

Western New York

VOLUME 5 / 2013

PHYSICIAN

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Encouraging New Detection and Treatment Options For Lung, Breast and Colorectal Cancers

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Cover Story



Photo: Lynne Tseng

Special Feature

Encouraging New Detection and Treatment Options For Lung, Breast and Colorectal Cancers

Through volumes of cancer cases – regional oncological experts describe gaining traction in beating cancer through improved diagnostics and innovations in treatment. Our cover story hears about success with Stereotactic Body Radiation Therapy, genetic understanding for better informed care decisions and the enhanced imaging and targeted therapeutics which aid physicians and benefit the patient.

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With prescription drug use on a steep incline, ACM Labs steps in with a newly developed screening test to help physicians obtain a clearer assessment of their patients' opiate usage for pain. Not only will this test aid in confirming proper prescribed usage but also help tighten the floodgate of opiates that find their way to non-patients.

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On the cover: Dr. Lori Medeiros operating with Lisa Fronczak, RPAC.

Photo credit: Lynne Tseng



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Welcome to Volume 5 - 2013 of *Western New York Physician* where you will find informative stories and articles *about and for* physicians in western NY.

About 580,350 Americans are expected to die of cancer this year, that's almost 1,600 people per day. Cancer is the second most common cause of death in the US, exceeded only by heart disease, accounting for nearly 1 of every 4 deaths. *American Cancer Society. Cancer Facts & Figures 2013*

While these numbers are staggering, the good news is that more and more people are becoming cancer survivors due to progress in early stage diagnosis and improvements in cancer treatment. In our cover story this month, we meet with a few of the regions oncological experts to learn more about some of the advancements in treatment and the latest resources aiding physicians and patients to better understand diagnosis, risk and prevention.

According to the National Cancer Institute, 13.7 million people happily call themselves Cancer Survivors. Recognizing the challenges for this unique and growing demographic, The Wilmot Cancer Center at the University of Rochester Medical Center has recently launched the Judy DiMarzo Survivorship Program designed to help navigate the complexities of cancer survivorship care. See the article titled The Journey Forward: Cancer Survivorship & Patient Care to learn more about this innovative program.

In the coming months, Western New York Physician magazine will be launching its sister publication in the Buffalo region – expanding the clinical and practice management collaboration and discussion between our neighboring healthcare communities. For those wishing to be a part of the premier issue, please email me at WNYPhysician@gmail.com.

As always, we thank each of our supporting advertisers – your continued partnership ensures that all physicians in the region benefit from this collaborative sharing of information and provides the WNYP editorial staff with a deep pool of expert resources for future interviews and articles.

Best regards –

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The Challenges of Wound Care in the Cancer Patient



Toufic Rizk, MD,
Medical Director,
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Wound care, even in relatively healthy patients, can at times be quite challenging, depending on the nature of the wound and the presence or absence of chronic conditions that may interfere with wound healing. This challenge is magnified in cancer patients whose wound physiology is significantly altered by a combination of nutritional deficits and the deleterious effects of radiation therapy and chemotherapy. In this patient population, the wounds may be the results of surgical intervention, disease progression or radiation therapy.

Wound healing follows an orderly sequence of steps, all of which may be altered by the cancer process and/or the different modalities used to treat it.

Let us consider the effects of each of these modalities separately, while keeping in mind that they can all be occurring simultaneously and have additive noxious effects on wound healing.

RADIATION THERAPY

Radiation therapy (RT) may cause early and late effects in the skin it penetrates to achieve its intended results. The early effects (within weeks to months) include skin burns and dermatitis, the development of atrophic, inelastic dry skin, decreased cell reproduction and collagen formation, and result in decreased wound tensile strength and therefore negatively affect wound healing. RT also causes an elevation of matrix metalloproteinases which compromises the extracellular matrix and stalls wounds. The delayed effects of RT (within months to years) are the results of injury to the microvasculature with

the development of obliterative endarteritis, producing tissue ischemia, a deficiency in angiogenesis and loss of resistance to injury. In patients undergoing RT, the timing of elective surgery should ideally be between 6 weeks and 6 months after the end of treatment.

CHEMOTHERAPY

Chemotherapy (CTX) affects patients' wounds differently, depending on the different agents used and if used in combination. In general, CTX drugs downregulate fibroblast and reduce the efficacy of macrophages in their role as wound modulators. Common drugs known to affect wound healing negatively include cisplatin and doxorubicin. One can easily extrapolate the wound damaging effects of combining RT with CTX. While the steroid use's negative actions on wound healing are well known, when combined with CTX agent, their deleterious effects are amplified. If elective surgery is contemplated in this patient population, it is recommended to wait between 10 and 14 days after the end of treatment before proceeding.

NUTRITION

The percentage of cancer patients who develop malnutrition ranges between 40% and an astonishing 80%. This typically is the result of a catabolic state that develops in these patients as a result of their disease process, and is often worsened by superimposed fevers, progression of disease, and the stress of critical illness and surgery. Therefore this makes them very susceptible to infection and poor wound healing.

WOUND CARE CENTER & HBOT:

With these complicating factors, referring the cancer patient with chronic, nonhealing complex wounds to a specialized wound care center (WCC), with dedicated, trained staff to assist in hastening the healing process, may at times be lifesaving. In this setting, close monitoring of the problem wound takes place until healed. In addition to the wide armamentarium

of advanced wound care products (tissue-engineered skin substitutes) and techniques (debridements) available at the WCC, patients also benefit from the expertise of experienced wound care providers who use evidence-based medicine to heal their complex wounds. Also available at the WCC is hyperbaric oxygen therapy (HBOT) which has its place in difficult to heal wounds. For example, with cutaneous radionecrosis, laryngeal chondroradionecrosis, and osteoradionecrosis of the jaw, supplemental HBOT significantly increases wound healing potential. Another chronic debilitating condition that responds particularly well to HBOT is hemorrhagic radiation cystitis.

HBOT mechanisms of action promoting wound healing include increased tissue oxygenation, increased angiogenesis, fibroblast proliferation, as well as collagen synthesis. The concern that increased tissue oxygenation may boost multiplication of residual malignant cells, or rekindle dormant cancer cells to start proliferating has never been shown, and may in fact have the exact opposite effect.

To avoid significant wound problems in cancer patients who need elective surgery, it is paramount for the different physicians involved in the care of these patients to communicate about the best timing of their treatment (RT &/or CTX) in relationship to surgery, if needed.

Dr. Rizk earned his MD degree from SUNY-Upstate Medical University in Syracuse, NY. He did his residency in General Surgery at Robert Packer Hospital, and won an NIH National Research Service Award during his Postdoctoral Fellowship at Albany Medical College. He also completed a fellowship in vascular surgery at SUNY Buffalo Hospitals. He is board certified by the American Board of Surgery in general surgery with added qualifications in general vascular surgery.

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Encouraging New Detection and Treatment Options For Lung, Breast and Colorectal Cancers

Julie Van Benthuisen



Dr. Claudia Hriesik performing a laparoscopic surgery with Barbara Macey, NP

Photo: Lynne Tseng

Recent cancer survivor Raymond N. would in all probability not be alive today if his multiple treatments had taken place a decade ago. When he was diagnosed with colon cancer a while back, it had already metastasized to his liver, which required resection. Two years ago, cancer had again metastasized, this time to his lung – most likely a product of the original colon cancer. Because of severe emphysema, surgeons were unable to allow surgical resection or even a biopsy to clarify the diagnosis. Even so, Raymond was able to undergo a procedure called Stereotactic Body Radiation Therapy (SBRT) to treat the cancerous lung. Today, he is cancer-free. “Historically, we would have considered a metastasis to the lung or liver to be incurable,” says Dr. Jeffrey Haynes, Radiation Oncologist at Rochester General Health System (RGHS) and Lipson Cancer Center. “Raymond is a testament to how far cancer care has come.”

In cancers of the lung, breast and colon, doctors are witnessing an exciting paradigm shift in prognosis and cure rates. For lung cancer, SBRT has become the standard of care in just the past few years, with recently published reports indicating a 90-98% likelihood of controlling the primary lesion.

SBRT is most effective when delivering a few very high doses of radiation to small, well-defined tumors in the chest, abdomen or pelvis that can't be removed surgically or treated with conventional

radiation therapy. This high dose radiation can be enough to kill the cancer while minimizing exposure to surrounding healthy organs. SBRT is typically used to treat small, early-stage lung tumors, or isolated recurrences or metastases from various types of cancer. It's also been used successfully to treat early-stage, non-small cell lung cancer, recurrent lung parenchyma cancer, pancreatic cancer, and metastatic cancers in the lung, liver, adrenal glands, and spine.

The amount of radiation that can be safely delivered, however,

may be limited if the cancer is located close to a sensitive normal structure, like the spinal cord or bowel. SBRT uses multiple narrow radiation beams to target small, well-defined areas with precision; it also uses immobilizations techniques that limit, monitor and adjust for any movement during treatment. In the past, longer radiation periods lasting 6 ½ weeks only resulted in a local control rate of about 40%. “Now, with limited side effects, SBRT allows us to target the cancer better,” says Dr. Haynes. “It’s exciting to treat patients now knowing the potential for more successful outcomes.”

The common thread in SBRT treatment is the ability to administer large doses into tissues within a few millimeters of the target area vs. conventional radiation. Patients are generally given one to five treatments within a two week span. While up to five times the amount of radiation is used per treatment, the complication rates are lower because it’s more targeted.

While statistically, lung cancer causes more deaths than the next three most common cancers combined (colon, breast and prostate), SBRT represents a promising opportunity to reverse the statistics. “SBRT is a refinement of what we’ve been doing for a long time,” he says. “The imaging is much better, and we can locate our tumor within millimeter accuracy.” Surgeons are now equipped to perform CAT scans on the machine during treatment, because patients are positioned precisely where they need to be. “Through evolution and more training, we’ve all become more comfortable managing this process, including therapists who can now read the CAT scan as well.”

