

Western New York

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THE LOCAL VOICE OF PRACTICE MANAGEMENT AND THE BUSINESS OF MEDICINE



**Growing Success in Regional Telehealth Initiatives
A Win/Win for Patients, Providers
and Entire Healthcare Systems**

**Cash Balance Plans for Professional Firms:
Understanding a Hybrid Approach**

**Medical Practice Audits:
Risk Analysis and Prevention**

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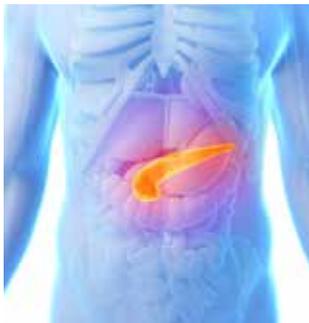


Growing Success in Regional Telehealth Initiatives

A Win/Win for Patients, Providers and Entire Healthcare Systems

Over the past decade, forward-thinking leadership at RGH recognized the future value of investing in and developing a telehealth program to expand access to care and better serve patients in outlying rural communities. Capitalizing on the extraordinary advances in technology and a newly merged health system, Rochester Regional Health Care stands at the vanguard. The opportunities to deliver excellent care to more patients in a cost-managed way are endless.

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On the Cover:
Cindy Gordon, Director of Tele-Health for
Rochester Regional Health System

Cover Photo: Lynne Tseng



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Welcome to the Oncology Issue of Western New York Physician where you will find a variety of informative stories and articles about and from physicians in the Rochester region.

What will the future of health care look like? How will systems, health care providers and ancillary centers care for the estimated 10 million newly insured's and a growing demographic of aging patients who are naturally becoming less mobile all while striving to operate under an Accountable Care model? Our cover story explores Telemedicine – one of the key elements in navigating these hurdle points. With an eye on the future, leadership from the Rochester Regional Health System discuss early beginnings, care and access opportunities and patient satisfaction.

Back in the Practice, Financial and Liability sections you will find timely articles from local experts on Cash Balance Plans for Professional Firms, the latest array of legal news important to your practice, and coverage on Risk Analysis and Prevention in Medical Practice Audits.

Participate in the Conversation

Sharing your expertise is a powerful way to communicate with your medical colleagues and strengthen your position among referring physicians.

Looking ahead to 2015 – we kick off with a current regional look at Cardiac Disease and Care. How are we improving care delivery and reducing risk of developing cardiac disease, how are regional resources poised to care for an ever-growing population of patients with cardiac disease and what new surgical, imaging and pharmacological developments are underway.

If you specialize in one of these areas, you'll want to be included. Contact me directly to learn how.

In good health –

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Western New York PHYSICIAN

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Sleep Care in Cancer Patients



Jacob Dominik, MD



Dr. Jacob Dominik is board-certified and fellowship-trained neurologist and sleep specialist at Sleep Insights..

Q. What are the primary causes of sleep disturbance in the patients with cancer?

A. Any sleep disorders may occur in patients dealing with cancer, and sleep disturbances occur more frequently in these patients than in the general population. The most common problem is insomnia, difficulty falling or staying asleep, which may be due many different causes, including the psychological impact of a cancer diagnosis and associated stress, anxiety and depression, physical factors such as pain and discomfort from the disease itself or from treatments or due to side effects of medications, as well as alterations in the sleep-wake pattern from hospitalizations. Conversely, many of these factors may also contribute to fatigue or excessive sleepiness during the daytime. Medications commonly used by patients with cancer, such as sedatives and narcotics may also affect respiration and contribute to development or worsening of sleep-related breathing disorders such as sleep apnea.

Q. What is the impact of sleep disturbances in these patients?

A. Sleep disturbances can have wide-ranging impacts in patients battling cancer. They may worsen the fatigue commonly experienced due to the cancer and associated therapies, and negatively impact quality of life, as well as worsening mood-related

symptoms that often accompany a cancer diagnosis and make it more difficult to maintain a positive outlook. Poor quality sleep may have detrimental effects on immune function and hormone levels which are an important part of the body's response to cancer, and may also diminish a patient's pain threshold.

Q. What is the value of a sleep assessment?

A. Clinical evaluation by a sleep specialist would determine which, if any, sleep disorders may be present and contributing to a patient's symptoms, determine whether any testing is required, establish a diagnosis and initiate treatment. The sleep specialist may assume responsibility for managing these problems on a chronic basis, as many sleep disorders may persist even once cancer is in remission or has been cured.

Q. What are the latest options for management?

A. Treatment depends on the particular sleep disorder diagnosed. Sleep disorders are generally treatable and some common sleep disorders, such as insomnia and sleep apnea, may be successfully treated without the use of medications.

