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## OncoLog Volume 51, Number 04, April 2006

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REPORT TO PHYSICIANS

APRIL 2006 Vol. 51, No. 4

# OncoLog

## Redefining Unresectable Disease Strategies for Treating Liver Metastases from Colorectal Cancer

by Sunni Hosemann

**New ways to treat liver metastases from colorectal cancer are improving survival rates.**

Certain cancers tend to spread to favorite sites. Breast cancer, for example, has a tendency to metastasize to the bone or lung, and lung cancer tends to metastasize to the brain. Colorectal cancer commonly metastasizes to the liver; the appearance of liver metastases has long been regarded as an ominous sign and is a leading cause of colorectal cancer-related morbidity and mortality.

In fully one third of patients who die of colorectal cancer, metastatic disease is found *only* in the liver—meaning that effectively treating liver metastases could make a huge difference for many patients.

Patients who undergo surgical resection of liver metastases from colorectal cancer have a higher survival rate than those who undergo other treatments, and some are truly cured of cancer. Now, doctors are finding ways to make liver resection an option for more patients.



### Moving hepatic resection forward

Eddie Abdalla, M.D., a hepatobiliary surgeon and assistant professor in the Department of Surgical Oncology at The University of Texas M. D. Anderson Cancer Center, is one of a group of physicians who treats and studies treatments for liver metastases from colorectal cancer. “Analysis of data for hepatic resection from 1992

(Continued on next page)

**Dr. Abdalla (r) and Leigh Samp, P.A.,** examine the portogram of a patient with liver metastases from colorectal cancer who presented with unresectable disease. After chemotherapy, staged resection, and portal vein embolization, the patient is disease free.

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# Redefining Unresectable Disease

(Continued from page 1)

to 2002 at multiple institutions,” he said, “revealed a dramatic difference in survival—an increase from 35% to 58%—between the pre- and post-1992 periods.”

Dr. Abdalla launched a study to look more closely at the relationship between rates of recurrence and survival in patients with colorectal cancer liver metastases and the aggressive treatments the patients received at M. D. Anderson (surgical resection, radiofrequency ablation, or chemotherapy).

Again, what Dr. Abdalla and his colleagues found was noteworthy: patients who underwent surgical resection as a primary treatment fared significantly better—in terms of both survival and recurrence—than those who received other primary treatments. Despite advances in chemotherapy, it alone was insufficient: few patients who received chemotherapy as their sole treatment reached the 5-year survival mark, even when metastatic disease was limited to the liver. Survival rates (less than 20% at 5 years) for patients who underwent radiofrequency ablation alone or a combination of radiofrequency ablation and resection paled in comparison with the 5-year survival rate of 58% for patients whose lesions were surgically resected.

Intrigued by the benefit of aggressive approaches to hepatic resection for colorectal metastases, Dr. Abdalla and his colleagues delved further, this time looking only at patients who had solitary liver tumors and who had been treated and undergone thorough radiologic follow-up at M. D. Anderson. Focusing the study on this population ensured the highest standard of documentation for procedures and recurrences. What the researchers found was astonishing: resection of solitary colorectal metastasis was associated with a 5-year survival rate of 71.5%.

“This survival rate for patients with stage IV colon cancer is remarkable,” Dr. Abdalla said. “Furthermore, those who remain disease free at 7 years frequently stay that way, and some may actually be cured.” In fact, the 5-year disease-free survival rate in this study

was 50%. This improved outcome has encouraged the development of methods to further expand the limits of safe hepatic resection for more patients.

## Making more patients candidates for surgery

Surgical resection is clearly the treatment associated with the best chance for long-term survival of patients with colorectal cancer liver metastases. There is one problem, however: most patients with colorectal cancer liver metastases present with “unresectable” disease and are thus not considered candidates for surgery.

“Now that we know resection can be curative for some patients, the goal is to expand the number of patients who can benefit,” said Robert A. Wolff, M.D., an associate professor in M. D. Anderson’s Department of Gastrointestinal Medical Oncology.