Research has shown that some organs can tolerate more than previously thought. “It truly raises the bar in treatment by knowing your anatomy. When you realize how much an organ can handle, you can better determine which direction to go -- whether it’s smaller or larger doses of radiation,” he adds. “The old dogma was that if the cancer had metastasized, there was nothing you could do. Now, we can image the chest annually, and if we find one to three metastasized spots, we can cure a higher percentage of them through SBRT.” Even in the case of multiple spots, he says, patients have a higher percentage cure rate than ever before. On the other hand, conventional radiation would do peripheral damage.

“Primary Care doctors need to know that if their patients aren’t well enough to tolerate lung tumor surgery, or if the masses are just too great, they can still be treated through SBRT with an encouragingly high cure rate.”

Genetic Testing for Breast Cancer

Unfortunately, the vast majority of lung cancers are due to smoking, a preventable lifestyle choice that can impact a patient decades after smoking has ceased. In the case of breast cancer, however, more women than ever are taking preventative measures to avoid a diagnosis. “Every day, I speak with women with a family history who didn’t realize they could do something about it,” says Jessica Salamone, Genetic Counselor at Elizabeth Wende Breast Care. “Women can empower themselves through screenings, surveillance and risk-reducing surgeries.”

Salamone receives numerous calls each week from women inquiring about genetic testing for breast and ovarian cancer genes, specifically BRCA1 and BRCA2. Patients typically fall into one of two categories.

The first are those women who’ve already been diagnosed with breast or ovarian cancer. They may be pursuing genetic testing to help in surgical decision-making (a lumpectomy vs. a bilateral mastectomy), to help determine recurrence risks either for their initial cancer or another type of cancer or to help their family members understand their risks and begin appropriate screening.

The second category includes patients concerned about their family history and how it impacts their personal risk. “They typically want to know if their current screening practices are sufficient, to help determine their lifetime risk of cancer and to help other family members understand both their risk and possible need for screening.

Unfortunately, the BRCA1 and BRCA2 mutations carry an 85% risk of breast cancer compared with a typical woman’s risk of 12%, and a lifetime ovarian cancer risk of 27-44% compared to a typical woman’s risk of just 2%. More patients are deciding to undergo a pre-emptive prophylactic double mastectomy like actress Angelina Jolie, after she learned she also carried the BRCA mutation that took the life of her mother with ovarian cancer at 56. “Women are deciding they want to live their life rather than live in



RGHS Lipson Cancer Center radiation oncologists Drs. Sheema Chawla, Jeffrey Haynes and Dr. Meri Atanas, Chief, Department of Radiation Oncology. Photo: Jeff Blackman

fear every six months undergoing aggressive screenings,” she says.

“It’s definitely the most effective prophylactic measure,” adds Dr. Lori Medeiros, Medical Director at Rochester General Breast Center. “We perform close to a dozen of them each year.” Genetic testing for BRCA1 and 2 should be considered in women with a personal or family history of breast cancer diagnosed before age 45; a personal or family history of ovarian cancer diagnosed at any age, male breast cancer, pre-menopausal breast cancer; and/or a family history where the rate of breast cancer is more than 1:8 women with an earlier than average age of diagnosis. BRCA1 and BRCA2 mutations also confer a risk for prostate cancer, male breast cancer, melanoma, pancreatic and kidney cancers. While only about 5-10% of breast cancers can currently be tracked to gene mutation, says Dr. Medeiros, those who test positive for it have an 80% likelihood of getting the cancer during their lifetime.

A genetic counselor can help women obtain a three-generation family history and determine the appropriateness of genetic testing. A blood or saliva sample can provide results within three weeks. While BRCA testing is expensive, insurance will typically cover the cost of analysis when appropriate personal and family history conditions are met. The Genetic Information Nondiscrimination Act of 2008 prohibits health insurers from denying coverage to a healthy individual or charging higher premiums based solely on a genetic predisposition to developing a disease in the future.

If results are positive, the best clinical management plan can be devised. Typically, a woman would be given the option of yearly mammograms and MRI’s and/or transvaginal ultrasounds and bloodwork starting as early as age 25 and mammograms at 30.

“Unfortunately, mammograms have limited reliability in younger women.” She encourages yearly MRIs linked with mammograms, staggered at six-month intervals, to monitor any changes. “It’s also critical that women realize there’s always a first time in a family history to test positive for BRCA, so they need to be diligent with breast self-exams to watch for lumps, have them biopsied immediately, and have regular pap smears.”

Some patients who test positive for the mutation opt for a mastectomy and/or hysterectomy, which drastically reduces the cancer risk. Tamoxifen is often used to lower a woman’s chance of developing breast cancer, by blocking the actions of estrogen. The drug has been shown to lower risk by 40%; however, side effects may include early menopause and a higher risk of blood clots and endometriosis. Prophylactic ovary removal is another option, but not recommended to younger patients during childbearing years. “We don’t want to put patients into early menopause if we can wait longer.”

Dr. Medeiros urges Primary Care doctors to advise their at-risk patients to undergo individualized cancer risk assessment and genetic testing services as soon as possible. Identifying these at-risk individuals means personalized medical management

interventions that foster early cancer detection and even prevention, and improved quality of life for patients and their families. “It’s critical that physicians look for the major red flags, because most mutations are not genetic in nature.” By the same token, knowing family history is incredibly important to determining eligibility for genetic testing.

Exciting Developments in Treating Colorectal Cancer

Despite increased awareness of colon cancer and the effectiveness of colonoscopies in detecting it, only about half of Americans age 50 or older are up-to-date with colorectal cancer screening. Like other cancers, colorectal cancer is much easier to treat effectively if it’s detected early. Once patients learn about heredity, the risks and even diet and hormonal factors, they can start their screening sooner if necessary.

“Colon cancer is an equal opportunity killer,” says Dr. Claudia



Dr. Lori Medeiros operating with Lisa Fronczak, RPAC.
Photo: Lynne Tseng

Hriesik, a colorectal surgeon at Rochester Colon & Rectal Surgeons. “It’s not rare and it’s not a disease of the elderly. Patients are developing it in their 40s, 50s and 60s, and statistically women get it as often as men.” In fact, 11% of female cancers are colorectal, and with more than 140,000 new cases each year with up to 50,000 deaths, regular anal exams should be a critical component of any good checkup. “If doctors aren’t comfortable performing them, we urge them to send patients our way. For women, pap smears should be tied to anal exams and doctors need to be O.K. with that.”

The top complaint and warning sign, says Dr. Hriesik, is bleeding in the stool. “I say to my patients, if you’re bleeding from the eye, you’d go to the doctor, so you should do the same if you detect a bloody stool. It’s never normal to bleed. Doctors need to make sure there aren’t other causes beyond hemorrhoids, especially in

older patients who complain that something isn't normal." The second red flag is dominant pain and/or a change in bowel habits. "If you go from being very regular to pencil-thin stools, that's not a good sign." In fact, it tends to suggest the cancer is more advanced. Unexplained weight loss and anemia are also warnings signs.

New tests have been developed that look at the activity of many different genes in colon cancer tumors, and can be used to help predict which patients have a higher risk that the cancer will spread. New imaging and lab tests are also being developed, including one with more accurate ways to look for changes in the stool that might indicate colorectal cancer. Fecal immunochemical tests can better detect blood in the stool and another test can detect changes in the DNA of cells in the stool.

"The colonoscopy procedure itself has also improved tremendously," says Dr. Hriesik. "The technology of magnification imaging is better and there's much less required of the patient ahead of time. Patients don't need to drink a gallon of solution anymore – it's more like half a gallon of ginger ale or apple juice, and it's better timed with the exam so they're not so uncomfortable." Better sedative drugs are also available for anxious patients.

Dr. Hriesik performs CT colonographies that can identify many colorectal polyps and cancers early. This test is typically performed once the colon is cleaned out with a large amount of liquid laxative. Colonoscopies are recommended at age 50, but patients with a family history should start at 40. If a colonoscopy identifies a Stage 1 polyp or other small pre-cancerous polyps, doctors will monitor at five-year intervals. For Stage 1 cancerous but confined polyps, the polyp can be removed and oftentimes that may be all that's needed.

"My generation of board certified, fellowship trained surgeons has really embraced minimally invasive, laparoscopic and robotic surgeries," she says. "Robotically, we have better access to pelvic rectal cancer now, so the intervention is better and the sphincter can be spared and reconnected."

Laparoscopic surgery, done through several small incisions in the abdomen instead of one large one, allows patients to recover faster with less pain post-op. "We now have a better understanding of



Dr. Lori Medeiros operating on a breast surgery case in the operating room. Photo: Lynne Tseng

what makes colorectal surgery more likely to be successful," she says, "like ensuring enough lymph nodes are removed during the operation."

However, if surgery is only part of the treatment plan or not an option at all, other modalities can still ensure a successful outcome. In Stage 2 colon cancer, where the polyp has grown and invaded the rectal and colon wall, or traveled to the liver and other organs, doctors need to develop a combined treatment plan – including chemotherapy with radiation therapy, targeted therapies and/or immunotherapy.

"With more targeted therapies, patients can tolerate the cycle of chemotherapy better, which might mean surgery isn't even necessary." Many of these breakthrough chemo drugs are much less toxic on the entire body while assisting with tumor destruction. "Many patients don't even experience the expected hair loss from these new drugs,

especially if they're active." She references one of her rectal cancer patients who decided to take up running again while undergoing chemotherapy. "Patients, especially younger ones, want to maintain normalcy during their treatment, and find they can complete chemo more successfully if they're reasonably active. Many of the potential side effects like nausea can actually be thwarted by staying fit."

Also encouraging are newer chemotherapy drugs and drugs that are already used against other cancers (such as cisplatin or gemcitabine), which are finding success with colon cancer treatment. There are new ways to combine drugs already known to be active against colorectal cancer, such as irinotecan and oxaliplatin, to improve their effectiveness, she adds. Researchers are also studying several vaccines to try to treat colorectal cancer or prevent it from recurring after treatment. Unlike vaccines that prevent infectious diseases, these vaccines are meant to boost the patient's immune reaction to fight colorectal cancer more effectively.

