

**REPORT TO
PHYSICIANS**

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THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER
Making Cancer History™

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MD Anderson Oncology

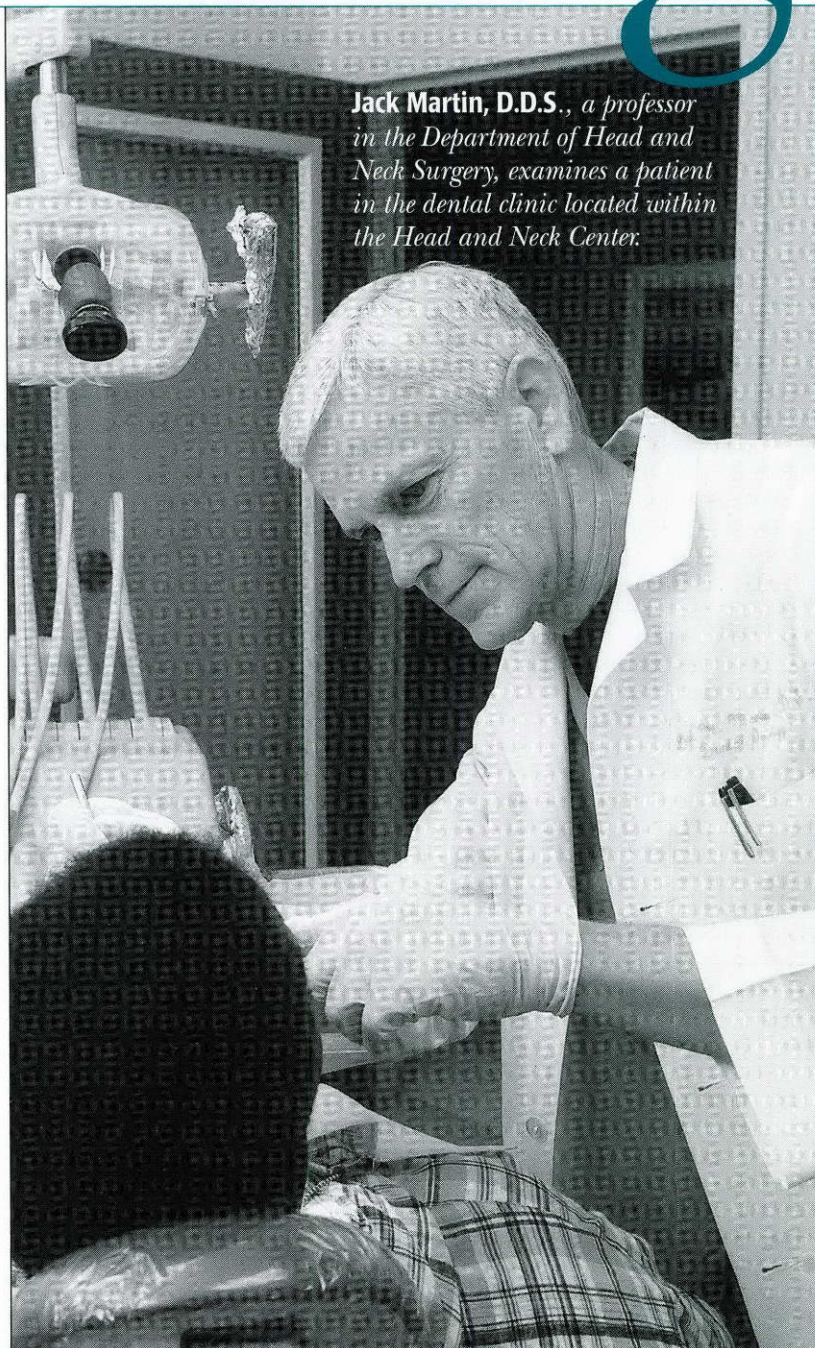
Dental Oncologists Prepare Patients with Head and Neck Cancer for Radiation Therapy

by Jude Richard

For patients who are about to undergo radiation therapy for head and neck cancer, a dental examination before treatment can do more than give them a healthier smile. By precluding many complications that could jeopardize treatment options or delay recovery, a pretreatment dental evaluation can also give patients something to smile about—more successful radiation treatment and a smoother recovery.

“When combined with other medical consultations, the dental examination can help the head and neck specialist determine the best and most productive course of treatment,” said Jack Martin, D.D.S., chief of the Section of Oncologic Dentistry and Prosthodontics, Department of Head

(Continued on next page)



Jack Martin, D.D.S., a professor in the Department of Head and Neck Surgery, examines a patient in the dental clinic located within the Head and Neck Center.

Dental Oncologists Prepare Patients

(Continued from page 1)

and Neck Surgery at The University of Texas M. D. Anderson Cancer Center.

The five dental oncologists in the Head and Neck Center at M. D. Anderson each treat 10 to 15 patients a day on an outpatient basis (all together about 650 patient visits a month). Roughly 60% to 80% of these patients have head and neck cancer, and a large percentage, said Dr. Martin, have a poor dental status and a history of tobacco and alcohol use. The dental clinic's location within the Head and Neck Center makes patient referrals more convenient and promotes communication between the dental oncologists and other members of the multidisciplinary treatment team, Dr. Martin said.

The immediate job of the dental oncologists in the Head and Neck Center is to help patients achieve—via a comprehensive oral/dental assessment and, if necessary, dental treatment and prophylaxis—sound oral health, which will allow their disease to respond better to treatment by the head and neck medical team.

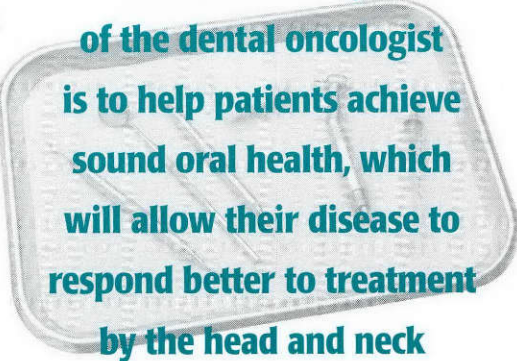
According to Rhonda Jacob, D.D.S., a professor in the Department of Head and Neck Surgery, irradiation immediately puts the patient with head and neck cancer at high risk for treatment-related complications including dry mouth (xerostomia), oral infections, oral muscle fibrosis, and jawbone destruction (osteoradionecrosis).