Dr. Abdalla said, “The key question is: what proportion of these patients can we convert into candidates for potentially curative surgery?” One of the latest efforts is a prospective trial underway for patients with extensive liver metastases; the study uses combination chemotherapy, staged hepatectomy, and portal vein embolization to make them eligible for complete resection.

The major limiting factor for hepatic resection has traditionally been the volume of metastatic disease in the liver. There is a limit to how much liver can be removed before liver function is too severely impaired. Multiple lesions, large lesions, and lesions affecting multiple lobes of the liver have long been considered to be unresectable. Dr. Abdalla and his colleagues have taken a different approach to determining the resectability of liver tumors: they have shifted away from the analysis of tumor size and number and now focus on how much of the liver will remain after surgery. This new way of thinking allows the doctors to explore different ways to shift a patient’s status from unresectable to resectable.

## Preoperative chemotherapy

One critical tool in increasing the number of patients who can undergo surgery is chemotherapy, which can shrink lesions to a point where it is possible to surgically remove them with adequate disease-free margins. Tumor reduction in response to chemotherapy may be a good prognostic sign, because it suggests that any microscopic disease is also being affected. According to Dr. Wolff, new drugs and new strategies to optimize their use—for example, using cytotoxic agents in conjunction with



Dr. Wolff (r) and [redacted] who was diagnosed with metastatic colon cancer in 1998, discuss [redacted] condition since receiving a novel chemotherapy.



## Now that we know resection of colorectal cancer liver metastases can be curative for some patients, the goal is to expand the number of patients who can benefit.” – Dr. Robert A. Wolff

biologic agents such as bevacizumab—have improved the response rate to over 50%. “That is a dramatic improvement in the last 10 years,” he said.

Even in patients who do not become clear candidates for surgical resection, there can be sufficient tumor reduction to dramatically improve the patient’s overall condition, said Dr. Wolff. In these cases, additional tools are needed to render hepatic metastases resectable. To that end, two important surgical approaches are being brought to bear.

### Portal vein embolization

The first approach is portal vein embolization (PVE), a strategy that addresses the problem of unresectable disease in a different way. Unlike chemotherapy, PVE does not reduce the tumor burden but rather induces an increase in the volume and function of the liver that will remain after resection. This procedure grew out of the observation that when the portal vein on one side of the liver was occluded, the ipsilateral lobe of the liver atrophied, but the contralateral lobe *grew*.

When the portal vein is occluded, diversion of blood flow to the opposite side of the liver triggers hypertrophy. Hepatocyte regeneration begins within hours throughout the nonembolized liver, while apoptosis leads to atrophy of the embolized lobe. Regeneration rates are fastest in patients with healthy livers and slower in patients with cirrhosis or diabetes (insulin plays a physiologic role). In a patient with metastases in an otherwise healthy liver, adequate hypertrophy to enable surgery can be achieved within 2 to 4 weeks. In patients with diabetes or cirrhosis, this typically takes longer—6 to 8 weeks—and the volume increase may be smaller.

PVE-induced liver hypertrophy helps to make unresectable disease resectable and directly improves patient care. First, PVE increases the volume and function of the liver remnant. Second, it allows the future liver remnant to adjust to portal pressure changes several weeks before surgery in order to minimize tissue damage to the liver remnant. Dr. Abdalla and his colleagues have used this under-

standing of liver regeneration, refined the indications and technique for PVE, and used PVE and liver volume analysis to increase the number of patients who can safely undergo extensive hepatic resection. Finally, according to Dr. Abdalla, PVE does not preclude any other treatment. “It closes no doors,” he said. Patients can safely receive chemotherapy while their liver is growing.

### Staged resection

Staged resection is another strategy that has made a dramatic impact on the treatment of patients with extensive colorectal cancer liver metastases. For example, patients with bilateral liver tumors typically receive preoperative chemotherapy and then undergo first-stage surgery to resect the tumors but preserve most of the liver parenchyma on one side of the liver. This side will be the future disease-free liver, but because it is small, PVE is performed to induce hypertrophy. After sufficient liver growth, the tumor-bearing liver on the opposite side is resected to completely remove all remaining disease. Dr. Abdalla cites a 5-year survival rate of 40% for this procedure—a rate that is striking when compared with the near-zero survival rate in patients with otherwise unresectable disease.