By continuing to remain at the forefront of cancer detection and treatment, these Rochester region surgeons see only brighter prospects ahead. Continued collaboration with PCPs will ensure that patients address potential cancers as early as possible and better understand the many options available to them.

THE JOURNEY FORWARD

Cancer Survivorship & Patient Care



Alicia Maston Coffin

Factors such as breakthroughs in research and treatments, earlier detection, and more accurate diagnoses have resulted in a swell in the number of cancer survivors. The latest estimates from the National Cancer Institute say at least 13.7 million survivors are living in the U.S. today—and that number is expected to grow. This is a cause for celebration!

However, cancer often comes with a host of long-term or delayed health issues, leaving patients with as many questions after completing treatment as when they learned of their diagnosis. They want to know how often follow up visits should occur, what tests should be done to make certain the cancer has not recurred, or what the signs and symptoms of recurrence might be, and what should trigger a phone call to a doctor between scheduled visits. They are also appropriately concerned about the possible long-term effects of the treatment on their health and how they can be best protected.

The goal of a survivorship program is to help patients navigate the complexities of survivorship care and to answer the many questions patients have, which takes a multi-disciplinary oncology team and support system of family, friends and the primary care physician.

In order to make lifelong follow-up care and monitoring easier and more effective, cancer patients can benefit from a personalized, written summary for the next step in their care—a treatment summary and care plan for the future:

The **treatment summary** should include the exact stage and type of cancer, any surgery or procedures, what type of

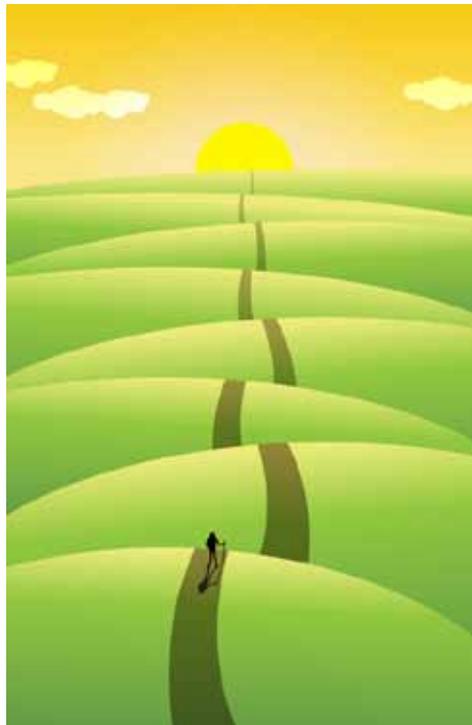
chemotherapy and the dose, as well as radiation dosages and locations of the body delivered.

The **care plan** will provide patients with the potential late effects of the specific treatment received, and map out a plan for how to monitor for these possible effects. This may include monitoring of heart-related concerns, skin reactions to radiation or bone density if hormonal therapies were used in treatment. In addition, it may include contact information for physical therapists, fertility experts, and social workers, as well as helpful facts about diet and exercise.

Patients come away with all the information they need to facilitate and communicate their care with all of their physicians; the care plan simultaneously educates and empowers survivors. The multi-disciplinary approach places an emphasis on the collaboration between all physicians involved in treatment and post-treatment, as well as the primary care physician, and the patient and family. If problems develop, a panel of specialists is ready to see patients right away.

The experience for each patient is often very different, with some people more vulnerable than others. Clearly, though, with an increasing number of people who live many years beyond cancer, it's critical that health providers do whatever possible to improve the quality and duration of the lives of every patient. Survivorship programs play a much-needed role in the delivery of this care:

The James P. Wilmot Cancer Center at the University of Rochester Medical Center is helping patients navigate the



Connecting survivors with support groups in the community, as well as online.

Suggest ways to incorporate healthy habits such as a nutritious diet and exercise.

Identify unhealthy habits that could impede a healthy lifestyle—such as smoking, drinking alcohol or sun protection.

Management of post-treatment symptoms such as lingering pain, fatigue and “chemobrain” that impairs your memory or ability to focus.

Address financial concerns associated with treatment and/or missed work.

complexities of cancer survivorship care with the Judy DiMarzo Survivorship Program—the first in the region to offer this comprehensive approach to survivorship. The ultimate goal of the program is to become a regional resource for all cancer survivors and work with primary care physicians and community programs across the region to best serve this growing population. A nurse coordinator for each discipline is responsible for scheduling the patient’s after-treatment transition meeting, where details of the treatment summary, necessary follow up care, possible needs of the patient and the resources available to meet those needs are discussed. For more information about the program, please call 585-275-6956.

Alicia Maston Coffin is the lead coordinator for the Judy DiMarzo Survivorship Program at the University of Rochester Medical Center. She received a bachelor’s degree in nursing and a master’s of science in family nursing with an advanced certificate in nursing education, all from Binghamton University. She serves as the President-Elect for the Genesee Valley Oncology Nursing Society and is also a member of the national Oncology Nursing Society.



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Integrating Palliative Care and Oncology: *The New Standard of Care*

“Helping Cancer Patients Live Longer, Better.”



Aaron Olden, MD
Director of the Outpatient
Palliative Care Clinic at
Unity Health System MSHA

This headline was echoed on nightly news reports, morning talk shows, and mainstream newspapers a few summers ago when the New England Journal published Dr. Jennifer Temel’s groundbreaking study examining palliative care for patients with lung cancer (Temel 2010). Her conclusion was something that we already knew from our work with oncology patients, but we now had the data: patients with lung cancer have a better quality of life and live longer when they receive palliative care alongside the usual care. We had finally reached the tipping point – bringing palliative care into forefront and solidifying a new standard of care for patients with cancer.

Palliative care is defined by the National Consensus Project as “patient and family-centered care that optimizes quality of life by anticipating, preventing, and treating suffering” (Dahlin 2013). It is considered “an essential part of cancer control” by the World Health Organization. The Joint Commission has introduced an Advanced Certification for Inpatient Palliative Care programs and several area hospitals are now certified. There is no doubt that palliative care has established itself as an essential component of the care plan for patients with cancer, but one question remains: how can we make this a reality?

Inpatient palliative care consultation teams are well-established at all of Rochester’s major hospital systems, and some have been in place for more than a decade. Consultation teams help primary care physicians, oncologists and hospitalists to manage pain and other symptoms and help patients and families to fully understand and make decisions about the direction of care. This inpatient model of palliative care is now familiar to many providers – but leaders locally and nationally have come to realize that forging a close bond with oncology means moving beyond hospital walls to community and outpatient settings (Beresford 2013).

Earlier palliative care for patients with a diagnosis of cancer is nearly impossible without some method of delivery in the outpatient setting. In order to ensure that patients with cancer receive adequate control of symptoms such as pain, fatigue, and depression, palliative care must be consistently available along

the continuum of health care settings. Palliative care programs have responded to this need in part through the formation of outpatient consultation clinics. In addition to specialized management of symptoms, outpatient palliative care can also help to reduce acute care hospitalizations and emergency department visits and increase practice efficiency for partners in oncology.

One of the initial challenges in the development of an outpatient palliative care program is determining the model of delivery. Several models of delivery exist (Barbour 2012, Smith 2013), and the choice of model depends on several factors such as the availability of providers (physician, advance practice provider, social work), finances, and location. The most common models are co-located clinics (palliative care clinicians sharing space with other clinicians) and embedded clinics (shared clinics with a defined collaborative relationship between the clinic and palliative care staff). These models reduce the financial investment required by the hospital system and increase the contact between palliative care providers and referring providers. Embedded clinics may even utilize clinical pathways to ensure patient flow from oncologists to palliative care providers (such as automatic referrals for patients with stage IV lung cancer).

At Unity Health System, we have had a single-provider outpatient program since 2010, with palliative clinic services co-located within one of our primary care practices. This has allowed us to accept referrals from our partners in oncology and other specialties as well as follow up with our patients that we have met in the inpatient setting. In many cases, we have been able to reduce emergency room visits and inpatient hospitalizations and to facilitate the transition between health care settings (including hospice when appropriate).

The feedback we’ve received indicates that our patients have found these services to be tremendously valuable, as have our referring providers. Dr. Alexander Solky of Interlakes Oncology has stated, “Outpatient palliative care has played an

essential role in the treatment of several of my cancer patients. Some patients are afraid to address their concerns regarding pain, depression or anxiety, and having a palliative care provider allows us to address these important issues earlier in the illness.” At Unity Health System. We are currently exploring the embedded clinic model to allow for an even closer relationship between our providers.

Outpatient palliative care is no longer the “wave of the future.” At least for patients with oncologic disease, outpatient palliative care is now! And, as patients and families learn more about how palliative care has helped others and how it can help them, it is something that they are looking to their physicians and health care systems to provide alongside their usual care.

Aaron Olden, MD, MS, is a palliative care physician at Unity Health System. He attended medical school at the University of Buffalo and completed a residency in Internal Medicine and fellowship in Palliative Medicine at the University of Rochester, Strong Memorial Hospital. He was a chief medical resident and obtained a master's degree in clinical investigation after his formal clinical training. He is the director of the outpatient palliative care clinic at Unity Health System and is board certified in internal medicine and palliative medicine. To maintain balance in his life, he enjoys practicing yoga and recently became a Registered Yoga Teacher.

