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**M. D. Anderson
Cancer Center**
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NON-CIRCULATING

REPORT TO PHYSICIANS

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It's all about collaboration, say Dr. Bradley Broom, (l), associate professor in the Department of Biostatistics and Applied Mathematics, and Dr. Donald Berry, professor and chair of the department.

Biostatistically Speaking

by David Galloway

In biomedical research today, biostatistics is much more than static number crunching. At M. D. Anderson Cancer Center, biostatisticians are central to the analysis of complex biological problems and the design of the clinical trials of tomorrow.

On a molecular level, cancer comes in a staggering number of forms. "The mutations required to create a cancerous tumor can occur in any of the large number of genes that regulate cell growth, programmed cell death, and DNA repair," said Bradley M. Broom, Ph.D., an associate professor in the Department of Biostatistics and
(Continued on next page)

THE UNIVERSITY OF TEXAS
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Biostatistically Speaking

(Continued from page 1)



Although they frequently use supercomputers for advanced computations, sometimes an everyday laptop still fills the bill. Here, **Dr. Broom** (l) and **Dr. Berry** discuss a project.

Applied Mathematics at M. D. Anderson Cancer Center. “Consequently, the number of possible combinations and permutations of cancer-causing mutations is enormous.”

Examining all of those billions of possibilities requires considerably more computing power than a desktop computer can provide. To deal with the need for this type of advanced computation in cancer research, Dr. Broom and colleagues at M. D. Anderson have formed the Gulf Coast Center for Computational Cancer Research, a joint project with Rice University.

Researchers in the center have access to a terascale cluster on the Rice University campus, which is a group of interconnected computers capable of executing one trillion floating-point operations per second. “So, say there’s a computer program that commonly takes a day to run, but our researchers want to test the feasibility of making it run in a few minutes so it could be used in a clinical situation. We can do that using the terascale cluster,” Dr. Broom said.

“For instance, we have an application that provides four-dimensional magnetic resonance imaging scans of the lung. Currently, it’s too slow to be

“We’re building trials that, well, they’re not your mother’s clinical trials.”

— **Donald Berry, Ph.D.**

clinically useful, so we’re working to make it run faster,” he said.

The need for computing power grows exponentially, because each new variable added to a problem can more than double the amount of computer time needed to solve the problem. “So if you’re going to do something with five more variables, you may need 30 times as much computing power,” Dr. Broom said.

Searching through databases of billions of genetic mutations is a daunting task, even for this kind of supercomputer. “So just searching faster is not going to help,” Dr. Broom said. “We need to be able to search ‘cleverer’ to identify the right signposts to look at as we’re searching this space to find something that is optimal or very good in a reasonable amount of time.”

“And it has to involve the biologists who understand much more than we do about the way these things work and where the signposts might lead,” said Donald Berry, Ph.D., professor and chair of the Department of Biostatistics and Applied Mathematics. “So it really has to be a collaborative effort.”

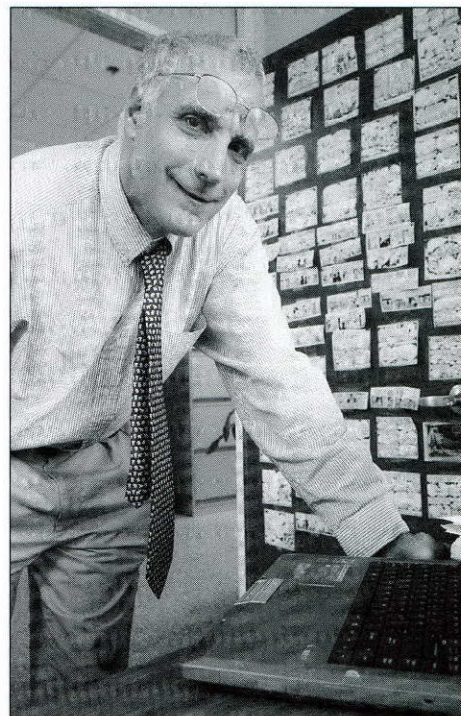
With the help of modern computers, M. D. Anderson’s biostatistics faculty and analysts collaborate with physicians and research scientists throughout the institution to provide advanced statistical analysis, mathematical modeling, and database development. Recently, such joint efforts have led to new statistical designs for clinical trials.

