 5-FU/LV) who were treated for a period of 24 weeks between 1998 and 2001 at 164 centers worldwide. The primary study objective was to show equivalence in disease-free survival between Xeloda and intravenous 5-FU/LV. Secondary objectives included: relapse-free survival, overall survival and safety.

Xeloda three-year disease-free survival and relapse-free survival rates demonstrated non-inferiority to 5-FU/LV (intent-to-treat analysis, $P < 0.0001$; $P=0.0407$, respectively). Xeloda was associated with fewer adverse events than 5-FU/LV ($P < 0.001$).

With a median follow-up of 7 years, updated study results presented at ECCO show five-year overall survival rates for Xeloda at 71.4 percent compared to 68.4 percent in the 5-FU/LV arm.

Xeloda is the only FDA-approved oral chemotherapy for both metastatic breast cancer and adjuvant and metastatic colorectal cancer.

Hematologic Malignancies:

Sexual Function Affected By Stem Cell Transplant

A long-term study found that a type of stem cell transplant used for patients with life-threatening diseases, such as leukemia and lymphoma, results in decreased sexual function and activity for recipients.

Further, males are likely to recover from these changes over time, while the sexuality of female patients remains compromised. Neither male nor female long-term cancer survivors regained levels of sexual activity

and function equal to those of their peers who have not had cancer, according to a published earlier this month in Blood, the journal of the American Society of Hematology.

"Survival without a sex life should not be what cancer survivors settle for or what health-care professionals consider a successful outcome of cancer treatment," said lead study author, Karen Syrjala, co-director of the Survivorship Program at the Fred Hutchinson Cancer Research Center. "Sexual dysfunction in survivors of cancer needs to become a priority for research funding and a routine topic of discussion between doctors and their patients after cancer treatment."

In an allogeneic hematopoeitic stem cell transplantation, patients with diseases of the blood, bone marrow, or certain types of cancers receive an infusion of new stem cells from a sibling or tissue-matched unrelated donor to replace the damaged or destroyed cells in their bone marrow needed for the production of blood cells. Before the transplant, high-dose chemotherapy is administered to kill residual cancer cells and to suppress the immune system so that the patient's body will not reject the new tissue.

The results of questionnaires on sexual function were reported for 161 patients scheduled to receive this procedure at the Hutchinson center. The patients ranged in age from 22-64 years with an average age of 41 and a nearly even split by gender.

Before the transplant, study participants completed an assessment of their sexual health at the clinic, and, after the procedure, surveys were mailed to the patients to complete at the six-month interval and after one, two, three, and five years. The response rate to the questionnaire averaged 84 percent with all participants completing one or more surveys during the five-year period.

The surveys included 37 questions in the areas of interest, desire, arousal, orgasm, satisfaction, activity, relationship, masturbation, and sexual problems. The male and female versions had the same content except for variations in the problems section according to sex. In addition, those who were not sexually active were provided with a list of possible reasons and asked to mark as many as applied.

At five years, the assessments were compared against a control group consisting of siblings or friends of the study patients that were within five years of the participant's age and who were of the same gender, ethnicity, race, and educational background. If a local match was not available, the researchers recruited volunteers from the community that fit the criteria.

At the six-month mark, both genders had decreased sexual activity, but, by one year, sexual activity for the majority of the men (74 percent) had recovered to the levels seen at the beginning of the study. For women, recovery of sexual activity took longer, with just over half (55 percent) returning to sexual activity after two years. Though sexual activity was restored for these patients, for those who were sexually active at the five-year mark, 46 percent of the men and 80 percent of the women reported problems that disrupted sexual function.

According to the researchers, sexual dysfunction in transplant patients is likely caused by systemic therapies, such as total body irradiation and chemotherapy drugs known as alkylating agents, which are known to permanently damage endocrine glands that play a critical role in the development and regulation of the reproductive system.

Also, chronic graft-versus-host disease, a common complication of transplantation experienced by 65 percent of the patients in this study, may cause shrinkage of the vaginal tissues and changes to the vaginal lining that can contribute to sexual dysfunction in women. For males, testosterone levels and the cavernosal arteries of the penis are affected, eroding libido and erectile function.

Lack of interest or libido explained sexual inactivity in part for nearly 20 percent of female survivors at both six months and five years, suggesting that this problem did not improve over time. In contrast, for males, lack of interest or libido as a reason for inactivity declined from 14 percent to 6 percent between six months and five years.