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Minimize Exposure to Stark Law Enforcement Actions through Due Diligence and Understanding Exceptions



David Hou, Esq., Boylan Code

If you are a physician or provider, when was the last time you reviewed your written services contracts for compliance with the Stark Law? Do you have written agreements for all of your financial relationships relating to designated health services? Do you have any financial relationships that generate compensation based on the value or volume of referrals? If you find yourself in any of these common circumstances, you may be at risk of violating the Stark Law. Generally, the Stark Law, Section 1877 of the Social Security Act, 42 U.S.C. § 1395nn, *et seq.*, prohibits a physician from having a financial relationship with another entity to provide designated health services (DHS) to Medicare patients, unless one or more of thirty-five statutory exceptions apply. Broadly speaking, these exceptions require that providers receive fair market value for their services, that written agreements be in place for said services, and that compensation be set in advance, and not depend on the volume or value of said services. Common exceptions include physicians in designated rural or Health Professional Shortage Areas, in-facility physician and ancillary services, arms-length rental of office space and equipment, and *bona fide* employment. The Stark Law is a law of strict liability, meaning that a party's actual intent is irrelevant to the imposition of liability and damages, and that even a technical noncompliance with the law may provide grounds for liability. Damages under the Stark Law includes means full repayment of Medicare funds paid, penalties of up to \$100,000 for each violating referral arrangement, as well as exclusion from future Medicare participation.

Most of the time, physicians and providers do not enter into relationships with the intent of rewarding referrals in violation of the Stark law; nevertheless, despite all good intentions, technical violations still commonly occur when parties mistakenly believe that an exception applies. Particular care and attention is warranted in all circumstances because the breadth and nuances of exceptions can be difficult to grasp, and make it all too easy for a physician or provider to

misunderstand that an exception may apply when in fact it may not. Ongoing amendments and interpretations of previously gray areas of the law as applied to the myriad arrangements that may exist make it even more important that diligent review protocols are established and followed.

It should be apparent that the federal government's ever-present need to meet budgeting shortfalls gives ample incentive to increase enforcement efforts. Indeed, to date in 2013 the

“damages under the False Claims Act include additional penalties of up to \$11,500 per claim, treble damages, and even imprisonment”

Justice Department's enforcement efforts have resulted in wave after wave of provider settlements involving Stark Law self-referral violations and unlawful physician compensation. Although current regulations have not formally extended Stark Law's applicability to Medicaid, there appears to

be increasing consideration by policymakers of whether, and how, to apply the Stark Law to Medicaid claims; a prudent physician or provider would be well-advised not to rely on that mere distinction to avoid liability under the Stark Law for false Medicaid claims.

In any case, it is important to understand the practical perspective that regardless of whether or when the Stark Law may apply to Medicaid claims, significant liability nevertheless exists under the False Claims Act, 31 U.S.C. § 3729 *et seq.* The False Claims Act provides an alternative cause of action for the government to seek damages for unlawful claims Medicare. Under the False Claims Act, a false claim is created upon an intentional failure to disclose a Stark Law violation within sixty days of identifying the overpayment due to the violation. Importantly, damages under the False Claims Act include additional penalties of up to \$11,500 per claim, treble damages, and even imprisonment. Damages under the Stark Act may be cumulative to any additional penalties that may be imposed under the False Claims Act.

As always, it is important to keep in mind that enforcement of unlawful claims via referrals or kickbacks is not limited to claims brought directly by the U.S. Justice Department. The threat of whistleblower lawsuits is ever-present; the fact that

whistleblowers stand to gain as much as thirty percent of each settlement or judgment gives them strong incentive to pursue legal action on behalf of the government, and is only further reason to ensure that diligent compliance measures are implemented and followed. Recent cases illustrate the impact that whistleblowers have on the Justice Department's enforcement efforts.

For instance, in May, 2013, in a case that originated as a whistleblower action, after a retrial, the 242-bed Tuomey Healthcare System in South Carolina was found by a federal jury to be guilty of Stark Law violations and the False Claims Act. The jury awarded a judgment in excess of \$39 million, representing more than 21,000 false claims in violation of the Stark Law, and Tuomey also faces up to \$237 million in additional fines and treble damages under the False Claims Act. At issue in Tuomey was referral fees used to incentivize "part-time" physicians to refer business to the hospital. The government relied in part on the fact that the physicians received compensation that was far in excess of the fair market value for their services, as evidence that their employment agreements improperly took into account the volume or value of their referrals to the hospital.

Similarly, currently pending is a lawsuit seeking as much as \$1.14 billion brought by both the Federal government and a whistleblower (the hospital's director of physician services) against Halifax Health, a 678-bed public hospital system in Daytona Beach, Florida. At issue are more than 74,000 alleged false Medicare and Medicaid claims and Stark Law violations involving oncologists and neurologists who entered into contracts with the hospital to receive compensation in the form of bonuses based on the volume of business referred to the hospital's oncology department. Part of the hospital's defense, and one that is commonly relied on by providers, is that its compensation scheme was necessary to retain quality physician services, and that their compensation was in-line with fair market value. Some of the Justice Department's allegations include the driving up of hospital census from the increased referrals, at the expense of quality patient care. The case is presently scheduled for trial in March, 2014.

While the largest, news-making judgments are often those involving institutional providers like hospitals and laboratories, due in part to the sheer number of allegedly false claims submitted, physicians and providers in smaller facilities have no reason to stand content of the prospect of "flying under the radar" or avoiding significant liability simply through a smaller volume of claims. Recall first that the False Claims Act allows for treble damages; a seemingly small number of claims may easily cause penalties to balloon under this framework. Consider also the fact that a smaller penalty amount may simply affect a

smaller facility proportionately, but no less significantly, than a large penalty may affect a large facility.

Institutional providers often face scrutiny for false claims arising out of compensation to physicians based on volume of referrals. Smaller providers, on the other hand, are more likely to deal also with Stark Law violations for such things as compensation to out-of-facility providers for personal services without written agreements in place, or, particularly, leasing office space for less than fair market value. In each of these instances, written agreements for a term of at least one year should be in place, and the agreements should specify the compensation in advance, and not be based on revenue raised or per-unit of services rendered, and must be based on fair market value.

So, in light of the ongoing escalation in enforcement cases under the Stark Law, and the very real prospect of significant damages, penalties, and fines, what types of diligent compliance action can be taken? Providers should first be sure to review their arrangements under which referrals may be provided, to ensure that an appropriate Stark law exception applies; as part of this process, experienced legal counsel should be sought. In addition, written agreements should be periodically reviewed to ensure that they are current and not expired. Office leases should be periodically reviewed to ensure that they are current and not expired, at fair market value and/or are not tied to the volume of any referrals generated. Finally, providers should consider regular review of services contracts, particularly "evergreen" contracts to ensure that such services are still remunerated for fair market value and that such services are necessary and for legitimate business purposes.

Additionally, the CMS' Self-Referral Disclosure Protocol should be implemented and stringently complied with to resolve any potential Stark Law violations that may be discovered throughout the compliance process. Self-disclosure of potential Stark Law violations is one way to mitigate potentially significant damages. However, before going straight to the SDRP, it is vitally important for providers to consult with legal counsel for an opinion as to the practices or conduct in question, and to devise a strategy for addressing past and future violations. It may well be possible that another Stark Law exception applies, or that the arrangement does not in fact violate the Stark Law at all. All of these measures will not only help negate or minimize the risk of exposure under the Stark Law and the False Claims Act, but will also help mitigate damages by increasing the likelihood of favorable settlement.

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Computer Self-Defense

*Several times per week, I receive a phonecall from an otherwise intelligent person (doctors, lawyers, and business owners) claiming that their computer is slow. It's giving them a lot of cryptic errors, asking them to perform obscure maintenance tasks, and they proceed to tell me that they're stupid and/or technically illiterate. **Stupid, imagine that!***



Marc-Anthony Arena

Step back a second. We all know doctors aren't stupid.

Why, then, would these people feel that way?

- Their "computer guys" talk down to them
- They believe computers still require constant maintenance such as defragging
- Their computers have constant popups with irrelevant technical info
- They're bombarded with buzzwords that sound scary, such as "cookies" and "identity theft"
- They haven't had a basic class on computer concepts to give them the confidence they need.

Let me put things in terms you'll understand...

- Would you talk down to your patients if they couldn't perform surgery on themselves? Of course not.
- How would you feel if new patients came to you asking you to perform bloodletting or some other archaic practice?
- I'm sure you have had patients who come in asking what toxins or magnetic bracelets do.

So, here are some tips on how you can feel more confident with your technology:

- Viruses are essentially irrelevant. The new threats to watch out for are Rootkits, Fake PC Cleaners (basically anything that says Mechanic, Cleaner, Registry, etc.), and gray-market browser hijackers such as Babylon, MyWebSearch, or Ask.com.
- Nigerian-style Viruses (there is NO security software in the world that can prevent one of these). These babies impersonate antivirus software (the newer ones even show the FBI logo) and scare you in the hopes of getting your credit card number.
- Your computer guy may not know this, but Defragging is also irrelevant. The REAL reason why your computer slows down over the years has to do with how many companies are lurking in your computer. One of my favorite examples of legal, corporate malware is HP Customer Participation Program. How many of you knew your HP printer reported your behavior back to the mothership?
- Although this is hard to do in the professional world, use Macintosh computers. If you do so, it is virtually impossible for you to contract a case of malicious software.

- Sure, Electronic Medical Records are faster and more efficient than paper charts, but find out who has access to them, including your vendors and regulatory bodies.
- Sign up for my class at Perinton Community Center, entitled How to Protect Yourself from Your Computer. There you'll learn concepts such as memory, hard drives, processors, the Cloud, and how to avoid Windows 8.

About the author:

Marc-Anthony Arena is founder and President of Teknosophy, LLC in Rochester. His company focuses on protecting its customers from viruses, toolbars, online scams, and nag-ware. He is also the host of "The Computer Exorcist Show" on WYSL radio 92.1FM, and teaches computer self-defense classes at Perinton Community Center. You can reach him at 789-1856.

Visit Marc Anthony Arena's blog at www.teknosophy.com

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New Cancer Imaging Technology Shows Promise



A new imaging technology that combines ultrasound and laser technologies has been shown to be highly effective in identifying prostate cancer. The system, which was developed by University of Rochester Medical Center (URMC) researchers, could also ultimately be deployed to detect and track breast, kidney, liver, skin and thyroid cancers.