According to Dr. Abdalla, these advances have shattered previous notions of what is “unresectable” and the idea that stage IV colon cancer is always incurable. “Tumor burden used to define resectability. Now, we can look at ways of not only reducing tumor burden but also maximizing the amount of liver that will remain after treatment,” he said.

### Liver volume after resection

How much of the liver must remain to support life and avoid complications? Dr. Abdalla and his colleagues conducted a study that showed that in a healthy liver, it is safe to remove 80%

of the liver and that the complication rate is low.

Accurate measurement of liver volume is critical to ensure safe resection and is made possible by three-dimensional computed tomographic volumetry. A formula for total liver volume that is based on body surface area is used to standardize the measured liver remnant size to a patient’s size—smaller patients need smaller liver remnants, while larger patients need larger remnants. An M. D. Anderson study showed that when this approach, plus PVE when indicated, is used, extended hepatectomy has an operative mortality rate of only 0.8%, much lower than any previously reported rate.

### Sorting through the variables

In addition to the advances in chemotherapy and surgery, Dr. Abdalla cites “better anesthesia, better postoperative care, and better imaging” as critical contributors to the goal of offering potentially curative treatments to more patients. The key is to use all of the tools strategically. Because patients present in various degrees of health, with various degrees of tumor burden, Dr. Wolff noted that “deciding which tools to use is best done by a multidisciplinary team that can evaluate all of the factors and tailor a treatment to the individual patient.”

“Combining some or all of these options requires collaboration between surgeons, imaging radiologists, medical oncologists, and interventional radiologists so that treatments can be tailored to the specific patient,” said Dr. Abdalla. “Our job is to help each patient make the right decision. To do that, we have to know as much as we can about the tools and how to safely combine them to enable the best outcome for the person we are treating.” ●

**FOR MORE INFORMATION,** contact Dr. Abdalla at (713) 745-1839 or Dr. Wolff at (713) 792-2828.

# Cancer Screening Guidelines Revised:

by Martha Morrison

**H**ow does recent research affect our recommendations about breast self-exams? Is it beneficial for women to perform breast self-exams every month? Is it all right to tell some patients they will never need a Pap smear again? These are some of the major issues M. D. Anderson physicians considered when updating the institution's cancer screening guidelines (right), which are also available at [www.mdanderson.org/patients\\_public/prevention](http://www.mdanderson.org/patients_public/prevention). While most of the guidelines stayed the same, there were changes to the breast and cervical screening guidelines. We asked Therese B. Bevers, M.D., medical director of the Cancer Prevention Center at M. D. Anderson, to discuss these changes and explain how physicians can best use the guidelines.

**Q** What is the role of primary care physicians in interpreting cancer screening guidelines?

**Dr. Bevers:** While the guidelines are available for patients to see, physicians are the ones who need to interpret them in light of an individual patient's circumstances. The guidelines are for individuals at average risk for a specific cancer site and are not applicable to everyone. Doctors can best determine whether the guidelines are appropriate for a particular patient. They know their patients and can decide whether a patient is at average risk and the guidelines are appropriate or if a patient is at increased risk and needs something different.

We must tailor our screening recommendations to our patients' risks for a particular type of cancer, their other health conditions, and their life expectancies. For example, if a woman has severe heart disease and wouldn't be able to tolerate treatment, it may not be appropriate for her to undergo mammography.

Doctors and patients should discuss and routinely re-discuss risk factors. If a patient's risk factors change, we need to reevaluate and perhaps change his or her cancer screening recommendations.



Dr. Therese B. Bevers

**Q** Do women who have had total hysterectomies still need cervical cancer screenings?

**Dr. Bevers:** Some groups believe that a woman who has had a total hysterectomy can stop cervical cancer screening altogether, unless the hysterectomy was for cervical cancer or a precancerous condition. But we were concerned that this didn't take into account the possibility of a woman's risk factors changing over time. Certainly, we recognize that with women living longer, they may have new sexual partners later in life. These new partners create new opportunities for exposure to the human papillomavirus, the primary cause of cervical cancer.