A dental examination before irradiation of head and neck cancers is important, Dr. Martin said, for two reasons: to impress on the patient the need for fluoride therapy and to remove any unrestorable, abscessed, or periodontally diseased teeth in the field of radiation therapy. Many of these patients may also require fabrication of a radiation stent.

"In many instances, teeth will need to be extracted before radiation treatment because once the patient has radiation treatment, oral and

periodontal surgery may be contraindicated," Dr. Martin said. "When extractions are required, they can be done under local or general anesthesia, depending on the degree of difficulty and the patient's medical status."

In some cases, radiation therapy cannot wait for dental treatment, and the head and neck physician will opt to deal with future dental sequelae as they arise. In most cases, however, dental evaluation and



The immediate job of the dental oncologist is to help patients achieve sound oral health, which will allow their disease to respond better to treatment by the head and neck medical team.

treatment can be done before radiation therapy and should be considered medically necessary, Dr. Martin said.

In patients who have been or are about to be irradiated, the biggest dental problems, said Dr. Jacob, are dental caries and periodontal disease.

"In the healthy mouth," she explained, "saliva balances the mouth's acidity and dilutes any sugars that are eaten. Yet, because it is very difficult to exclude the salivary glands from radiation fields in the head and neck and because an irradiated gland can no longer produce saliva, oral acids take advantage and begin to attack the patient's teeth. This greatly increases the chances for dental caries in every tooth."

As a result, the patient becomes prone to dental decay, jawbone destruction, and fevers due to these

infections, all of which may hinder the recovery from cancer treatment. This is most likely to occur in patients with head and neck cancer whose dental hygiene is poor and in patients who have been irradiated despite having a preexisting dental infection.

To prevent these types of treatment-related complications from occurring, dental oncologists at M. D. Anderson prescribe fluoride and advise patients to visit their regular dentists for routine cleaning and dental work when they return home. According to Dr. Jacob, it is important for community physicians to reiterate this advice to their patients.

"Unfortunately," said Dr. Jacob, "most patients tend to be more careful about their dental hygiene at the beginning of and during their therapy. Their dental regimen slips over time as follow-ups become fewer and as fewer people press them to keep up the dental care."

Consequently, she said, community physicians with patients who have been irradiated for head and neck cancer should, ideally, build a relationship with the patient's dentist.

"Many of our patients, once they have been treated, placed on fluoride treatment, and sent home, are cared for by their hometown dentists," said Dr. Martin. "We receive calls from their dentists asking if they can make a radiograph, pull a tooth, or perform an endodontic procedure. Being a part of this care is an important part of our function as dental oncologists."

Though its main focus is providing extra- and intraoral prosthetic rehabilitation and preparing patients with head and neck cancer for radiation treatment, the Head and Neck Center's dental clinic also evaluates and, if necessary, treats about 3% of patients receiving chemotherapy at M. D. Anderson. Most of those, said Drs. Martin and Jacob, are patients who have



A dental examination and care before radiation therapy for head and neck cancer can reduce the risk of treatment-related complications such as oral infections and jawbone destruction. Here, Rhonda Jacob, D.D.S., a professor in the Department of Head and Neck Surgery, examines patient Dinney Ng Wah.

had bone marrow transplants.

“Compared with patients who receive radiation therapy,” said Dr. Jacob, “cases involving patients receiving chemotherapy pose less of a problem for us since the sequelae of chemotherapy come and go with the cycles of treatment. So, we end up treating a lot of acute, but routine dental infections. During immunosuppressive chemotherapy these dental infections, which are usually self-limiting in a normal situation, can become life threatening.”

“On occasion,” Dr. Jacob added, “we also see patients who have received head and neck irradiation treatment outside M. D. Anderson, patients previously treated elsewhere who now have advanced dental problems such as osteoradionecrosis, and patients sent to us to receive special prostheses. These patients are sent to us on a ‘short-form’ registration basis to be seen only by the dental service. We work closely with the referring physicians and dentists

to resolve complications related to past or pending cancer therapy.” These cases total about 100 patients a year, Dr. Martin said.

Dental consultations ordered by the cancer specialist can do more than improve a patient’s cancer treatment by improving their oral health, said Dr. Martin. They can also strengthen the physician’s relationship with the patient. “In my experience,” he said, “most patients appreciate a physician who looks out for them by identifying possible treatment-hindering dental problems and sending them to see a dentist before cancer treatment begins.”

Dental consultations can also be very cost-effective. “For example,” Dr. Martin said, “hyperbaric oxygen is a treatment that allows us to operate on an irradiated jaw that needs dental extractions or has areas of necrosis, but it is very costly for the patient in both time and money—approximately \$15,000 for 20 preoperative and 10 postoperative treat-

ments. Even with these treatments, patients may still suffer jawbone loss and require costly jaw reconstruction. In most cases, taking care of the patient’s dental problems before irradiation would have made these procedures unnecessary.”

In the case of patients who are treated with chemotherapy, pretreatment dental consultation and care could eliminate costly hospital admissions for fevers of undetermined origin.

“So,” he concluded, “if you compare that cost with the cost of a basic oral examination with dental radiographs (approximately \$200), you can see that dental evaluation and treatment before cancer therapy is cost-efficient and, medically, more productive. The patient ultimately returns home healthier in all respects.” ●

The following is a list of faculty in the section of Oncologic Dentistry and Prosthodontics: Mark S. Chambers, D.D.S., oral and dental care of patients receiving radiation therapy; Rhonda F. Jacob, D.D.S., intraoral prosthetics and pre- and intraoperative care of patients with head and neck cancer; James C. Lemon, D.D.S., facial prosthetics and pre- and intraoperative care of patients with head and neck cancer; Jack W. Martin, D.D.S., intraoral prosthetics and pre- and intraoperative care of patients with head and neck cancer; and Bela B. Toth, D.D.S., oral and dental care of patients receiving chemotherapy.