The new medical imaging technology – called multispectral photoacoustic imaging – was created by Vikram Dogra, MD, a professor in URMC's Department of Imaging Sciences, in collaboration with Naval Rao, PhD from the Rochester Institute of Technology's Chester F. Carlson Center for Imaging Technology.

Physicians currently have a suite of tools at their disposal to test for prostate cancer. Monitoring PSA levels, digital rectal examinations, and transrectal ultrasound are all used as frontline screening tools. The current gold standard for a definitive diagnosis of an aggressive vs. slow growing prostate cancer is a prostate biopsy. But even this method – which is invasive, uncomfortable, and carries a risk of side effects – has its limitations; cancers are

only successfully detected 70 percent of the time.

Seeing the need for a noninvasive and effective imaging technology to detect cancerous tissue, Dogra and his colleagues began to explore the use of a hybrid technology that combines ultrasound and laser irradiation.

The system uses nanosecond long bursts of light from a laser to bombard the target tissue. This heats the tissue and creates thermal waves that can be detected by ultrasound. These signals are then used to recreate an image of the target tissue and – because different wave lengths elicit different responses – observe variations in light absorption. To accomplish this, the researchers used an acoustic lens to focus the image, a method that is more cost effective than the alternative electronic focusing system.

The system enables researchers to track the level of lipids (fat), water, and forms of hemoglobin found in the blood, all of which respond to different wave lengths from the laser. Fluctuations in these compounds can indicate a tumor's status. Hemoglobin, the protein in red blood cells responsible for transporting

oxygen, is of particular interest. Increases in the level of deoxyhemoglobin – the form hemoglobin without the bound oxygen – significantly raises the odds that the tissue is malignant.

“By observing increases and decreases in these things, particularly deoxyhemoglobin levels, we can tell if the tissue is malignant or benign,” said Dogra.

Earlier this year, the researchers presented the findings of the first study using multispectral photoacoustic imaging to evaluate prostate cancer specimens at a meeting of the meeting of the American Roentgen Ray Society. The system was able to identify 25 or 26 healthy prostates, and 12 of 16 cancerous prostates, a 96 percent and 81 percent success rate.

Dogra and his team are now in the process of developing a prototype version of their scanner and hope to begin clinical evaluation of the device within two years. They believe that the system will ultimately be significantly less expensive – both in terms of equipment cost and cost per test – than biopsies and that the underlying technology could ultimately be applied to several other forms of cancer.

URMC Study Clarifies Surgical Options for Kidney Cancer

Surgery is often the first step in treating kidney cancer, and new data from the University of Rochester Medical Center, which contradicts earlier research, questions whether removal of only the tumor (partial nephrectomy) is better than removing the entire kidney (radical nephrectomy).

The decided trend for the past decade has been toward a partial resection in the case of smaller cancers. It was based on several earlier studies suggesting that it's better to save as much kidney tissue as possible, and thus preserve kidney function and reduce the likelihood of kidney failure in the long run. Many physicians inferred that a radical nephrectomy would be worse for kidney cancer patients, due to a concern that even mild or moderate dysfunction in the remaining kidney could lead to an earlier death.

However, the URMC found the opposite to be true: that losing a whole kidney to surgery does not translate into poorer outcomes for patients. In fact, those people who received a partial nephrectomy did not have improved survival, according to the study published in *European Urology*.

“Our data appears to seriously question the assumption that by saving kidney tissue, we are helping patients avoid future kidney failure,” said Edward Messing, MD, chair of Urology at URMC. “It may be that losing kidney tissue from surgery is not the same as losing kidney function from medical diseases like diabetes or hypertension.”

The latter point is an important one for patients who're weighing surgical options, Messing added. Often, all types of kidney impairments are lumped into one category. It may be, however, that common medical conditions such as high blood pressure or diabetes take the biggest toll on kidney health. Therefore, if a patient is otherwise healthy and the second kidney is functioning well, he or she can safely consider a radical nephrectomy, if that seems to be the best option for cancer removal, he said.

URMC Ophthalmologists Introduce FDA's Tiniest Medical Device to Region

Flaum Eye Institute debuts iStent to ease eye pressure from glaucoma



Shakeel Shareef, MD

The iStent is just 1 mm long and the newest therapy for glaucoma.

Doctors at the University of Rochester Medical Center's Flaum Eye Institute are using the tiniest device ever approved by the FDA to help prevent the blinding effects of glaucoma.

Ophthalmologist Shakeel Shareef, MD, is the first in the region to use the iStent Trabecular Micro-Bypass Stent to manage the effects of glaucoma, one of the leading causes of blindness in the United States.

"This is an amazing device to use to support patients who are suffering with glaucoma and cataracts who can't tolerate the many eye drops required every day," said Shareef, the region's leading microsurgeon who has performed 18 procedures since mid-April. Since the tiny stents were placed, all patients experienced quick vision recovery, ended the use of glaucoma medications and had eye pressure drop dramatically.

This titanium device is invisible to the eye once it is implanted by a skilled microsurgeon.

The titanium, tube-like iStent is just 1 mm long and has a microscopic opening of 120 microns in diameter. It is implanted during surgery to remove cataracts.

High pressure in the eye is the only modifiable factor when treating glaucoma and the number one risk factor for developing glaucoma. The main cause of the elevated eye pressure is poor drainage in the eye. A section of tissue, called trabecular meshwork, gets clogged, creating resistance and then fluid builds up, increasing intraocular pressure. The iStent allows the fluid to bypass the trabecular meshwork redirecting it to drain through normal channels.

The device is only approved for use on adults who are currently using a daily regimen of eye drops, Shareef said.

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Helping Doctors Manage Patient Compliance, Curb Abuse

ACM's New Opiate Screening Test

by Julie Van Benthuisen

One of the most frustrating obstacles facing Primary Care doctors is patient non-compliance – particularly when it comes to managing prescription pain medicine. Whether it's the patient who doesn't take medication often enough because of negative side effects, or another who takes more than prescribed, physicians continue to struggle with treating these patients successfully over the long-term.



Dr. Mary Williamson, Vice President of Scientific Affairs and Laboratory Operations

In response, ACM Medical Laboratory has recently made available a new screening test called Opiates for Pain Management. Designed for use by providers prescribing opiate-derived medications like Codeine, Vicodin or Oxycodone, this test is significantly more effective than previously available tests.

“Opiates for Pain Management offers the clinician a much better option in monitoring the use of the medication to ensure patients are compliant with their prescription regimen,” says Dr. Mary Williamson, ACM's Vice President of Scientific Affairs and Laboratory Operations. The test employs both an Enzyme Immunoassay and a Gas Chromatography/Mass Spectrometry (GC/MS) test, considered the gold standard for urine drug testing. “It positively identifies drugs by comparing the sample to a known standard.”

The GC/MS test can detect use within one to three days, and has a positive cutoff of 50 ng/mL. Sample results will be reported as “Present” or “Not Present.” Because all samples are tested by GC/MS, a “Not Present” result can be relied on to accurately show the patient has not consumed the drug within the detection time window.

Until now, testing was performed using different methods based on higher levels. “This new screening test has the lowest cut off for determining if the sample is positive for the presence of a particular drug,” says Mike Peterson, ACM's Manager of Toxicology. Made available this spring, the test is already being used regularly by Unity Hospital doctors. “We're also seeing more outside clinics using the screening test, and are hoping it will soon spread to the broader medical community.”

The Opiates for Pain Management test represents a significant benefit to both provider and patient. “As doctors become more aware of its availability, they can begin to fix the misinterpretations present in other tests to better ensure their patients are following the right health regimen for their pain management,” he says. Establishing a relationship of trust is critical. Many doctors fear that requesting a urine sample might be interpreted as mistrusting the patient. However, if approached in a respectful, patient-oriented way, patients will likely agree that testing is their best chance for success. Being able to document that the patient is complying with his or her drug regimen will only confirm their mutually agreed-upon treatment plan.

Understanding Metabolism

While most physicians understand the effects of metabolism on opiate detection, Peterson stresses the importance of looking twice at a patient's results to become more familiar with the detection process. “It's often a product of their metabolism whether the opiate shows up in their urine or not.”

“When doctors better understand the basic metabolism of commonly prescribed drugs, especially opioids, they'll be able to better explain a test result that's positive for the prescribed medication and/or its metabolites,” says Peterson.

A doctor might order a drug screen, for example, to ensure a patient is using her Oxycontin prescription appropriately, before agreeing to endorse a new prescription. Because of the critical time factor involved that influences the test's sensitivity, Opiates for Pain Management is proving to be an invaluable tool. “It's ultimately designed to improve patient care and assist

the healthcare professional to advocate on the patient's behalf," he says.

"It's a win/win situation, because ultimately the patient wants to feel more confident in their provider as well."

When It's An Issue of Abuse

This new screening test couldn't come at a better time. According to the Centers for Disease Control (CDC), prescription drug use in America is at epidemic proportions and increasing every year, with up to 20% of Americans using prescription drugs for non-medical purposes. Enough painkillers were prescribed in 2010 alone to medicate every American adult every four hours for one month. In fact, the quantity of prescription painkillers



Photo: Walter Colley

sold to pharmacies, hospitals, and doctors offices was four times higher in 2010 than in 1999. What's more, Western New York actually reports one of the highest incidences of prescription opiate use in the country, she says.

Most people using drugs without a prescription obtain them from people they know, who originally got them from doctors. "Our region's physicians are under increasing pressure to provide better monitoring of compliance because of the rising incidence of street-sale opiates," says Dr. Williamson. Here in New York in the last year alone, more than 22 million prescriptions for painkillers were written in a state with less than 20 million people.