“We’re building trials that, well, they’re not your mother’s clinical trials,” Dr. Berry said. “For instance, we’ve developed new trial designs using adaptive randomization. Instead of waiting until the end of the study to analyze results, we look at the data after partial enrollment and adjust the randomization algorithm accordingly, assigning a higher percentage of patients

to the arm with the higher response rate. It’s a trial that adapts as we acquire more data.”

In adaptive randomization, the beginning of the process looks just like it does in conventional randomization: equal numbers of patients are randomly assigned to each study group. But the similarity ends there. In particular, in the classic model, equal numbers of patients continue to be assigned to each study group throughout accrual, and the results are not analyzed until all patients have been treated. Adaptive randomization, on the other hand, adjusts the randomization probabilities to reflect the interim results of the trial. For example, if the response rate appears to be twice as high in one study group, twice as many patients will be assigned to that group as enrollment continues.

Elihu Estey, M.D., a clinical investigator and professor in the Department of Leukemia, sees this approach to clinical trial design as corresponding more closely with the needs of practicing physicians and patients, while allowing for scientific accuracy. “Adaptive randomization allows patients to benefit



Dr. Elihu Estey, a professor in the Department of Leukemia, has worked with colleagues in Biostatistics to develop new clinical trial designs using adaptive randomization.

from the knowledge we're gaining as we get it, rather than years down the road," he said. Dr. Estey has collaborated with colleagues in Biostatistics to develop new trial designs that compare several experimental drugs and monitor multiple outcomes in one study.

According to Dr. Berry, somewhere between 50 and 100 clinical trials, mostly Phase I and Phase II trials, are using adaptive randomization. Most of the clinical trials at M. D. Anderson are Phase I and II trials, he said, which means the researchers have more latitude to try such innovative approaches. When it comes to Phase III trials, though, the U.S. Food and Drug Administration is less flexible.

However, Dr. Berry said the agency has recently approved the design of a Phase III clinical trial using adaptive randomization. "This is really quite an achievement that they've gone along with this," he said.

Adaptive randomization is related to the field of Bayesian statistics. Dr. Berry explained the difference between classical and Bayesian statistics with the common statistical model of a series of coin tosses. "You toss a coin a hundred times. If you get 60 heads, you say the null hypothesis is that the coin is a fair coin and gives heads half the time. The P value is the probability of observing 60 heads or more," Dr. Berry said. "That doesn't address the question of 'what is the probability that it's a fair coin?' The Bayesian approach addresses that specifically and, as data accumulate, allows you to update what that probability is."

Despite the use of supercomputers and complicated mathematics, the ultimate goal of these researchers is to accelerate the pace of progress in identifying effective new treatments for cancer. Eventually, Dr. Berry pointed out, all of these ideas that turn out to be successful will work their way outward from the laboratory to the clinic. "It's then that the work we're doing will really pay off," he said. ●

FOR MORE INFORMATION, contact Dr. Berry at (713) 794-4141, Dr. Broom at (713) 794-5985, and Dr. Estey at (713) 792-7544.

Chemotherapy may be unnecessary for rare breast cancer

Recent study results show that women with invasive lobular carcinoma often have a poor response to preoperative chemotherapy. Surprisingly, though, this does not predict a poor prognosis in these women.

"We were very surprised to find that chemotherapy treatment is not necessary to ensure a good prognosis in these women," said the study's lead author, Massimo Cristofanilli, M.D., an associate professor in the Department of Breast Medical Oncology at M. D. Anderson.

The study, published in the January issue of the *Journal of Clinical Oncology*, reviewed six different clinical trials with a total of 912 women with invasive lobular carcinoma and 122 with invasive ductal carcinoma (the most common form of breast cancer). Invasive lobular carcinoma accounts for 5% to 15% of breast cancers.

Both forms are currently treated with chemotherapy prior to surgery to reduce the size of the tumor. This also allows physicians to determine whether a patient responds to a particular chemotherapy drug, in the event that it is needed in follow-up care after surgery.

But now, Dr. Cristofanilli's study has shown that patients with invasive lobular carcinoma who were not helped by chemotherapy actually had a *better* long-term outcome than women with invasive ductal carcinoma who had a seemingly good response to chemotherapy.