FOR MORE INFORMATION about the Head and Neck Center, visit the center’s Web site at <http://www.mdanderson.org/centers/headneck/>.

Radiofrequency Ablation Surpasses Cryoablation as the Treatment of Choice for Localized, Unresectable Liver Malignancies

by Kerry L. Wright

In the few short years since physicians at The University of Texas M. D. Anderson Cancer Center began using radiofrequency (RF) ablation as part of the multimodality treatment of unresectable primary and metastatic liver tumors, the new technique has replaced cryoablation as a standard treatment at M. D. Anderson and is becoming a standard treatment at several other institutions across the country and around the world.

"It has been amazing to see how rapidly it has evolved," said Steven A. Curley, M.D., a professor in the Department of Surgical Oncology. "Two years ago, there were probably less than 30 or 40 institutions that had the ability to perform RF ablation. Now the number is in the hundreds."

Dr. Curley, whose role in the use of RF ablation at M. D. Anderson is

detailed in the March 1998 issue of *OncoLog*, was the principal investigator in a clinical trial of RF ablation conducted at M. D. Anderson and the G. Pascale National Cancer Center in Naples, Italy, through an alliance with the National Cancer Institute. Results from the first 123 patients treated with RF ablation for unresectable primary and metastatic liver malignancies were reported last July in *Annals of Surgery*, and today more than 370 patients have been treated at the two institutions.

Follow-up studies need to be performed for several more years before long-term effects can be accurately assessed, but current results have convinced Dr. Curley and other physicians that RF ablation is easier to perform and safer than cryoablation and that it results in fewer complications and side effects.

During RF ablation, a needle electrode is inserted into the tumor, and an electrical current from an RF generator is passed through it, destroying the diseased tissue and a small amount of surrounding tissue, which are then absorbed by the body over time.

Cryoablation, the use of extreme cold to destroy tumor tissue, can lead to cracking and bleeding of the liver, bleeding after probe removal, and the development of tumor lysis syndrome, which can cause kidney problems and even kidney failure in some cases.

"We have not seen any of that after RF ablation," said Dr. Curley. In addition, there is a very low recurrence rate (8% to 9%) in lesions treated with RF ablation, and most of these recurrences are in larger tumors, which are more difficult to treat with RF ablation.

"With the equipment currently available, it is very hard to ablate a

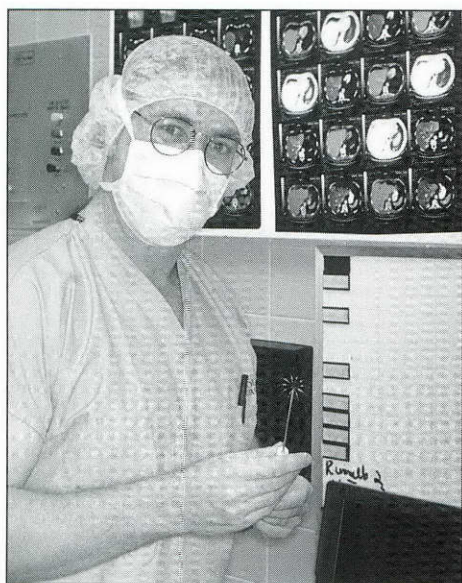
tumor that is more than 6 to 7 cm in diameter," Dr. Curley said. However, work is being done in animal research laboratories with a more powerful generator and larger needles that would allow physicians to treat larger tumors.

Currently, RF ablation is used to treat only small primary or metastatic tumors that are confined to the liver, Dr. Curley said, adding that systemic therapy is more appropriate for patients who have additional metastases elsewhere in the body. Also, because it is a local therapy, RF ablation does not prevent recurrence from micrometastases that might be present in the liver at the time of treatment. Combination therapies that include RF ablation and/or resection preceded or followed by neoadjuvant or adjuvant chemotherapy appear promising, according to Dr. Curley.

In one study of RF ablation being conducted at M. D. Anderson, Lee Ellis, M.D., an associate professor in the departments of Surgical Oncology and Cancer Biology, and colleagues Dr. Curley, Jean Nicolas Vauthey, M.D., an associate professor of Surgical Oncology, and Yehuda Patt, M.D., a professor of Gastrointestinal Oncology and Digestive Diseases, are recruiting patients for a phase II clinical trial to study the effects of RF ablation and adjuvant hepatic arterial chemotherapy on liver metastases in colorectal cancer.

RF ablation will also soon be used to treat lung tumors in a study led by Joe B. Putnam, Jr., M.D., an associate professor in the Department of Thoracic and Cardiovascular Surgery, and to treat breast malignancies in a study led by S. Eva Singletary, M.D., a professor in the Department of Surgical Oncology, and Bruno D. Fornage, M.D., a professor in the Department of Diagnostic Radiology. ●

FOR MORE INFORMATION, contact Dr. Curley at (713) 794-4957.



Holding a needle electrode, Steven A. Curley, M.D., a professor in the Department of Surgical Oncology, prepares for a radiofrequency (RF) ablation procedure.

Compass

CLINICAL DISCUSSION: Rectal Cancer

About These Clinical Practice Guidelines

These guidelines may assist in the diagnostic evaluation of patients with clinical symptoms or positive screening tests (if such testing exists). The clinician is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care.

M. D. Anderson Cancer Center's Practice Guidelines are continually updated as new information becomes available and are being expanded to include the entire spectrum of cancer management. New guidelines for screening and diagnosis are currently under development. Access the most current version of all our Practice Guidelines from the M. D. Anderson Home Page at <http://www.mdanderson.org>.

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About This Program

Scope of This Guideline

This guideline addresses the management of stages I-IV rectal cancer. It should be noted that treatment approaches for colon cancers (tumors above the peritoneal reflection) differ significantly and are addressed in a separate guideline. These and practice guidelines for other types of cancer are currently available on our Web site.