"It's critical that we continue to educate doctors on the risks associated with prescribing and taking controlled substance pain medications," she adds. Healthcare providers should prescribe prescription painkillers only when other treatments have not been effective for pain. "They should also be prescribing only the quantity of prescription painkillers needed based on the expected length of pain." Compliance is one thing, but abuse of the drug is another. Fortunately, recently passed legislation called IStop will make significant changes to the

way prescription drugs are distributed and monitored in New York State. IStop includes "real time" prescription tracking to provide more information to doctors and pharmacists, in an effort to prevent deaths from abuse and overdoses of prescription drugs, particularly painkillers.

The provisions of the legislation also include e-prescribing, making New York a national leader by moving from paper prescriptions to a system mandating electronic prescribing. This measure will help prevent people who abuse prescription painkillers by obtaining misappropriated prescriptions from friends or relatives.

"People are diverting these drugs to the street and it's becoming rampant," adds Peterson. For example, a patient in his early 20s might visit his doctor with symptoms of appendicitis, undergo an appendectomy and be prescribed oxycodone for pain relief. He may use a few of the pills and hold the rest back, which can then be sold on the street in excess of \$100.

Another patient might complain of non-specific back pain, receive a prescription, and turn around and sell the pills on the street for \$120 to \$240. On his return visit, he may crush a portion of a tablet and add it to his sample, so that the drug screen will show a positive result for oxycodone. However, if doctors use the Opiates for Pain Management test, it will more accurately show if the patient is taking their prescribed medication, by showing both the oxycodone and its metabolite, oxymorphone.

Unfortunately, back pain is subjective, Peterson says, so an alarming number of prescriptions are written to patients who either don't really need the drug or who see a quick way to make money. "It's a simple case of diversion," says Peterson. "Doctors have assessment tools, but it's difficult to monitor without the right screening."

The rising abuse reflects a combination of increasing prescriptions year over year, with the explosion of foreign internet pharmacies. While abuse in the younger population is slightly higher, he says, it's still an equal-opportunity offender. "The problem reaches across the board, regardless of age, race or economic status."

When the addicted patient enters the doctor's office, it's up to the physician to help diagnose relapse or drug misuse as early as possible. Whether the drug has been prescribed or not, the nature of drug addiction means it's hard to stop once you've started. Bingeing by the patient, for example, can result in unexpected negative urine reports if the patient runs out of medication prior to urine sample collection.

"Doctors now have the right tools for success," says Dr. Williamson. "The combination of the new screening test, the IStop initiatives and elevated physician awareness will ultimately help aid compliance and stop the more widespread abuse."

ACM Medical Laboratories Opens Patient Super Centers To Enhance Convenience and Overall Experience

By Julie Van Benthuyesen



Tom DePalma, ACM's Director of National Sales

Following a national trend to improve patient satisfaction, ACM Medical Laboratory has opened three Patient Service Centers (PSCs) for the collection of samples for medical laboratory testing. While ACM operates numerous labs throughout the Rochester region, these PSCs represent an opportunity to improve upon a tradition

of excellence it has maintained for close to 40 years. Traditionally, ACM's smaller, owner/operator centers scattered throughout Western New York have been one-person staffed, often resulting in long wait times and patient dissatisfaction.

By embracing a Super Center model, ACM can ensure that patients are seen within 10-15 minutes. The larger 2,000-2,500 square foot facilities provide a more comfortable, inviting setting for patients, particularly those required to fast prior to having blood drawn. Each center maintains one full-time receptionist to handle check-in and insurance processing and three full-time phlebotomists -- including a pediatric blood draw specialist.

"For our little patients, we have designated play areas. It makes for a much more calming place for child and parent alike," says Tom DePalma, ACM's Director of National Sales.

Each Super Center has been strategically placed in retail locations near convenient pharmacies, with better parking and handicap accessibility. With extended service hours (6AM - 5PM Monday through Friday and Saturdays from 6AM to noon), more patients are benefiting from faster lab draws and subsequently greater satisfaction with their lab visit.

ACM's first PSC was opened in September 2012 at the Elmgrove Crossings Plaza aside the Westside Family YMCA in Gates, resulting in the closing of three smaller ACM labs within a 3-mile radius. More recently this summer two additional locations were opened -- one on Webster's Empire Boulevard in Baytowne Plaza across from Walmart,

and in Ridge Hudson Plaza in Irondequoit just behind Walgreens.

"Already, our patient satisfaction scores have been exceptional, with 95% of people happy and seen in less than 20 minutes," says DePalma. While initial data is still being evaluated, it's already a clear gain for ACM in terms of cost



Photo: Jim Montanus at Unity.

efficiencies and increased patient volume, and for patients and doctors in time savings. "We want patients to have a positive encounter when they have their lab work done."

ACM staff is also benefiting from the new space, which includes a staff break room, more restrooms, and staggered lunch breaks so the doors stay open for patients visiting during their own lunch hours. "It's a huge booster shot for patients and staff alike," he adds.

Area physicians appreciate their patients' elevated satisfaction for good reason. "Doctors view our labs as an extension of their provider practice, so coming here should be a positive reflection on their practice as well." Many providers who see patients late into the afternoon can count on the later hours of operation, with ACM accepting lab requisitions from any physician's office.

"It makes sense that as we concentrate more on the patient, we'll continue to consolidate our smaller locations to enhance the Patient Super Center model."

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What is My Liability?

Medical Record Documentation

Issue

It has been said that “excellence in medical documentation reflects and creates excellence in medical care” perhaps because logical medical reasoning is reflected in good medical record-keeping. Documentation by healthcare providers within the medical record of a specific patient serves numerous diverse but equally important purposes, for example: (1) creation of a record memorializing the patient-physician/provider encounter; (2) creation and perpetuation of a patient’s medical history; (3) facilitation of formal communication among various members of the healthcare team; (4) contemporaneous memorialization and explanation of medical decision-making which occur during a specific encounter; (5) creation of a foundation for peer-review and quality-assurance activities; (6) justification of the level of professional and/or hospital charges submitted to third-party payers; (6) to provide data for medical research; and, (7) compliance with administrative and regulatory requirements. Elements of a complete medical record will range from consents to treat, imaging and laboratory data, and provider entries but may also include medical records obtained from prior treating providers. Physicians should understand that due diligence mandates review of all available data and the fact that the data has been reviewed, should be noted in the record.

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James E. Szalados, MD, MBA, Esq.

the healthcare team; (4) contemporaneous memorialization and explanation of medical decision-making which occur during a specific encounter; (5) creation of a foundation for peer-review and quality-assurance activities; (6) justification of the level of professional and/or hospital charges submitted to third-party payers; (6) to provide data for medical research; and, (7) compliance with administrative and regulatory requirements. Elements of a complete medical record will range from consents to treat, imaging and laboratory data, and provider entries but may also include medical records obtained from prior treating providers. Physicians should understand that due diligence mandates review of all available data and the fact that the data has been reviewed, should be noted in the record.

Medical records are legal documents that are used as evidence in courts of law. The most effective way for physicians to minimize the exposure attendant with a poor medical outcome is to ensure that the data and reasoning pertinent to a patient’s medical care has been entered into that patient’s chart. Malpractice claims are frequently asserted despite even when the physician acted at all times in accordance with good and accepted medical practice. When a patient-plaintiff’s attorney first begins to assess a potential claim, a process of discovery is initiated and the medical record is obtained through a *subpoena duces tecum* in accordance with a HIPAA compliant authorization signed by the patient or his or legal representative. Subsequently, the plaintiff’s attorney will have that record scrutinized by a medical expert who will attempt to build a theory or medical negligence based primarily on omissions, discrepancies, and poorly documented medical reasoning. In the absence of a well-documented medical record, a physician-defendant will face a challenge in arguing and proving that the care provided was in accordance with the standards of medical care. The issue of sufficiency of documentation is controversial: Many argue that a more superficial documentation improves defensibility by allowing for difficulties in recall of potentially incriminating aspects of a case, relying on “I didn’t write it down but I certainly remember doing it”, or, to facilitate the introduction of custom and habit, or other indirect defensive

arguments. On the other hand, many will argue that in the case of a lawsuit, there is rarely too much documented in the records, especially as it pertains to differential diagnosis, decision-making and patient counseling. Careful documentation infers that the documenter is careful, caring, considerate, and thoughtful. Medicine is not an exact science and unfortunate outcomes will occur even with the best of care and errors in judgment in themselves are not actionable, however juries are more likely to forgive mistakes when the documentation supports thoughtful analysis and consideration of competing alternatives. Non-documented recollections and habit testimony will affect the weight of a testimony and juries are more likely to believe a testimony which is supported by a strong medical record. Obviously however, complete documentation is an enormous, if not impossible, task given the time constraints of clinical practice. It is important to avoid open controversy in a note, since plaintiff attorneys will later seize on the apparent divisiveness in the care team and exploit it fully. Finally, it is important to avoid defensive entries in the record, especially when the note follows an adverse event since such entries may be construed as being self-serving.

Dictated and transcribed medical records have become an attractive alternative to handwritten notes both in written and electronic charts. The relative ease of dictation helps facilitate contemporaneous, more complete, and legible documentation. Most physicians can dictate more easily than they can either write or type without writing or typing fatigue. Proponents of dictation argue that ease and speed of dictation helps include the elements of history, examination, data review, differential diagnosis, and discussions to more optimally document the clinical encounter; whereas others argue that speech recognition errors and overly verbose progress notes can jeopardize the credibility and the functionality of the record since there can be too much information for subsequent caregivers to search through. Reasonable efforts to proof-read dictated notes are imperative although there is a tendency to subconsciously read a dictated note as it was meant to be dictated and not as it appears, especially if the proof-reading occurs soon after the dictation. Physicians dictating their notes should include a simple non-defensive disclaimer mentioning that the note was dictated and reviewed, but that it may contain some errors. Providers should not use a “dictated but not read” stamp since such blanket disclaimers help plaintiffs allege that the provider was “too busy” or “too unconcerned” to ensure the accuracy of the medical record.