As doctors, we need to periodically reassess a woman's risk factors—we can't flatly and permanently say a particular woman will never need a Pap smear again. Therefore, to keep physicians in the equation, M. D. Anderson's guidelines state that beginning at age 30 years, a physician and patient may choose to do Pap smears less frequently than once a year, depending on her risk factors, and assuming she has had three or more consecutive annual exams with normal findings.

Physicians have a crucial role in administering the guidelines, and they should discuss the issue regularly with their patients.

**Q** A very important study conducted in Shanghai (*Journal of the National Cancer Institute*, October 2, 2002) evaluated the effectiveness of instructing women in how to perform breast self-exams. The findings helped form M. D. Anderson's new breast screening guidelines. What was the study about and what was learned from it?

**Dr. Bevers:** Interestingly, the Shanghai study showed that instructing women in how to do breast self-exams did not change breast cancer outcomes. The study divided 266,040 participants into two groups and followed them for 10 years. The intervention group was taught how to perform breast self-exams, attended reinforcement sessions, and was reminded to perform breast self-exams monthly. The second group—the control group—received no educational intervention on breast self-exams.

Ultimately, researchers found that equal numbers of breast cancers were detected in the two groups. Surprisingly, the study found that the cancers in the intervention group weren't diagnosed at an earlier stage than in the control group and the breast cancer-related death rate in the two groups was equal. There was even a downside to breast self-exams: the group of women who were instructed in breast self-exams actually had more false-positive results than the control group.

Importantly, though the women in the control group weren't instructed in breast self-exams, they were still able to find breast lumps. This tells us that women don't have to be taught how to check their breasts and that people touch their bodies, consciously or unconsciously, and will call their doctors if something is unusual.

Millions of dollars a year have been spent on teaching women how to perform breast self-exams—from large cancer organizations to local hospitals, to the time in the doctor's office, to the production of shower cards. So much effort has been put forth—and now, the Shanghai study has shown that even without teaching women a technique, they can, and will, find breast masses.

# One on One with Dr. Therese Bevers

## M. D. ANDERSON'S CANCER SCREENING GUIDELINES

The following cancer screening guidelines are recommended for those people at average risk for cancer (unless otherwise specified) and without any specific symptoms. Individuals who are at increased risk for certain cancers may need to follow a different screening schedule, such as starting at an earlier age or being screened more often.

### BREAST CANCER

**Breast self-awareness:** All women should be familiar with their breasts so that they will notice any changes and report them to their doctor without delay. M. D. Anderson does not recommend that women conduct a "formal" breast self-examination anymore but instead recommends that women be familiar with their breasts.

**Between ages 20 and 39 years:** Clinical breast exam every 1 to 3 years.

**Age 40 years and older:** Yearly mammograms and clinical breast exams, continuing for as long as the patient is in good health. Try to schedule clinical breast exams at the time of regularly scheduled mammograms.

**Additional screening for patients at risk:** Women at increased risk of breast cancer (e.g., family history, genetic predisposition, past breast cancer) should talk to their doctors about the benefits and limitations of starting mammograms earlier, having additional tests (e.g., breast ultrasonography or magnetic resonance imaging), or having more frequent exams.

### CERVICAL CANCER

**Beginning 3 years after initiating vaginal intercourse (but no later than age 21 years):** Annual Pap test with pelvic exam.

**Beginning at age 30 years and depending on risk factors:** After three or more consecutive exams with normal findings, a physician and patient may choose to do them less frequently.

### COLORECTAL CANCER

Beginning at age 50 years, men and women should follow one of the five examination schedules below.

**Colonoscopy:** Every 10 years. (This screening method is preferred by M. D. Anderson.)

**Fecal occult blood test (FOBT):** A yearly take-home multiple-sample FOBT or fecal immunochemical test (FIT).

**Flexible sigmoidoscopy:** Every 5 years.

**Annual FOBT or FIT and flexible sigmoidoscopy:** Every 5 years. Having both of these tests is recommended over either test alone.