"We have always thought that a poor response to chemotherapy indicated a worse prognosis, but this study shows that is not true," he said. "In fact, these results suggest women with invasive

lobular carcinoma have a different kind of disease and may benefit from a treatment that is more adequately tailored to the biology of their cancer.

"Before this study, I don't think anyone realized the disease should be treated differently," Dr. Cristofanilli said. "Now we need to think about revising our clinical approach and, more importantly, the way we communicate prognoses to women with lobular cancer that has shown poor response to chemotherapy."

New tool aids in bladder cancer screening

Physicians now have a more dependable, less expensive tool to help detect bladder cancer. Researchers at M. D. Anderson Cancer Center found that a simple test that can be administered and read in the doctor's office is three times more effective than cytology, the conventional laboratory test for detecting bladder cancer.

In a study published in the February 16 issue of the *Journal of the American Medical Association*, researchers demonstrated that the NMP22 tumor marker assay was significantly more sensitive in screening for bladder cancer than cytology, said Dr. H. Barton Grossman, M.D., professor in M. D. Anderson's Department of Urology and the study's lead author. The NMP22 test can be read in the office within 30 to 50 minutes.

"This test is easy and may save lives," says Grossman. He cautioned, however, that NMP22 should not be used alone to detect bladder cancer, but should be combined with cystoscopy to provide an accurate diagnosis. "No single procedure is 100% sensitive, so a combination of procedures is recommended," Dr. Grossman said. ●

Novel Drugs Address Gleevec Resistance

In ongoing Phase I clinical trials at M. D. Anderson, two different molecularly targeted therapies are showing promise as the 'next-generation' agents for treating Gleevec-resistant chronic myeloid leukemia.

Five years ago, imatinib (Gleevec) ushered in the age of the smart drug—drugs targeted to fight specific cancer cells while leaving normal cells unharmed. Relatively nontoxic and easy to administer, Gleevec led to a marked improvement in survival for a majority of patients with chronic myeloid leukemia (CML), producing unprecedented clinical remissions and becoming the new standard of care. Still, some patients were unaffected by the drug and others eventually developed resistance to it.

Now, two new targeted therapies in early clinical trials show significant promise for treating Gleevec-resistant CML. After testing the novel compounds in laboratory studies, M. D. Anderson undertook two independent Phase I clinical trials, one of BMS-354825 in conjunction with the University of California, Los Angeles, and the other of AMN107 with the University of Frankfurt in Germany.

Encouraging response in Phase I trials

BMS-354825 has shown an impressive response rate, said Moshe Talpaz, M.D., a professor in the Department of Experimental Therapeutics at M. D. Anderson. "The majority of patients with advanced, Gleevec-resistant CML responded to the drug."

Of 22 patients with advanced, blast phase or accelerated phase CML, five had complete hematologic responses, while three additional patients showed no evidence of leukemia. Furthermore, of 29 patients with early-stage CML who were either resistant to Gleevec or could not tolerate the drug's side effects, 73% experienced a complete hematologic response.

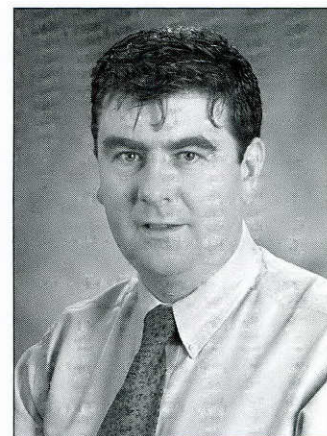
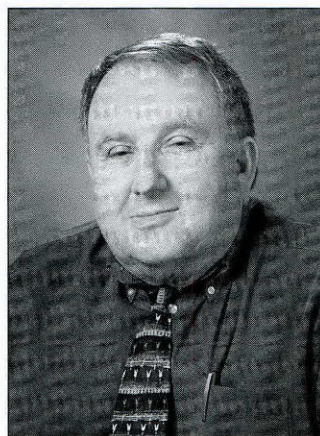
Dr. Talpaz expects the response rates to rise as the study progresses. "We haven't reached anything close to the maximum tolerated dose, yet we still are seeing very encouraging responses," he said.