Continuing Medical Education:

An expanded version of these materials with CME category 1 credit is available on the Internet. Choose 'Practice Guidelines' on M. D. Anderson's Home Page at <http://www.mdanderson.org>

Synopsis & Highlights

The initial evaluation for all patients presenting with rectal cancer is geared to:

- determining the tumor's size and location, specifically, its proximity to the anal verge
- determining the clinical stage or extent of disease invasion
- assessing the number, location, and potential resectability of metastases, and
- assessing the patient's medical operability.

The initial evaluation should include a patient history taken with attention to symptoms, comorbidity, and family history of cancer (particularly colorectal) and a thorough physical exam including pelvic and rectal examinations as well as proctoscopy to assess tumor fixation and involvement of contiguous organs.

According to the guideline, the standard workup should include a colonoscopy with biopsy, expert pathology review of all biopsy specimens, and blood work including carcinoembryonic antigen (CEA). Endorectal ultrasound is used to assess depth of tumor penetration and presence of lymph node metastases. CT scans of the abdomen and pelvis are included to identify direct invasion of contiguous organs and the presence of metastases. A chest x-ray should be performed, and the thorax should also be scanned in patients whose chest x-ray results are abnormal or when pulmonary metastases are suspected. The physician may also want to consider liver function studies and in anticipation of surgery should include an ECG and any additional preoperative tests indicated for individual patients in the initial workup.

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Treatment Overview

The primary treatment of rectal cancer requires a true multimodality approach: while surgical resection with adequate margins represents the definitive treatment, chemoradiation (combined concurrent chemotherapy and radiotherapy) given either before or after surgery plays a prominent role in enhancing patient outcomes in locally advanced disease. One of the clinical challenges in the management of rectal cancer is to determine and coordinate the optimal sequence of these therapies for each patient.

Surgery: The goal of surgery in the primary treatment of rectal cancer is complete removal of the tumor, removal of local lymph nodes, and restoration of function, with preservation of the anal sphincter as a major consideration. Surgical resectability is determined by the size, location, and extent of invasion of the tumor. Rectal tumors are considered

unresectable when there is involvement of the sacrum above the second sacral vertebra (S2), where there is major blood vessel involvement (specifically the common or external iliac vessels), or when major involvement of the sciatic nerve or sacral plexus is found. "It should be noted, however," says Dr. Skibber, "that only about 10%-15% of locally advanced tumors are found to be unresectable. The vast majority are resectable with intent to cure, and sphincter sparing is possible in >80% of cases."

The surgical approach is largely dependent upon the tumor's extent and location; anatomic proximity to the anal verge is an important factor in determining whether sphincter preservation is possible.

Surgery also has a potentially curative role in the treatment of liver and lung metastases, when they are limited in number and surgically accessible, and a palliative role in the relief of symptoms caused by a tumor obstructing the bowel in unresectable disease.

Chemoradiation refers to the carefully orchestrated concurrent delivery of chemotherapy and radiation treatments, and it is an important tool in the treatment of rectal cancer. A typical regimen might consist of daily (5x per week) radiation treatments, concurrent with daily (5x per week) chemotherapy delivered as continuous-infusion 5-fluorouracil (5-FU), over a period of five to six weeks.

According to Dr. Sinicrope, the addition of chemotherapy to radiotherapy sensitizes tumor cells to radiation and has been shown to be more efficacious than the use of either modality alone. Continuous infusion rather than bolus chemotherapy is preferred unless the patient is unable to tolerate it or adequate supportive care is unavailable, as this achieves stable levels of chemotherapy during radiation. According to Dr. Janjan, "With the continuous infusion, higher total doses of chemotherapy are given that resulted in improved survival rates in one study,

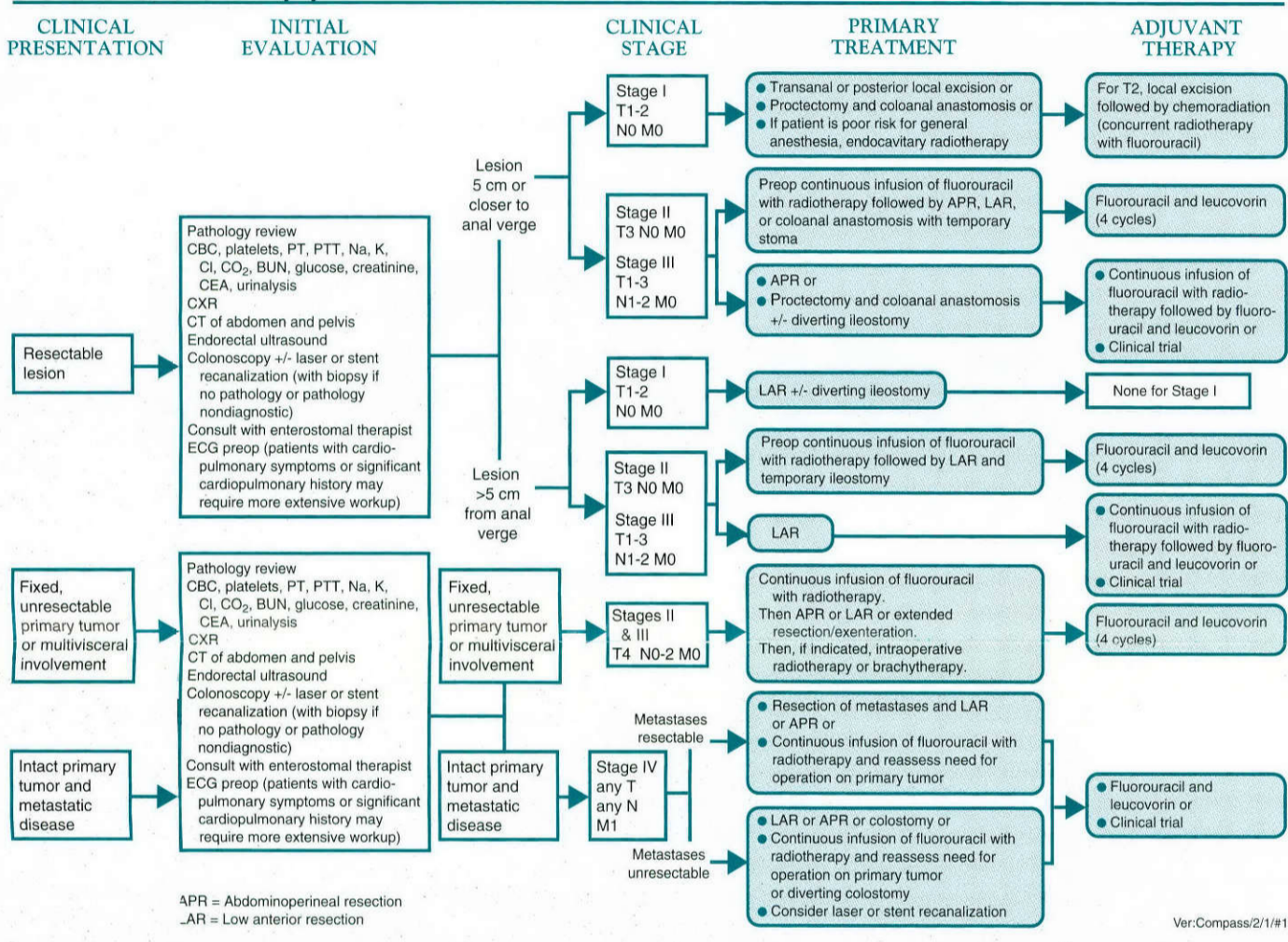
suggesting that the chemotherapy given during radiation has local effects by improving rates of tumor regression and systemic effects by reducing the risk for metastases."