Charts which have been altered after the fact can have a serious and detrimental impact on a provider’s ability to defend against a claim of malpractice or general negligence. Case law specific to the doctrine of spoliation of evidence upholds the theory that if any pertinent medical documentation or data cannot be made available when subpoenaed, the court is permitted to infer, and

to instruct the jury to infer, that the materials, if they would be available, would be detrimental to the defensibility of the case. Thus, in a sense, when, aspects of the medical record are missing, the court and jury may reasonably infer that they had been intentionally hidden or destroyed in an attempt to hide the true facts. A chart which has been materially altered is notoriously difficult to defend in a malpractice proceeding.

The information contained in the medical record is the property of the patient; thus, the physician’s office or the hospital are merely custodians of that record. Patients are increasingly requesting that they have access to their records to make corrections and notations – a controversial notion which might undermine the fundamental purpose of the chart as a physician’s work-product. Nonetheless, patients must be permitted to obtain copies of their records for a nominal (usually statutory) fee.

Physicians and institutions have a responsibility regarding not only the maintenance but also the retention of medical records. Rules and regulations regarding the retention of medical records are found in a number of state and federal laws, medical board and association policies, institutional policies, and medical liability insurance carrier recommendations. In addition, the type of record, such as for example, an adult patient versus a pediatric patient record, will also determine the applicable regulations. Failure to maintain medical records for predetermined statutory periods of time may result in civil liability and sanctions against one’s licensure by the State Department of Health. Medicare Conditions of Participation require hospitals to retain records for five years; six years in the case of critical access hospitals. OSHA requires employers to retain medical records of employees who have been exposed to toxic substances and harmful agents for a period of 30 years. In all cases, medical records should be retained for at least as long as the length of time of the statute of limitations for medical malpractice claims, which vary by state. In NY State, the Statute of Limitations is typically 2.5 years; however, that statute of limitations may be extended in the case of continuous ongoing treatment for the same medical condition, or, in the case of minors, for example. Before destroying old medical records, patients should be given an opportunity to claim their records or to request that the records be forwarded to another physician. In the case that a practice is sold, merged, or dissolved, it is important that physicians consult with an attorney with expertise in healthcare law to best navigate the multiple legal mandates pertaining to medical record retention.

Dr. Szalados is a licensed physician engaged in the practice of anesthesiology and critical care; a senior-level hospital administrator, and an attorney admitted to the practice of Law in New York and concentrates his practice in the areas of Health Law. Dr. Szalados is an attorney with healthcare law firm of Kern Augustine Conroy & Schoppmann, P.C.



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A HIPAA REFRESHER COURSE

Question

I've been running a medical practice since before HIPAA became a fact of life, and have reviewed HIPAA forms and attended HIPAA training for years now. But I'm not sure I really understand all that is required. At the least, I need a refresher course. Short of reading the new regulations, how can I update my knowledge?

Answer

If you were practicing medicine in 2003, when the HIPAA Privacy Rule became effective, you hopefully have absorbed at least the minimum of HIPAA knowledge you need (assuming you added HIPAA Security and Data Breach Notification requirements to your knowledge base, as well). But you probably acquired a few HIPAA myths along the way that need to be debunked. And, if you've been following our recent Q&A's, you know that we have entered a new HIPAA phase.

You can't assume that your Notice of Privacy Practices, standard release of information form, and employee confidentiality agreements will be enough to help you deal with a patient's HIPAA complaint or provide adequate documentation for an Office for Civil Rights' audit.

One way to refresh your knowledge of HIPAA is to view the training videos and written educational materials made available free of charge by OCR and Medscape and which have the added benefit of CME credit. To access the training materials, which have been updated to address recent changes in the rules, visit: <http://ow.ly/oKACH>. This training doesn't replace your own policies and procedures and full staff training, but it is a good start for acquiring the knowledge that will help you comply in this new HIPAA era.

For more HIPAA information and resources, please contact our Managing Partner, Michael J. Schoppmann, Esq at 1-800-445-0954 or via email at MSchoppmann@DrLaw.com.

“Playing tennis at a moderate to vigorous intensity on a regular basis is a good way to get aerobic exercise and can even help lower your blood pressure. All of that helps reduce the risk of developing heart disease or of having a cardiovascular event, such as a heart attack or stroke.”

Gordon Blackburn, PhD,
*exercise physiologist at the
Cleveland Clinic Heart and
Vascular Institute*

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What's Old Is New Again

The Art and Science of Compounding

Stacy Wright

Once upon a time, before there were brand name pharmaceutical medications, there were compounded medications. At one time, nearly all prescriptions were compounded, but the 1950's and 60's heralded mass drug manufacturing, therefore greatly lessening the need to create tailored medications. Naturally, the demand for pharmacists and physicians to be trained on compounding also declined, and the one-size-fits all approach rose to the medicinal forefront.

Compounding is the art and science of preparing personalized medications for patients, and recent years have seen its resurgence in almost every area of healthcare. Why? It's designer medication for your patients. Almost any kind of medication can be compounded and thus becomes ideal for any patient requiring unique dosages and/or delivery devices.

BENEFITS

- The primary reason for compounding is to avoid patient non-compliance. A medication is ineffective if a child spits it out or if the patient is unable or unwilling to use the medication as directed. Adjusting the strength or formulation of a medication can ensure tolerability and compliance.
- Many patients take more than one medication—compounding can often combine these into one simple-to-take formulation.
- An extensive variety of tailored delivery forms waits for patients: topical gels or creams that can be absorbed through the skin, suppositories, sublingual troches, capsules, liquid suspension, or even lollipops. Consider patients who have difficulty cutting pills in half: they can have a decreased dose compounded. Children who balk at their unpleasantly flavored medications can have them delivered in grape troches or banana suspensions.
- Avoid unwanted ingredients such as dyes, preservatives, lactose, gluten, or sugar—ingredients can easily be excluded from medications due to allergies or other sensitivities.

If you have any patients dealing with conditions such as chronic pain, aches, neuropathies, or wound healing, they can benefit from a topical compound designed to target a specific location on the body—without the unwanted side effects of an oral drug. Likewise, hospice patients suffering from pain, nausea, and other symptoms who can't tolerate certain oral medications gain relief from these site-specific compounds.

Buffalo Pharmacies has been operating in the Buffalo area for 50 years and compounds for many institutions, such as Dent Neurological Institute, Rochester Brain

and Spine, The Buffalo Zoo, and Roswell Park Cancer Center. The Pharmacy manages requests from oncology providers who need medications for patients who have low tolerance for side effects from oral medications. "We can combine an anti-emetic, pain reliever, NSAID, and local anesthetic in one prescription," said Mike Heins, one of Buffalo Pharmacies' compounding pharmacists. "The patient pays for one prescription—not four, the medication is site-specific and absorbed through the skin—not systemically, and we can select a delivery method or flavor that works for the patient."

When asked about the cost and prescription coverage of the compounds, Buffalo Pharmacies said that they may not cost more than conventional medication. Cost typically depends on factors such as the type of ingredients and equipment required, plus the time the pharmacist spends researching and preparing the medication. Many commercial insurance plans cover the cost of compounded prescriptions; if they do not, the pharmacy tries to come up with a more cost effective alternative: "It's an option that is easily explored. If a compound is faxed over, we call the patient to determine coverage and work with them to determine their best cost option."

The FDA recognizes compounded prescriptions as both ethical and legal as long as they are prescribed by a licensed practitioner for a specific patient and compounded by a licensed pharmacy. In addition, compounding is regulated by state boards of pharmacy. While most larger chain pharmacies don't offer compounding options, highly specialized independent pharmacies will often offer this valuable service for their patients.

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Physicians Should be Cautious in Asset Protection Planning

Question

I have been advised to move my assets into an asset protection trust. What are the pros and cons of such a trust?

Answer

Physicians should do asset protection planning because of the liability associated with the practice of medicine. However, not all asset protection plans are the same. The United States Tax Court recently held, in the case of *Vlach v. CIR*, T.C. Memo 2013-116, that a doctor's asset protection plan was a sham and caused the doctor and his wife to pay over \$300,000 in taxes and penalties.

The doctor was advised to transfer his home and medical practice to an asset protection trust. In addition, there were a number of shell corporations set up. He and his wife were the trustees of the trust. The doctor was further advised that he could deduct payments to the trust for expenses like mortgage payments and property taxes. Needless to say, the doctor and his wife were incorrectly advised by a trust scammer who has spent time in federal prison for his activities.

The rule of thumb in asset protection is if it sounds too good to be true, then it probably is. An asset protection plan should be designed specifically for you, your family, and your medical practice and should take into account your retirement needs and tax consequences, as well as liability protection. Some asset transfers can negatively affect compliance with regulations applicable to medical practices and ancillary service providers. Make sure that you work with an estate planning and asset protection attorney who is reputable in the community and familiar with planning for physicians.

If you have any questions or would like to discuss protecting your assets, please contact our Managing Partner, Michael J. Schoppmann, Esq at 1-800-445-0954 or via email at MSchoppmann@DrLaw.com.

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in Area Healthcare



RGHS

Dr. Eugene P. Toy Named Chief of OB/GYN and Director of Gynecologic Oncology

Rochester General Health System (RGHS) has named Eugene P. Toy, MD, to the dual positions of Chief of Obstetrics and Gynecology, and Director of Gynecologic Oncology.

Dr. Toy received his MD from the Mount Sinai School of Medicine, and completed a residency in Obstetrics and Gynecology at the URM. He completed a fellowship in Gynecologic Oncology at Yale University School of Medicine, and is board certified in Obstetrics & Gynecology, and in Gynecologic Oncology.

Dr. Toy, who pioneered the use of robotics in gynecologic oncology surgery at RGH, has practiced in the Rochester area for the past 11 years. In addition to his clinical and administrative duties, he is an active researcher in scientific studies of cancer-causing proteins of the human papillomavirus.