**Double-contrast barium enema:** Every 5 years.

All positive tests (FOBT, FIT, flexible sigmoidoscopy, barium enema) should be followed up with colonoscopy.

### PROSTATE CANCER

Screening risks and benefits should be discussed with a health care provider.

**Beginning at age 50 years:** Annual digital rectal exam (DRE) and prostate-specific antigen (PSA) blood test.

**Beginning at age 45 years:** DRE and PSA for men at increased risk, i.e., African-American men and men with a family history of prostate cancer.

### SKIN CANCER

Patients should promptly show doctors any suspicious skin area, non-healing sore, or change in a mole or freckle.

### ENDOMETRIAL, OVARIAN, AND LUNG CANCERS

Benefits of screening individuals at average risk for endometrial, ovarian, and lung cancers have not yet been proven, and screening is therefore not recommended. The following are related conditions to consider:

**Women with hereditary non-polyposis colorectal cancer:** Annual endometrial biopsy is recommended beginning at age 35 years.

**Women with a hereditary ovarian cancer syndrome:** Annual or semi-annual pelvic exam, CA 125 blood test, and/or transvaginal ultrasonography.

Wouldn't it be better to spend the money and time promoting screening tests that have been proven to be beneficial?

**Q** M. D. Anderson now recommends "breast self-awareness." What is it and how does it differ from "breast self-exams"?

**Dr. Bevers:** "Breast self-awareness"

means that a woman should be familiar with her breasts so she will notice any changes and report them to her doctor without delay.

The term "exam" implies that you are taking a test and there is a right and wrong way to do it, which some women may find intimidating and even off-putting. But there is no wrong way for a woman to check for changes in her breasts. When women say to me, "I

don't do breast self-exam because I don't know how to do it," I assure them that they know their breasts better than anyone and are in the best position to identify a change in their breasts.

Some women say their breasts are naturally lumpy and they are concerned that they wouldn't be able to distinguish between that and a tumor. I assure them that, in all likelihood, they would be

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# Cancer Screening Guidelines Revised

(Continued from page 5)

able to, and I use this scenario to illustrate: I ask them to imagine picking up a bag of grapes and feeling the lumps and bumps of the grapes. I explain that their breasts are made up of numerous lobules, so it is natural for their breasts to feel lumpy, like the bag of grapes. Then, I tell them to imagine that a rock or marble has been added to the bag of grapes. They would know there was something unusual or different there, wouldn't they? And it's the same with their breasts. If something feels different, women will be able to distinguish it from normal breast lumps.

This message is reassuring for women. Women know what feels "normal" in their own breasts and are the ones most likely to notice something different that may signal a problem.

## Q What would you say to physicians who may be reluctant to recommend "breast self-awareness" instead of "breast self-exams"?

**Dr. Bevers:** Doctors should be relieved that they no longer have the responsibility to teach women how to do breast self-exams. Physicians often did not have the time to do this before. They now can have the comfort of knowing that even without teaching women how to check their breasts, the women will still be able to notice a problem. Most women who have found cancerous lumps weren't doing formal self-exams. Instead, they found their lumps naturally—while taking a shower or changing clothes.

Breast self-awareness is a win-win for the patient and the doctor. The patient is reassured that she will notice a change and doesn't have to worry if she is examining herself correctly. And the doctor can focus on other important issues during clinic visits. There are many screenings and preventive measures to talk with patients about, so if one isn't of benefit, let's use the time to talk about the strategies that do have proven benefits. ●

**FOR MORE INFORMATION,** contact the Cancer Prevention Center at (713) 745-8040.

## IN BRIEF

### Breaks in "Backward" DNA Associated with Leukemia

When otherwise normal DNA adopts an unusual shape called Z-DNA, it can lead to the kind of genetic instability associated with cancers such as leukemia and lymphoma, according to a study by researchers at M. D. Anderson.