"Also exciting is the fact that clinical responses matched very well to preclinical testing in animal models. A specific mutation that was resistant to BMS-354825 in the test tube and animal model was also associated with resistance in patients. This suggests that we may be on the road toward developing treatment tailored to the molecular profile of the disease in different patient subsets."

Another new agent, AMN107, has shown promise not only in CML but also in patients with acute lymphocytic leukemia (ALL) associated with the Philadelphia chromosome.

More than half of 65 patients with Gleevec-resistant CML who have joined the study since it began in May 2004 have had responses—including cytogenetic and molecular responses in some patients, said Francis Giles, M.D., a professor in the Department of Leukemia. "And we have not yet seen any consistent severe side effects."

"Gleevec changed everything in CML. It has led to marked improvement in survival in all three phases of the disease, and it also has shown benefit in treating the 20% of ALL that shares the same genetic abnormality as CML,



Dr. Moshe Talpaz (l), a professor in the Department of Experimental Therapeutics, and **Dr. Francis Giles**, a professor in the Department of Leukemia, are optimistic about the new drugs being studied for use in CML. "We may be on the road toward developing treatment tailored to the molecular profile of the disease in different patient subsets," said Dr. Talpaz.

"The bottom line is that rational drug design is a reality and effective targeted therapies will rapidly increase in number, which means that options for patients are expanding."

— Francis Giles, M.D.

the Philadelphia chromosome," Dr. Giles said. "But a drug that can cope with resistance to Gleevec might do even better across the board, although it must be remembered that we are still learning how to optimally use Gleevec itself, a drug which we have only had available for a few years."

Other Recent Findings in Hematology

M. D. Anderson investigators reported a number of key findings at the American Society of Hematology's annual meeting in December 2004. Significant studies presented at the meeting, in addition to the two promising new drugs featured here, included:

- Vaccination with the PR1 peptide produced an immune response in 60% of study participants with leukemia and complete molecular remission in three. This is the first study to demonstrate complete remission after peptide vaccination (Qazilbash, Wieder, Rios, et al.). (Look for more on cancer vaccine research in the next issue of *OncoLog*.)
- Treatment with imatinib (Gleevec) may be the most significant prog-

nostic factor for improved survival in patients with chronic myeloid leukemia in accelerated phase, changing the natural history of this disease by extending median survival to more than three years. Doubling the standard dose resulted in higher rates of complete cytogenetic and molecular remissions (Cortes, Talpaz, O'Brien, et al.).

- In an international Phase 2 study of oral R11577 (tipifarnib, Zarnestra), 33% of 82 patients with high-risk myelodysplastic syndrome responded with complete and partial remissions lasting more than a year, and toxicity was minimal. Tipifarnib has also produced complete remission in 20% of elderly patients with acute myelogenous leukemia

who were not candidates for more aggressive therapy (Kurzrock, Fenaux, Raza, et al.).

- Valproic acid, an agent used traditionally to treat seizure and bipolar disorders, safely enhances antileukemia activity when combined with low-dose decitabine (Garcia-Manero, Kantarjian, Sanchez-Gonzalez, et al.). *In vitro* studies also suggest that valproic acid or suberoylanilide hydroxamic acid combined with idarubicin has a potent antileukemia effect, which the authors recommend studying further in clinical trials (Sanchez-Gonzalez, Hoshino, Bueso-Ramos, et al.).

—Compiled by Carol Howland

Engineering 'better-fitting' drugs

Like Gleevec, BMS-354825 and AMN107 reduce the activity of an abnormal tyrosine kinase enzyme (Bcr-Abl) that leads to uncontrolled cell growth in CML. However, these new, "next-generation" drugs are more potent than Gleevec because they were designed to more efficiently bind to the enzyme.

"Through molecular, chemical, and crystallography studies, we now know the detailed structure of the enzyme, which allowed the development of better-fitting drugs," Dr. Giles said. "This increases the effectiveness of the agents and perhaps reduces the potential of developing resistance by treating more of the mutations that arise.

"These are engineered drugs, so we know exactly how they work, but we cannot yet say whether there are clinically meaningful differences between them," he continued. "More studies are needed to see how the drugs will ultimately perform.