This regimen may be given pre- or postoperatively for locally advanced tumors (T3-T4 or N1-N2) in which it has been shown to reduce recurrence rates and improve patient survival rates. When given preoperatively, it can cause tumor regression and in many cases make complete yet sphincter-sparing resection possible in patients who would otherwise require colostomy. An additional advantage of preoperative over postoperative radiotherapy is that a lower total dose of radiation is necessary, and a smaller volume of the small bowel is exposed, thus lowering the risk of side effects from radiation. The potential for surgical complications, however, is inherently higher, but studies have indicated that this is reduced with increasing experience of the treatment team. "The surgeon's experience in handling irradiated tissue is critical to the success of this combined modality treatment, as is the use of special radiotherapy techniques," says Dr. Janjan.

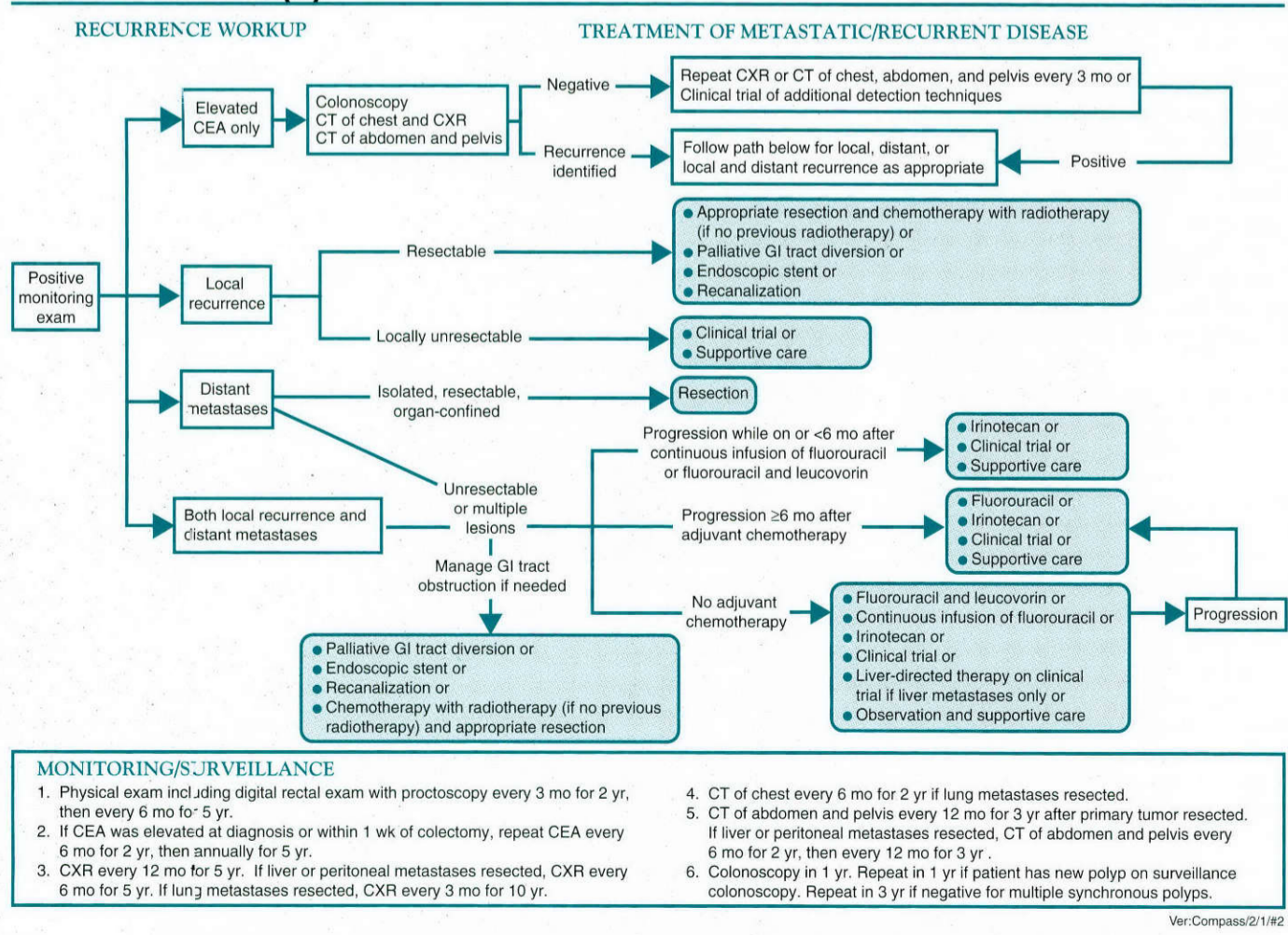
Other Radiotherapeutic Options in the primary treatment of rectal cancer that are shown in the guideline include:

- Intraoperative radiation therapy (IORT) is administered in the operating room using a dedicated linear accelerator. The advantage of IORT is that all adjacent critical structures can be moved away from the radiation beam so that only the area at highest risk for residual tumor receives radiation.
- Brachytherapy, the placement of radioactive sources in a tumor either during surgery or under CT guidance, is used in patients who have unresectable (T4) rectal tumors. It can also be placed over an area that is at high risk for residual tumor after surgical resection.
- Endocavitary radiation, which directly places the radiation over a tumor located low in the rectum, may be an alternative to surgery in some stage I rectal cancers. Because the radiation is given through a cone, no other areas receive radiation.

Rectal Cancer (1)



Rectal Cancer (2)



(Continued from previous page)

radiation to reduce the possibility of recurrence or the development of distant metastases.

■ *Patients presenting with locally advanced disease:*

The primary treatment of patients with locally advanced disease with full-thickness involvement of the rectal wall or with regional lymph node involvement includes surgery with chemoradiation given either pre- or postoperatively. These options are shown as equivalent in the guidelines, representing an area where the physician must make a judgment based on the individual patient. "At M. D. Anderson, we favor the preoperative approach to downstage disease for sphincter preservation," says Dr. Abbruzzese.

■ *Patients presenting with fixed or unresectable primary tumors or multivisceral involvement:*

These patients are treated with chemoradiation followed by a reassessment of the possibilities for surgical resection. Chemotherapy with fluorouracil and leucovorin is used adjuvantly. Intraoperative radiation or brachytherapy is considered in patients who have close or minimal surgical margins.

■ *Patients presenting with a primary rectal tumor and suspected or proven metastases:*

Evaluation of the location, size, and number of metastases is very important; this information directs treatment decisions. Patients whose primary tumor is resectable and who have a solitary or few resectable metastases in the liver or lung have more favorable prognoses and may have the primary tumor and the metastases removed by surgery. Chemoradiation may be employed as the initial treatment in more complex

cases, followed by a reassessment of surgical options. Systemic chemotherapy is indicated in either case.

For patients in whom disease remains extensive or unresectable even after chemoradiation, surgery may be done to relieve obstruction. Other options to relieve obstructions without major surgery include laser recanalization or endoscopically placed stents.

■ *Patients presenting with progressive or recurrent disease:*

Chemotherapy is the mainstay of advanced or recurrent disease treatment. Patients whose disease progresses during or within 6 months after fluoropyrimidine-based chemotherapy should be treated with irinotecan or enrolled in a clinical trial. Liver-directed chemotherapy (delivered intra-arterially via an implantable pump surgically placed in the abdomen) may be appropriate in the setting of a clinical trial in patients whose metastases are confined to the liver. Resectable lesions and obstructions may be surgically removed, and radiotherapy may be considered for patients who have not had previous radiation treatments.

Monitoring/Surveillance

Patients who have been successfully treated for rectal cancer should be actively monitored according to guideline recommendations every 3 months for the first two years and every 6 months for the next five years.

Authors' Perspectives

The success of sequencing and delivering multimodality treatment is utterly dependent upon an experienced, multidisciplinary team and expert supportive care. Dr. Janjan

stresses that chemoradiation in concert with surgery is a powerful tool in the treatment of rectal cancers but that it is critically important in sequencing these therapies to have a team who works together in a closely coordinated fashion. She also emphasizes the importance of expertly coordinated supportive care, without which it would be difficult for patients to tolerate these potent therapies.

One of the biggest problems with rectal cancer is a delay in medical attention, according to Dr. Skibber. Many patients come to medical treatment late even though they are symptomatic. Often they have ignored changes in bowel patterns or attributed rectal bleeding to hemorrhoids or other benign causes. Our experts agree that patients should be counseled to heed warning signs and to promptly seek medical evaluation and that asymptomatic patients should be actively screened.

Clinical trials are the preferred choice where shown as an option in the guideline. Clinical trials are an appropriate choice at any stage of disease management, and trials for screening, detection, and prevention are also available.

Find more information about current clinical trials at M. D. Anderson at <http://www.mdanderson.org/research/>

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Coping with Chemotherapy

Chemotherapy is a common and effective treatment for many different types of cancer, but some chemotherapy regimens can cause unpleasant side effects. However, there are steps that patients can take to ease the side effects of chemotherapy and improve their overall well-being.

Chemotherapy is the treatment of cancer with drugs that can destroy cancer cells.

When cancer develops, abnormal cells in the body keep dividing and forming more cells. The anticancer drugs used in chemotherapy destroy these cancer cells by stopping them from growing or multiplying. Chemotherapy is used to cure or control the cancer.

Sometimes, chemotherapy is a patient's only treatment, but more often it is used with other treatments such as surgery, radiation therapy, or biological therapy. Increasingly, two or more anticancer drugs are given in combination to enhance their effectiveness.

Most people receive chemotherapy on an outpatient basis, though sometimes a patient beginning treatment may briefly stay in the hospital so that the effects of the drugs can be monitored.

Chemotherapy is most frequently given intravenously (IV), but it can also be administered by mouth, through an injection, or by application to the skin. In the IV treatment, a thin needle is inserted into a vein, usually on the patient's hand or lower arm. When patients need many IV treatments over several weeks, a catheter—a thin, flexible tube—may be placed in a large vein. The catheter remains there for as long as needed, so a needle doesn't have to be used each time the drugs are given.

In the course of killing cancerous cells, chemotherapy damages healthy cells.