The study, presented in the February 21 edition of the *Proceedings of the National Academy of Sciences*, demonstrates for the first time that the odd shape can cause DNA breaks in mammalian cells. Interestingly, sequences prone to forming Z-DNA are often found in genetic "hot spots," areas of DNA prone to the genetic rearrangements associated with cancer. About 90% of patients with Burkitt's lymphoma, for example, have DNA breaks that map to regions with the potential to form these odd DNA structures.

Imagine untwisting the DNA ladder and then winding it up the other way. The resulting "Z-DNA" would be a twisted mess with segments jutting out left and right and with the all-important base pairs that hold the DNA code zigzagging like a jagged zipper. It just doesn't look right, and it doesn't act right, either, according to Karen Vasquez, Ph.D., lead author of the study and assistant professor of carcinogenesis at M. D. Anderson's Science Park Research Division. This awkward shape can cause the DNA molecule to break completely apart.

"Our study shows that DNA itself can act as a mutagen, resulting in genetic instability," said Dr. Vasquez. "The discovery opens up a new field of inquiry into the role of DNA shape in genomic instability and cancer."

### Preventing Cancers in Women with Lynch Syndrome

Women diagnosed with Lynch syndrome, a condition often associated with colon cancer, also are at

high risk for endometrial and ovarian cancers—both of which can be eliminated by having a prophylactic hysterectomy and oophorectomy, according to a study published by researchers from M. D. Anderson in the January 19 issue of the *New England Journal of Medicine*.

Lynch syndrome is an inherited disorder in which affected individuals have a much higher-than-normal chance of developing colon cancer and/or certain other types of cancer, usually before the age of 60.

"The key reason that we embarked on this study was that women with Lynch syndrome often don't realize that they are at an extremely high risk for two gynecological cancers," said Karen Lu, associate professor in M. D. Anderson's Department of Gynecologic Oncology.

Women with Lynch syndrome have a 40% to 60% lifetime risk of developing endometrial cancer, and a 10% to 12% lifetime risk of ovarian cancer, said Dr. Lu. In the general population, the risk of endometrial cancer is about 3%, and the risk of ovarian cancer is 1% to 2%.

"This study is an important reminder to physicians to pay attention to a woman's family history of colon, endometrial, and ovarian cancers, with genetic counseling becoming of utmost importance. If women with Lynch syndrome are identified, there needs to be coordinated care between the gastrointestinal and obstetrics and gynecologic medical disciplines," Dr. Lu said.

#### Erratum

In the March In Brief about Dr. Qingyi Wei's research on skin cancer, we incorrectly called basal cell carcinoma and squamous cell carcinoma "nonmalignant" instead of "nonmelanoma." These tumors can and do spread locally, regionally, and diffusely, and there are several thousand deaths each year in the U.S. from these two skin cancers. We regret the error.—Eds.



## What Is “Breast Self-Awareness”?

“I don’t do breast self-exams because I don’t know how.” That’s what many doctors hear from their patients. But new screening guidelines are demystifying the process and assuring women that they will know if something is wrong with their breasts. Today, doctors believe that women should practice “breast self-awareness” by being familiar with how their breasts look and feel and reporting any changes to their doctor immediately.

### Breast self-awareness found to be effective

M. D. Anderson no longer recommends that women follow a formal technique in checking their breasts for suspicious lumps or changes—a practice that was once called “breast self-exam.”

The shift to breast self-awareness was made for several reasons:

- **The idea of breast self-exams confused women.** Some women weren’t sure if they were conducting breast self-exams in the right way, and because of that, many did not practice breast self-exams at all.
- **A specific technique is not needed.** Research has not shown a benefit for women in finding breast lumps by following a formal technique.
- **Women find suspicious lumps without any training or technique.** M. D. Anderson breast oncologists saw that most of their patients found a breast lump or other symptom of breast cancer when they were going about everyday activities, such as showering or dressing.

Breast self-awareness does not require special training—women just need to know their own bodies. M. D. Anderson recommends that women be familiar with the look and feel of their breasts—and that there’s no right or wrong way to do that. Touching can range from informal touching, such as in the shower, to conscious touching to feel for any changes.

The following are frequently asked questions and answers about breast self-awareness.