"The bottom line, though," said

Dr. Giles, "is that rational drug design is a reality and effective targeted therapies will rapidly increase in number, which means that options for patients are expanding. The prognosis of diseases that were, until very recently, rapidly

fatal is getting better at an unprecedented rate." ●

FOR MORE INFORMATION, contact Dr. Talpaz at (713) 792-3522 or Dr. Giles at (713) 792-8217.

PROTOCOLS

Based on the response rates and low toxicity of both BMS-354825 and AMN107 in Phase I studies, a dozen new clinical trials of these drugs are now enrolling at M. D. Anderson, many of them Phase II studies. Protocols are available for patients with chronic, accelerated, or blast phase CML that is resistant to or intolerant of imatinib mesylate, as well as those with Philadelphia chromosome-positive acute lymphoblastic leukemia and hypereosinophilia mastocytosis. Principle investigator for the BMS-354825 studies is Dr. Moshe Talpaz; principle investigator for the AMN107 studies is Dr. Francis Giles.

There are many clinical trials in progress at M. D. Anderson for hematological malignancies as well as solid tumors. For more information about these studies, call the M. D. Anderson Information Line at (713) 792-3245 or (800) 392-1611. Or visit the M. D. Anderson Cancer Center clinical trials Web site at www.clinicaltrials.org for a broader listing of clinical research protocols.

OBESITY:

A Weighty Contributor to Cancer

The connection between cancer and excess weight has grown as more cancers—and cancer deaths—are linked to obesity.

by David Galloway

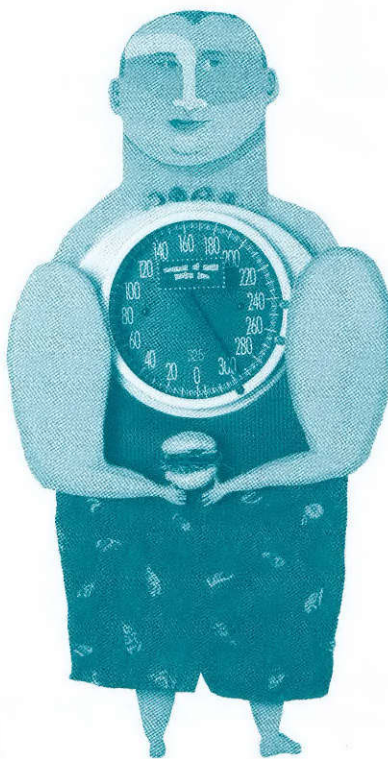
In the 1990s, the World Health Organization began sounding the alarm about a worldwide epidemic of obesity. At the time, it might have sounded like Chicken Little warning that the sky was falling, but the statistics reveal the truth: In 1995, there were an estimated 200 million obese adults worldwide; by 2000, the total had risen to 300 million.

It is widely known that obesity contributes to serious health problems, especially cardiovascular disease and diabetes mellitus. Another side effect of obesity that has drawn less attention is its link to cancer. Research from the American Cancer Society (ACS) suggests that, at least in the United States, obesity is responsible for 20% of all cancer deaths in women and 14% in men. The ACS further estimates that 90,000 people each year are dying from obesity-related cancers.

In the United States, research in 2000 showed that 65% of all adults were overweight. Of those, 31% were obese. The categories were based on body mass index (BMI), a measure of weight adjusted for height. People with a BMI of 18.5 to 24.9 are considered normal weight, those with a BMI of 25.0 to 29.9 are considered overweight, and those with a BMI over 30.0 are considered obese. Thus, a man 5 feet 11 inches tall and tipping the scales at 215 pounds is obese, as is a woman 5 feet 3 inches tall and 169 pounds. The upper limit of normal weight is 178 pounds for a man who is 5 feet 11 inches tall and 140 pounds for a woman 5 feet 3 inches tall.

Higher death rates

A study published in 2003 in the *New England Journal of Medicine*¹ showed that obese men had cancer



Americans seem blithely unaware that excessive weight gain increases their risk of cancer.

death rates that were 52% higher than those of normal-weight men. For women, the news was even worse, with obese women dying of cancer at a rate 62% higher than that for normal-weight women.