The aim is to maximize cell death and minimize the inevitable side effects, which can include fatigue, nausea, pain, hair loss, anemia, and infections. The kinds of side effects patients experience usually depend on the type and dose of chemotherapy they receive and how their bodies react. The patient's doctor will discuss the side effects most likely to occur with the specific anticancer drug before treatment begins.

Normal cells generally recover when chemotherapy is finished, so most side effects gradually go away when treatment ends and the healthy cells start to grow normally.

People react to chemotherapy in different ways.

Most people, though, tire easily during treatment but feel well enough to continue work or other routine activities. To help cope with this fatigue, it is often helpful to take short naps or breaks and perhaps work part-time for a while. Taking short walks, meditating, eating well, and drinking lots of fluids are also helpful.

Great improvements have been made in preventing and treating the side effects of chemotherapy.

Many new drugs destroy cancer cells more effectively while doing less harm to healthy cells. New drugs

Taking short walks, meditating, eating well, and drinking lots of fluids are helpful when undergoing chemotherapy.



also can prevent or lessen nausea and vomiting in most patients and help control pain. Patients should make a point of discussing with their physician or nurse any unpleasant side effects they are experiencing to get help in controlling them.


Emotional support is also important.

Chemotherapy, like cancer, is stressful to almost everyone, and many people understandably feel anxious, angry, or depressed. Talking to doctors, nurses, and counselors about these feelings is often very helpful. Talking to family members and friends and letting them know how to help is also beneficial. Support groups with other people who are going through similar cancer treatments have been shown to be especially beneficial.

For further information about chemotherapy, a useful booklet is the National Cancer Institute's "Chemotherapy and You: A Guide to Self-Help During Cancer Treatment." The Cancer Information Service (1-800-4-CANCER) is also an excellent source of information. ●

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

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

 (713) 792-6161 *in Houston and outside the United States.*

March 2000

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Nurses Contribute *Unique* Skills, Perspective to Research Efforts at M. D. Anderson

by Vickie Williams

Laura Esparza-Guerra, R.N., beams with pride as she lists some of the drug trials she has been involved in at The University of Texas M. D. Anderson Cancer Center.

"Paclitaxel, docetaxel, ondansetron—these are just some of the major drugs we have researched here," she said. "I feel like I have helped pioneer the development of some of the major chemotherapy regimens for breast cancer, and, along the way, I've also been a pioneer in the field of research nursing."

As one of the first research nurses at M. D. Anderson, Esparza-Guerra, a research nurse supervisor in the Department of Breast Medical Oncology, has witnessed firsthand the expanding role of nurses in oncology research during the last quarter century. Physicians and other investigators now recognize that, in addition to their unique perspective on patient care, nurses are well-prepared to contribute to research studies by collecting data, educating patients, and opening lines of communication.

Nurses at M. D. Anderson participate in research at two levels: as research nurses and as nurse researchers. Research nurses work in collaboration with a principal investigator but take the lead in executing many aspects of the study. Nurse researchers, acting as principal investigators, actually initiate and implement their own studies. In both cases, nurses are proving to be valuable contributors to the institution's research efforts.

The formal role of research nurses at M. D. Anderson began to evolve a little more than 20 years ago, about

the time some major cancer drugs were being introduced. Esparza-Guerra, who has worked at M. D. Anderson for 26 years (20 as a research nurse), remembers well those early years. "In the early 1970s, chemotherapy research was booming," she said, "and as one of the leading cancer centers, M. D. Anderson was involved in a substantial number of these clinical trials. As the institution's involvement in these trials grew, so did the physicians' patient loads and their data management responsibilities. The solution was to recruit qualified registered nurses to take on some of the administrative duties."

Leonard Zwelling, M.D., vice president for research administration at M. D. Anderson, said that as research nurses began to assume responsibilities on the research team, several interesting things happened. "Not only did it free up time for physicians to address technical issues," he said, "it also represented a new career path for nurses, and it enabled the institution to take on more protocol research."

The role of the research nurse may change from protocol to protocol and is defined by the principal investigator, but, in general, the research nurse performs a range of duties that include examining and interviewing patients; collecting data about patients' treatment responses, symptoms, and side effects; reporting these data electronically (in a database) or manually (on a report form); conducting educational sessions to teach patients and family members self-help and caregiver procedures; and serving as a liaison to study sponsors.

Nurses bring a lot of expertise to the research team with respect to

collecting data, Esparza-Guerra said. "This is an especially important task, as nurses well realize, because the data we compile about patient status, response to treatment, toxicity assessments, and other information form the basis for the physicians' analyses," she said.

Through education, the research nurse can empower patients at a time when they otherwise feel powerless. "Cancer takes away so much of the control that patients have over their own lives," said Esparza-Guerra. "When they leave the hospital, we want them to know what events might occur and what to do. Our education programs are designed to prepare them to take charge of their situation."

As communicators, nurses have an unmatched knack for building a candid rapport with patients. "When the doctor comes in and asks a patient how her chemotherapy session went, she might say, 'Oh fine, doctor,'" said Esparza-Guerra, "but when I ask the same question, she might say, 'It was terrible. I was up all night vomiting.'"

Although research nurses do not serve as primary investigators, Susan Frisbee-Hume, R.N., research nurse supervisor, Department of Medical Specialties, said that they often seize the opportunity to incorporate into an existing protocol a sub-study that focuses on a nursing consideration. "A research nurse might notice that patients on a particular chemotherapy regimen are getting mouth sores," she said. "With the primary investigator's approval, that nurse can design a sub-study to test the use of a certain prophylactic mouth rinse and report the results."

Kelly Larrabee, B.S.N., R.N., manager of research quality assurance, is heading up a team that is developing a program to train

Laura Esparza-Guerra, a research nurse supervisor in the Department of Breast Medical Oncology, has been involved in clinical research for 20 years. Research nurses like Esparza-Guerra work with a principal investigator in clinical trials while nurse researchers initiate and implement their own studies.

research nurses. "There are presently 130 research nurses at M. D. Anderson, with slots for 25 to 30 more," Larrabee explained. "The demand is up because physicians are increasingly realizing the contributions nurses can make in the area of research, but there is a shortage of nurses qualified to conduct research. Our program is designed to help nurses who are interested in research gain the knowledge they need to fill these slots."