At the five-year mark, the rates of sexual activity and sexual function for both male and female patients were below those of the control group, suggesting that they did not fully recover from the effects of the cancer itself or cancer treatments. Further studies are needed to determine if hormone treatments for both sexes or other therapies will help these patients achieve the same sexual function and activity as their peers.

The researchers also recommend that patients undergoing stem cell transplantation be made aware of potential changes in their sexuality and given resources to address these needs to help improve long-term quality of life.

Men may benefit from reassurance that erectile function and sexual desire should improve by one to two years after treatment, but that methods such as testosterone replacement, erectile-function medications,

and other adaptive strategies can be considered if problems continue.

For women, methods that focus on communication with their partners about changes in sensation, strategies for enhancing libido, and use of vaginal lubricants, dilators, or vibrators to assist with adapting to genital changes may help to maintain sexual responsiveness.

This work was supported by grants from NCI.

Heart Failure Rare Among Leukemia Patients On Imatinib

Congestive heart failure rarely occurs among leukemia patients who take imatinib, researchers at The University of Texas M. D. Anderson Cancer Center found after a review of the detailed medical histories of 1,276 patients who enrolled in clinical trials for the drug.

Researchers found 22 patients, or 1.7 percent, had symptoms that could have been caused by heart failure. Of those, 18 had previous medical conditions that could also cause heart failure, such as type II diabetes, hypertension, irregular heartbeat or coronary artery disease. Six had congestive heart failure before entering treatment.

The results were reported in the Aug. 15 edition of the journal Blood.

"Imatinib remains a safe drug, but monitoring patients and knowing their medical histories are always important," said Jorge Cortes, senior author of the report and professor in M. D. Anderson's Department of Leukemia. "There is no current need for routine cardiac-specific monitoring of all patients taking imatinib. However, those with significant cardiac history need to be closely monitored. Patients who develop symptoms of heart failure should be evaluated carefully and treated with standard therapy."

Of the 22 patients found to have cardiovascular conditions, 11 were able to continue on imatinib for their leukemia after dose adjustments and management of the heart failure symptoms. The standard of care for treatment includes the use of beta blockers and angiotensin converting enzyme inhibitors or angiotensin receptor blockers, said study co-author Jean-Bernard Durand, an assistant professor in M. D. Anderson's Department of Cardiology. Both classes of drugs are approved by the FDA for treatment of heart failure and recommended by the Heart Failure Society of America.

The team also found the incidence of congestive heart failure among patients receiving imatinib to be comparable to the expected incidence in the general population as reported by the Framingham Heart Study, a defining long-term study of cardiovascular disease in the U.S.

Imatinib, known by its brand name Gleevec and developed by Novartis Pharmaceuticals, is approved by FDA for the treatment of chronic myelogenous leukemia, Philadelphia-chromosome positive acute lymphoblastic leukemia d, and gastrointestinal stromal tumor.

Imatinib is a targeted therapy that inhibits two members of a class of enzymes called tyrosine kinases, which transmit growth and survival signals in cells. The drug also blocks a hybrid tyrosine kinase known to cause CML and Philadelphia-positive ALL.

Before the drug was developed, about only about half of CML patients survived for five years after diagnosis. The five-year survival rate of patients taking imatinib is 95 percent.

In a separate paper late last year, a research team led by scientists at the University of Pennsylvania reported that imatinib may be cardiotoxic in mammals. They found stress-induced damage to the mitochondria in cardiac muscle of mice given the drug. They also implicated inhibition of Abl, one of the tyrosine kinases targeted by imatinib, as the molecular mechanism that causes the damage.

Also, 10 patients at M. D. Anderson who developed congestive heart failure after exposure to imatinib were described in the paper. The paper did not assess the frequency of heart failure among patients taking imatinib or the potential risk factors involved.

Supportive Care:

Psychiatric Disorders Often Overlooked By Oncologists

Mental illness and emotional distress in patients with advanced cancer are often overlooked by oncologists but, if screened for, can be adequately managed to improve a patient's quality of life.

In an article to be published in the Oct. 15, issue of CANCER, a peer-reviewed journal of the American Cancer Society, Michael Miovic and Susan Block from the Dana Farber Cancer Institute and Brigham and Women's Hospital review the published literature of psychiatric illnesses in cancer patients.