### How do I know if my breast feels different?

It’s common to wonder whether you’d recognize a breast change. Generally, if you can’t tell whether you have a change in your breast, there probably hasn’t been a change.

For example, if you were grocery shopping and picked up a bag of grapes, you’d feel the lumps and bumps of the grapes. Now, imagine someone added a rock to the bag of grapes. Would you be able to tell the difference between the grapes and the rock? Of course you would.

Breasts are made up of numerous lobules, similar to a bag of grapes, so lumpy, bumpy breasts are perfectly normal. In the same way that you wouldn’t expect a bag of grapes to be smooth, you shouldn’t expect your breasts to be smooth either. But if you notice something that looks or feels different from what you’re used to, tell your doctor immediately.

### Should I touch my breasts at a certain time of the month?

For premenopausal women (women still having periods), the ideal time to touch the breasts is usually right after a menstrual period. After a woman’s period, hormone levels are lower, making breast tissue softer and less tender and making changes easier to feel.



*Women should be familiar with the look and feel of their breasts—and there’s no right or wrong way to do that.*

### What kind of changes should I look for?

Many changes aren’t cancer, but here are some changes to look for. If you notice any of these changes—or even a breast change not on this list—and it lasts for more than 2 weeks, tell your doctor promptly:

- Lump or mass in your breast
- Enlarged lymph nodes in the armpit
- Changes in breast size, shape, skin texture, or color
- Skin redness
- Dimpling or puckering
- Nipple changes or discharge
- Scaliness
- Nipple pulling to one side or a change in direction ●

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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[www.mdanderson.org/patients\\_public/prevention](http://www.mdanderson.org/patients_public/prevention)

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# OncoLog

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## DiaLog

### The Revolutionary Cervical Cancer Vaccine

**Therese B. Bevers, M.D.**  
Medical Director  
Cancer Prevention Center



The cervical cancer vaccine is groundbreaking and has the potential to significantly reduce the incidence of cervical cancer, the second most deadly cancer in women worldwide, causing 300,000 deaths a year. M. D. Anderson supports any proven cancer prevention strategy and is excited by the promise of this new vaccine to make a meaningful difference.

The vaccine prevents infection from two subtypes of human papillomavirus (HPV) that are strongly associated with cervical cancer. Studies have shown that the vaccine can reduce the risk of infection from HPV by over 90%. Efficacy with regard to prevention of clinical disease has been reported as high as 100% in short-term studies. Two vaccines, each slightly different, are being investigated by two pharmaceutical companies. Merck's version (Gardasil) is a quadrivalent vaccine that includes two HPV subtypes (16 and 18) that cause 70% of cervical cancers and two HPV subtypes (6 and 11) that are associated with genital warts. Merck's vaccine is undergoing priority review at the Food and Drug Administration, which is expected to be completed in June of this year. GlaxoSmithKline's vaccine (Cervarix), which is in phase III trials, is a bivalent vaccine of strains 16 and 18.

I had the exciting opportunity to participate on an advisory board for Merck as it explored the implementation of its vaccine into the general population. It is still being determined at what age the vaccine series (three injections in a 6-month period) will be given, but it must be given before a girl becomes sexually active and possibly exposed to HPV. Eventually, as the vaccines are studied more, they may be available for younger girls and may even become part of childhood immunizations, but for now, studies have only been conducted in women over 16 years old.

Once girls start receiving the vaccine, we are likely to see the incidence of cervical dysplasia decrease because the HPV infection will have been prevented. Because of this, in decades to come, we will need to re-examine the role of Pap smears.

While we have 3700 deaths a year from cervical cancer in the U.S., this rate is very low compared with that in developing countries, which lack screening and treatment facilities. The vaccine can make a profound difference in the developing world and reduce death rates from this cancer.

It's phenomenal to trace how far science has come in the prevention of cervical cancer. In the 1930s, it was the leading cause of cancer deaths in the U.S. Then, with the advent of the Pap smear in the 1930s, we were able to test for and treat cellular abnormalities; since 1955, deaths from cervical cancer have significantly declined. And now, with the promise of the cervical cancer vaccine, we are on the verge of another revolution in the prevention of this cancer. ●

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