The findings of that study also reinforced earlier reports indicating a link between obesity and cancers of the breast, colon, esophagus, gallbladder, kidney, rectum, and uterus. The study connected obesity with several types of cancer that had not been previously linked to excess body weight: cancers

of the cervix, liver, ovaries, pancreas, prostate, and stomach, plus non-Hodgkin's lymphoma and multiple myeloma. Women's risk of breast cancer is doubly affected because obesity not only increases the risk of developing breast cancer but also of dying from it.

Another ACS study showed that Americans seem unaware of the link between obesity and cancer. A survey conducted in 2002 showed that only 1% of the respondents knew that maintaining a healthy weight was an effective way to reduce their risk of cancer.

Possible links

The mechanism of the link between body weight and cancer is not clear, but some researchers suspect a hormonal connection. Obesity may trigger the beginnings of cancer by increasing the levels of hormones such as estrogen or insulin. A disruption of insulin metabolism, for example, can increase the risk for colon cancer. Other components of a person's diet can affect inflammatory response, the metabolism of carcinogens, cell death, and DNA repair, all of which can be involved in the development or progression of several types of cancer.

The ACS recommends maintaining a healthy weight by balancing calorie intake with physical activity and by eating at least five servings of fruits and vegetables every day, choosing whole grains over processed grains, and limiting red meat consumption. The society also recommends that adults participate in at least 30 minutes of moderate physical activity five days a week. ●

¹ Calle EE, Rodriguez C, Walker-Thurmond K, Thun MJ. Overweight, obesity, and mortality from cancer in a prospectively studied cohort of U.S. adults. *N Engl J Med* 2003;348:1625-1638.



When a Friend Has Cancer

What should I say? What should I do? When someone you know is diagnosed with cancer, these questions can be among the first to spring to your mind. Our society stresses health and vitality, leaving many people feeling uncomfortable about how to respond when a loved one is seriously ill.

Relax. These tips may help you offer the kind of support that's 'just what the doctor ordered.'

Let your relationship guide you

When offering your support to someone who is ill, tailor the gesture to the type of relationship the two of you have as well as to your friend's specific needs. For a very close friend whose home you've been to many times, doing some household chores like laundry or cleaning up the kitchen may be greatly welcomed. For more casual acquaintances, dropping off a meal or a small gift may be a good way to say, "I'm thinking about you."

Be sensitive to the person's level of comfort with accepting help. For some, having people "make a fuss" over them can be an uncomfortable reminder that they're not well. Simply sending a thoughtful card to say you're thinking about someone can mean a lot.

In *The Etiquette of Illness—What To Say When You Can't Find the Words*, Susan P. Halpern says it is important to be "thoughtful, compassionate, and respectful." Practicing such sentiments will help you take a practical, non-intrusive, caring approach that is especially meaningful to your friend.

Lend an ear

People with cancer are often bombarded with well-meaning advice, but

it's the rare friend who will just listen. "When someone is dealing with a serious illness, what they often need most is to talk—to express how they feel emotionally and physically," says Irene Korcz, Ph.D., senior social worker at M. D. Anderson Cancer Center. Just by being an attentive, unbiased listener, you can help your friend sort through thoughts and emotions, make decisions, and perhaps even find peace.

Your friend is still the same person you knew before cancer came into the picture.



Gift Ideas

- Light reading, such as magazines or humor
- A massage or day at the spa
- A CD or movie
- Bookstore gift cards; books on tape
- Housekeeping service
- Homemade soup
- A beautiful scarf or hat (to disguise thinning hair)
- Stationery and stamps
- A basket of indulgent goodies – bubble bath, body lotion, new pajamas

Ways to Help

- Accompanying your friend to doctor visits or treatments
- Running errands
- Bringing a meal (ideally in disposable containers)
- Organizing a schedule of meal deliveries with friends and neighbors
- Taking the children on a special outing
- Pet sitting during a hospital stay
- Renting favorite movies (and returning them!)

Lighten the load

Most people won't take you up on a nonspecific offer like, "If there's anything I can do..." Instead, suggest a couple of specific things you think might be helpful, and see what your friend would like. Maybe you can accompany her during some of the treatments, provide an afternoon of childcare, or do the week's grocery shopping for her. If out-of-town guests will be visiting when your friend is very ill, consider offering to host them at your home. That will allow your friend to use her limited energy enjoying the visit instead of playing host.