They found that 50 percent or more of patients with advanced or terminal cancer suffer from at least one of three major psychiatric disorders: adjustment disorders, anxiety disorders and depressive disorders. These disorders have distinct symptoms that oncologists can

screen for and manage through medications or referral to mental health professionals and/or support groups.

Though medical management of cancer has significantly improved in the last decade, integrating the management of related mental health issues has lagged. Studies demonstrate those depressive symptoms impact patients' attitudes toward life and death, as well as quality of life, even more so than pain. Despite available effective therapies, less than half of patients with advanced cancer under the care of oncologists receive treatment.

More than 30 percent of patients with advanced disease and almost 20 percent of patients with terminal disease suffer from an adjustment disorder, consisting of symptoms of emotional distress such as irritability, mood swings, anxiety, or sleep disturbance. Additionally, up to 30 percent of patients with advanced disease and 20 percent of patients with terminal cancer are affected by a depressive disorder, such as major depression. Also, anxiety disorders affect nearly 10 percent of patients with advanced disease and 14 percent of patients with terminal cancer.

The most important screening tool for the oncologist is communication. "By listening, the physician provides the patient a chance to be heard and understood, explore fears and concerns, mourn losses, articulate hopes and final wishes and share the unique meaning that illness has for each individual," the authors wrote.

This review provides oncologists with an instructive framework from which to screen and manage their patients. Miovic and Block conclude: "oncologists can help reduce psychological distress in patients with advanced cancer through effective communication, providing routine emotional support, screening for psychiatric disorders, appropriately prescribing anxiolytic and antidepressant medications, referring patients to support groups, collaborating with mental health professionals, and dealing with end-of-life issues."

NCI Cooperative Group, Cancer Center Trials Listed

The National Cancer Institute's Cancer Therapy Program approved the following clinical research studies last month. For further information about a study, contact the principal investigator listed.

Phase I

Phase I Study of ABT-888 in Combination with Topotecan Hydrochloride Health in Adults with Refractory Solid Tumors and Lymphomas. National Institutes of Health, protocol 7981, Kummar, Shivaani, phone 301-435-5402.

Phase II

Phase II Study of Sunitinib (SU11248) in Patients with Kaposi's Sarcoma in East Africa. Case Western Reserve University, protocol 7831, Remick, Scot, phone 216-844-1210.

Phase II Study to Determine the Response to Second Curettage as Initial Group Management for Persistent Low Risk, Non-Metastatic Gestational Trophoblastic Neoplasia. Gynecologic Oncology Group, protocol GOG-0242, Osborne, Raymond, phone 416-480-4026.

Phase II Study of the c-SRC Inhibitor, AZD0530 After Four Cycles of Cytoreductive Chemotherapy for Patients with Extensive Stage Small Cell Carcinoma. North Central Cancer Treatment Group, protocol NO621, Molina, Julian, phone 507-538-1760.

Phase II Study of Temozolomide and Everolimus (RAD001) Therapy for Metastatic Melanoma. North Central Cancer Treatment Group, protocol NO675, Rao, Ravi, phone 507-284-2511.

Adjuvant 3DCRT/IMRT in Combination with Androgen Suppression and Docetaxel for High Risk Prostate Cancer Patients Post-Prostatectomy: A Phase II Trial. Radiation Therapy Oncology Group, protocol RTOG-0621, Hurwitz, Mark, phone 508-235-5700.

Phase III

Randomized Phase III Trial of Consolidation Therapy with Bortezomib(VelcadeÆ) - Lenalidomide (RevlimidÆ) – Dexamethasone Versus Bortezomib(VelcadeÆ) - Dexamethasone for Patients with Multiple Myeloma Who Have Completed a Dexamethasone Based Induction Regimen. Eastern Cooperative Oncology Group, protocol E1A05, Fonseca, Rafael, phone 480-301-6118.

Other

Children's Oncology Group Protocol for Collecting and Banking Osteosarcoma Specimens. Children's Oncology Group, protocol AOST06B1, Gorlick, Richard, phone 718-741-2342.

More Chemotherapy Versus Less Chemotherapy in ER-positive and ER-negative Subgroups in Breast Cancer DataMart Trials. National Surgical Adjuvant Breast and Bowel Project, protocol BCDM N0441, Anderson, Stewart, phone 412-383-2553.