"After an exhaustive search, we were delighted to find our new Chief of OB/GYN Services already within the Rochester General community," said Robert Mayo, MD, Chief Medical Officer. "Dr. Toy's exceptional clinical and administrative skills are matched by an intuitive patient-focused sensibility. We are extremely fortunate to have him rejoin our health system in this permanent and important role, as we continue to refine and enhance our OB/GYN, gynecologic oncology and robotic surgical offerings."

vice will enable patients and families living in Wayne County and the Finger Lakes Region to receive high quality pulmonary care in their community.



Newark-Wayne Community Hospital Welcomes Two New Physicians to the Medical Staff

Emily Beers, MD, a plastic surgeon, is now seeing patients at the Department of Surgery

at Newark. Dr. Beers earned her MD at the Ohio State University College of Medicine and completed her residency in Plastic and Reconstructive Surgery at the URM.

She is available to diagnose and treat conditions requiring cosmetic and reconstructive plastic surgery using the latest techniques including: facial trauma, breast reconstruction, hand surgery, lesion removal and more. Dr. Beers is on staff with the Plastic Surgery Group of Rochester. Appointment can be made by calling (585) 922-5840.

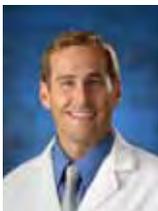


Peter Stasko, DPM, a fellowship-trained foot and ankle surgeon has joined Newark-Wayne Community Hospital's medical staff. Dr. Stasko attended attended Des Moines University College of Podiatric Medicine.

He completed his residency training at the Western Pennsylvania Foot and Ankle Surgical Residency program in Pittsburgh, PA, where he served as chief resident. In addition, he completed a foot and ankle fellowship at the Mon Valley Foot and Ankle Reconstructive Fellowship with The Orthopedic Group in Pittsburgh, PA, where he focused on advanced reconstruction, arthroscopic procedures, and trauma.

Dr. Stasko sees patients at the Finger Lakes Bone and Joint at offices in Newark and Geneva. Appointment can be made by phone in the Newark office (315) 359-2696 in the Geneva office (315) 789-5061.

FINGER LAKES HEALTH



FLH Medical welcomes Orthopaedic Surgeon Dr. Andrew Ritting

Dr. Ritting has extensive fellowship training in hand and upper extremity conditions and

offers comprehensive services to improve function and relieve pain in the hand, wrist, elbow and shoulder.

Dr. Ritting attended medical school at Wake Forest University School of Medicine, completed his residency in Orthopaedic Surgery at the University of Connecticut-School of Medicine and a fellowship in Orthopaedic Hand and Upper Extremity at the University of California-Irvine.

treatments. He will also be seeing patients at the Wilmot Cancer Center.

Dr. Bylund recently completed his residency in Radiation Oncology at the URM. He completed a preliminary year of residency training in internal medicine at Saint Louis University in 2009.

He is a member of the American Society for Radiation Oncology, Radiological Society of North American and American Brachytherapy Society.

NEWARK COMMUNITY HOSPITAL



Pulmonary Services Now Offered at Newark-Wayne Community Hospital

Gary Wahl, MD and David Lee, MD, from the Department of Pulmonary/Critical Care Medicine at Rochester General Health System (RGHS) will provide consultative pulmonary services for inpatients and outpatients at Newark-Wayne Community Hospital.



Dr. Wahl is the chief of Pulmonary/Critical Care Medicine for RGHS. This new ser-

HIGHLAND HOSPITAL



Dr. Kevin Bylund Joins Highland Radiation Oncology

Highland Hospital welcomes Kevin Bylund, MD, to the Radiation Oncology Department where he will be caring

for patients undergoing radiation cancer

UNITY HEALTH SYSTEM



Unity Welcomes New Providers – Paul A. Patrick, MD and Yana Levin, MD

Dr. Patrick will join the Unity Emergency Center. He earned his Doctor of Medicine degree from the URM. He completed his residency in emergency medicine at Strong Memorial Hospital. Dr. Patrick is a member of the American College of Emergency Physicians.



Dr. Levin joins Unity's Intensive Care Unit. She earned her Doctor of Medicine degree from Mt. Sinai Medical School of New York University and completed her residency in internal medicine and a fellowship in pulmonary and critical care medicine at the URM. Dr. Levin is board certified in internal, pulmonary and critical care medicine. She is a member of the American College of Chest Physician and the American Thoracic Society.

Unity Welcomes New Providers – Lisa J. Downing, MD, MPH, Maria Morales, MD, Briani Kiseana Jackson, MD



Dr. Downing will join Unity Geriatric Associates. She earned her MD from the UCLA/Charles R. Drew University of Medicine & Science Combined Program and completed her residency in family medicine from the University of Rochester Family Medicine Residency Program. Dr. Downing is a member of the American Academy of Family Physicians.

Dr. Morales will join Unity Ob/Gyn at West Main. She earned her MD from the University of Puerto Rico School of Medicine and completed her residency in obstetrics/gynecology from the University of Puerto Rico School of Medicine. Dr. Morales is a member of the American College of Physicians.

Dr. Jackson will join Unity Family Medicine at Country Village. She earned her MD from the State University of New York at Upstate Medical University in Syracuse and completed her residency in

family medicine at University of Rochester Highland Family Medicine. Dr. Jackson is a member of the American Academy of Family Physicians.

URMC

Stoner joins URM as Chief of Vascular Surgery



Michael C. Stoner, MD, RVT, FACS, who specializes in complex open and endovascular surgery and a nationally recognized expert in comparative effectiveness research, was selected chief of Vascular Surgery at the URM.

His surgical interests center on comprehensive arterial vascular and endovascular techniques, with emphasis on open and minimally invasive thoracoabdominal and visceral aortic surgeries.

He earned his MD at the University of Buffalo, completed his internship and residency in surgery at Medical College of Virginia and a fellowship in vascular surgery at Harvard University's Massachusetts General Hospital.

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Volume VI

THE AGING PATIENT

Orthopaedic Issues: *Issues, Imaging, Rehab*
Medical Innovation
A New Look at Medical Space Design

Space Reservation Deadline: November 15, 2013
Ad Materials Deadline: November 20, 2013

Volume VI

HEART DISEASE

Hypertension
Cardiac Rehabilitation
Autoimmune Disorders

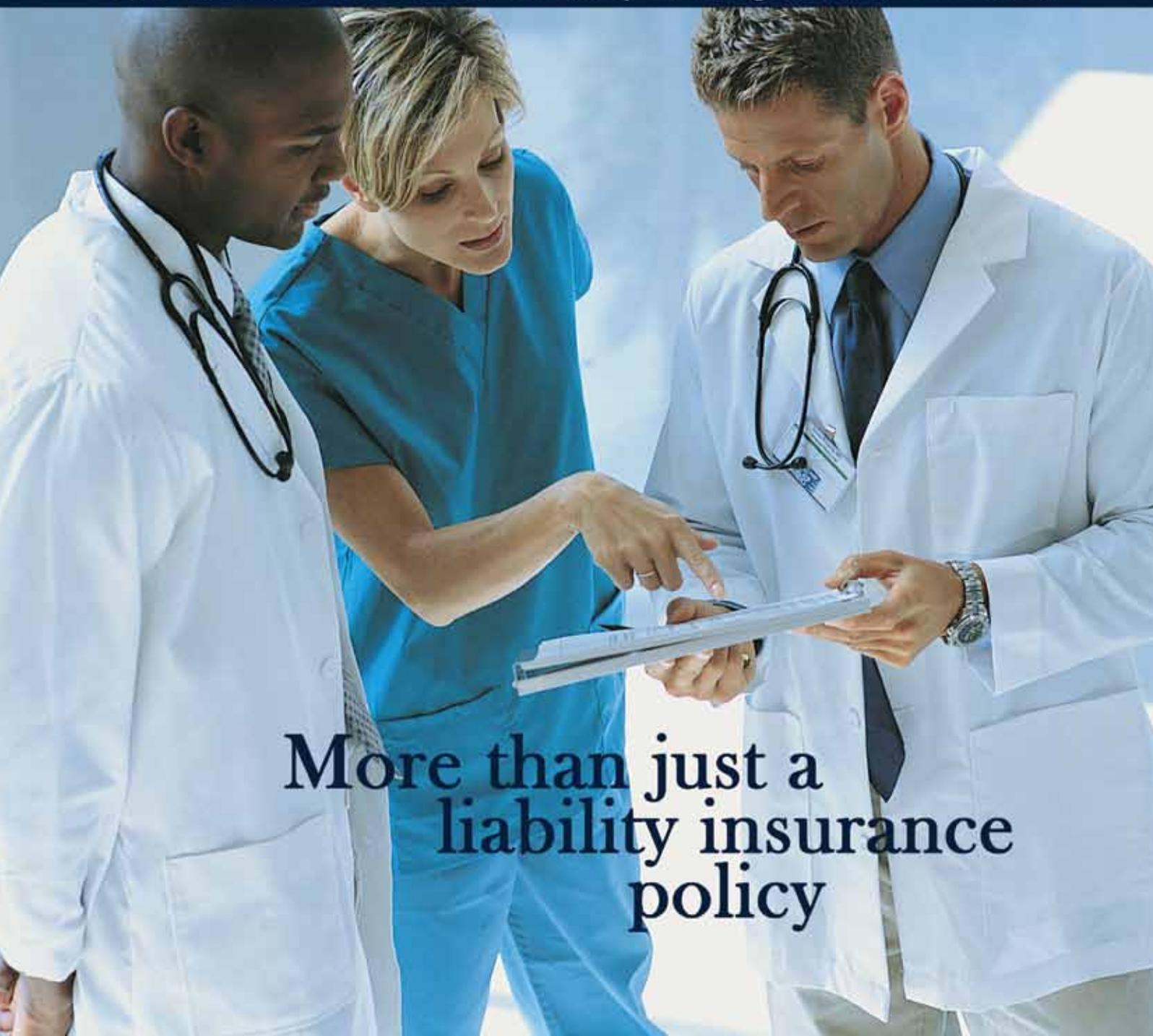
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