Remember, too, that very simple but heartfelt gestures can mean just as much or more than big ones. When catastrophic illness upends someone's life, it's often the little things and the daily rituals that are missed most. Sharing everyday activities like seeing a movie, going for a walk, or watching the big game on TV can help return a sense of normalcy and take the focus off medical issues for awhile. "The main idea," says Halpern, "is to do something"—ideally, something tailored to meet the needs of your friend. Your friend is still the same person you knew before cancer came into the picture, so think more in terms of the person you know rather than the disease in deciding what to do.

Above all else, understand that simply being there may be the most valuable thing you can do for your friend. ●

For more information, contact your physician or contact the M. D. Anderson Information Line:

 **(800) 392-1611, Option 3,** within the United States, or

 **(713) 792-3245** in Houston and outside the United States.

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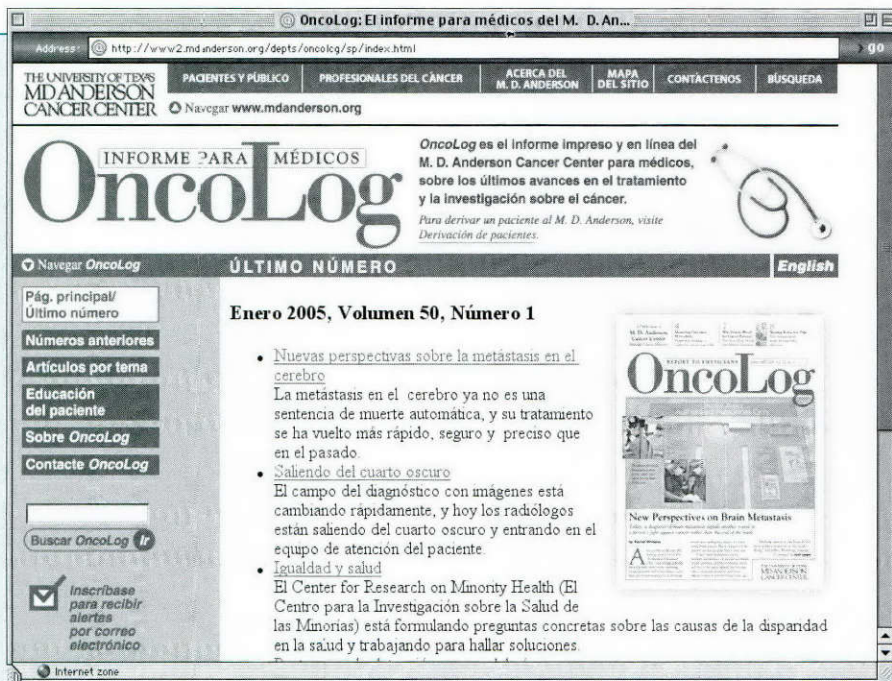
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OncoLog Now Online in Spanish

¿Habla español? If you are a physician practicing in the United States (especially in Texas), more and more of your patients and colleagues do. According to the U.S. Census Bureau, the Hispanic population in the United States is expected to surpass 102 million in 2050, from 12.6% of the total population in 2000 to 24.4% of the population in 2050.

To accommodate those who must, or simply prefer to, read in Spanish, *OncoLog*, M. D. Anderson's report to physicians, is now offering a Spanish version of its Web site. From the *OncoLog* page of the M. D. Anderson Web site (www2.mdanderson.org/depts/oncolog/), simply click the button labeled "Español." Like its English-language counterpart, the Spanish *OncoLog* site offers full-length versions of the articles found in the print edition of *OncoLog*, past issues of *OncoLog*, and a list of articles organized by topic.

Of particular interest to patients is the "Educación del paciente" section, which contains the House Call patient education articles.

Both the English and the Spanish versions of the *OncoLog* Web site have their own search engines that allow users to search the archives by topic. Site visitors can also register to receive email notification when a new issue is available online.

Speaking of Web Sites...

M. D. Anderson's Web site, www.mdanderson.org, was recently recognized as the fourth most visited hospital Internet site in the country, according to the publication *Modern Healthcare*. The easy-to-navigate site has become a trusted source of information for people with cancer and the health professionals who treat them. ●

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