As primary investigators, nurse researchers design and conduct studies that specifically address nursing priorities. "Nurse-initiated research may focus on behavioral, psychosocial, health systems, or quality of life issues that result from the diagnosis and treatment of cancer," said Terry Throckmorton, Ph.D., R.N., coordinator of nursing research in the Division of Nursing. The primary goal of nurse-initiated research, said Dr. Throckmorton, is to improve an aspect of nursing practice that will, in turn, improve patient outcomes. "We want patients to get well quicker and without side effects. If they do suffer side effects, we want to be able to treat them without extended hospital stays."

Dr. Throckmorton is the principal investigator of a multicenter study to evaluate how fatigue is perceived and managed in different cultural groups. "The first patients recruited will be American- and foreign-born African Americans and Caucasians," explained Dr. Throckmorton. "The goal of the study is to see how different cultures perceive of fatigue and how fatigue is managed with respect to traditional cultural practices."



Marlene Z. Cohen, Ph.D., R.N., coordinator of applied nursing research in the Division of Nursing, said that nursing research involves asking a research question from a nursing perspective or focusing on patient-care issues that nurses have the ability to affect.

Dr. Cohen and an interdisciplinary team in the Blood and Marrow Transplantation unit at M. D. Anderson are conducting a study that will lead to the development of plans to help the interdisciplinary team better manage patients' symptoms, including traditional symptoms like pain and fatigue and other factors that also affect quality of life such as distress and fear.

Other studies representative of the types of nurse-initiated research being conducted at M. D. Anderson include those focusing on aspects relevant to genetic testing, breast cancer in pregnant women, and relaxation techniques.

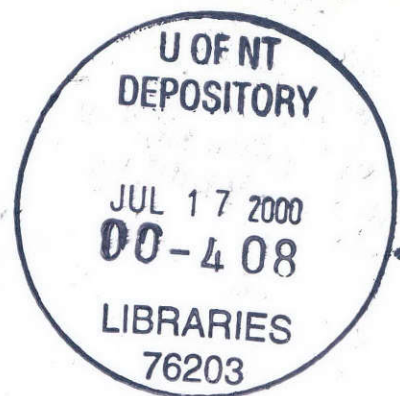
Nurse researchers and research nurses are both in great demand, said John D. Crossley, Ph.D., R.N., vice president for operations and nursing practice and head of the Division of Nursing.

Two of the nursing skills that Dr. Crossley sees as particularly useful in research are the ability to provide educational and psychosocial support. "Nurses are naturally empathetic, and they are great communicators. These skills are

particularly applicable in research because of the extra support and information that patients and their families need to face their situations and to understand both the opportunities and consequences of research participation," he said.

Most of the nurses involved in research at M. D. Anderson come from a clinical background. "It is not uncommon for a nurse to come to M. D. Anderson, gain clinical experience in an oncology specialty, earn an advanced degree or become certified, and then move into a research field," said Dr. Crossley. However, he explained, the segue into research is actually seamless because of the natural inclination for nurses to be inquisitive problem-solvers. "Cancer is the type of disease that stimulates a certain curiosity about the effects of treatment and symptom management," he said. "Who better to conduct research in such areas than nurses, who are in daily nonstop contact with patients?"

Dr. Cohen said that this personal contact with patients gives nurses a perspective on cancer that supplements the role of oncologists. "Our focus is on helping patients cope more effectively with cancer and cancer treatments," she said. "We are not prepared to fight the cancer, but we are prepared, and perhaps best prepared, to help the patient cope with the issues that result from the disease." ●

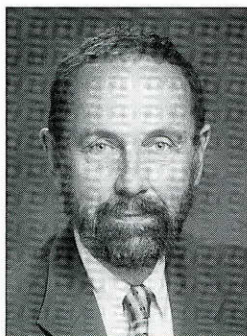


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Nurses Bring Personal Touch to Clinical Research

Charles S. Cleeland, Ph.D.
Professor, Pain Research Group,
Division of Anesthesiology and Critical Care

In the Pain Research Group, research nurses perform many critical functions: they recruit patients into studies and guide them through the protocols, they serve as project managers, and they even contribute to the design of our clinical trials. But, perhaps most important, research nurses serve as a communication bridge between the clinical research “system” and the individual patients who participate in clinical trials.



Because nurses are with patients during the critical, intimate, and distressful periods of an illness, a bond often develops between patient and nurse. This relationship not only benefits the individual patient; it also stimulates the nurse’s interest in improving patient care practices for all patients (a major focus of the Pain Research Group’s efforts). Because of their ability to communicate with patients and their knowledge of cancer care, nurses are the best sources for recommending patients for certain protocols and for helping us retain patients in our studies.

Before becoming involved in research, many of the research nurses in the Pain Research Group were clinical nurses at M. D. Anderson, and therefore have

contacts within the clinical nursing community. These connections make it easier for the research nurses to convey the importance of our studies to clinical nurses and their patients and to explain how studies involving only a few patients could ultimately lead to benefits for all patients.

Research nurses in our group also help us modify some of our protocols to optimize the amount and type of information obtained from the patients and to minimize patient discomfort. Without that nursing perspective, which includes being able to see things from the patient’s point of view, we might sometimes miss the critical clinical and patient comfort elements that contribute to effective study design.

It has been my experience that research nurses like to work on projects where they see a direct patient benefit. Patient comfort issues such as managing symptom distress, pain, and fatigue are extremely important to them. No matter what type of study they may be working on, however, the value of the research nurse goes beyond the technical expertise and experience they bring to the table. By thoroughly explaining the goals of the study to patients and communicating the needs of the patients to the study leaders, they help bridge the distance between abstract research goals and living, breathing patients, and in doing so, they help to create a true partnership between patients and researchers.

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