Q. Are there any special considerations in cancer patients with sleep disorders?

A. Symptoms which are common in patients with cancer, such as fatigue and sleepiness, are often expected and felt to only be a consequence of the cancer and associated treatments. With all of the other tests, hospitalizations, doctor's appointments, medications and concerns that cancer patients have to contend, the possibility of underlying sleep disorders contributing to these symptoms is often overlooked or felt to be of secondary importance. However, most sleep disorders can be successfully treated and doing so may improve the quality of life of patients with cancer and facilitate their battle with cancer.

References

Davidson JR et al. Sleep Disturbance in Cancer Patients. *Soc. Sci. Med.* 2002 May;54(9):1309-21
Joseph AR et al. Cancer-Related Fatigue and Sleep Disorders. *The Oncologist* 2007, 12:35-42
Sleep Disorders. National Cancer Institute at the National Institutes of Health. Retrieved October 9th 2014. <http://www.cancer.gov/cancertopics/pdq/supportivecare/sleepdisorders/Patient/page1/AllPages>



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Growing Success in Regional Telehealth Initiatives

A Win/Win for Patients, Providers and Entire Healthcare Systems

By Julie Van Benthuisen



Photo: Lynne Tseng

As the influx of newly insured patients continues, these regional leaders predict telehealth will play an even more critical role in expanding seamless access to specialty medical care throughout its broadening health system. L to R: Dr. Ralph Pennino, Chief of Surgery at RGH, Dr. James Szalados clinical leader of the Tele-Critical Care program at RGH and Kristen Stewart, R-PAC lead Physician Assistant, RGH Surgical Intensive Care Unit.

While most patients connect to hospitals and their respective healthcare systems through their primary care providers, the dynamic of that connection continues to improve in promising ways thanks to advancements in telehealth.

When patients require hospitalization, most would prefer to stay in their own hometown, under the watchful eye of their doctor who monitors in-patient care and makes preparations for post-discharge continuity of care. Until the advent of telehealth, however, patients in areas outside an urban hub had little choice but to uproot to a hospital typically miles from home.



By enabling highly-trained, experienced specialists and subspecialists based in a full-service center of excellence (the 'hub') to reach out to geographically separated, more rural or critical-access hospitals (the 'spokes'), telehealth is serving the needs of a broader, aging population across Western New York.

Over the past decade, telehealth techniques have made more hometown-based care possible — potentially increasing the quality of patient care by bringing subspecialty expertise to the bedside. These outlying patients utilizing telehealth are proving to be far more satisfied with their healthcare environment and have demonstrably improved medical outcomes when their families, friends, or caregivers are near at hand, says Dr. Ralph Pennino, Chief of Surgery at Rochester General Hospital (RGH).

Since 2004, Legacy RGH has been the region's telehealth leader — developing and deploying a technology-based platform within its entire delivery model. Dr. Pennino, along with Cindy Gordon, Director of Tele-Health for Rochester Regional Health System, and Dr. James Szalados, clinical leader of the Tele-Critical care program at RGH, has shepherded telehealth from its regional infancy to a statistically-proven success model that's expanding year over year.

Telehealth platforms help create 'online' partnerships between healthcare systems, healthcare systems and nonhospital providers, and between healthcare systems and other potentially allied care services like schools, rehabilitation centers, and nursing homes.

By enabling highly-trained, experienced specialists and subspecialists based in a full-service center of excellence (the 'hub') to reach out to geographically separated, more rural or critical-access hospitals (the 'spokes'), telehealth is serving the needs of a broader, aging population across Western New York.

"Telehealth has become much more than teleconferencing," says Dr. Pennino. "Via a secure line, anything that's digital can be communicated — from ultrasound imaging to utilizing various scopes." Patient and doctor can speak "face to face" without requiring travel time, cost, and its associated inconveniences and potential stress.

A Busy Decade of Growth

"Six years ago, we were only a few years into implementing telehealth," adds Cindy Gordon. "It wasn't a very well-known entity, and we were just trying to get the word out." In 2008, Newark Wayne Hospital purchased a \$250,000 "robot" to help connect patients within the rural hospital to specialists back at RGH, its larger affiliate. "While cost was a significant consideration, we saw the tremendous potential of investing in telehealth," she adds. "Fortunately, technology costs have gone down exponentially since then, and we've been able to build on that initial investment."

Pre- and post-operative surgical consultations and coordination of care meetings through the newly formed and renamed entity, Rochester Regional Health System, are being managed more often using telehealth. As the influx of newly insured patients continues, these regional leaders predict telehealth will play an even more critical role in expanding seamless access to specialty medical care throughout its broadening health system.

Remote Diagnosis and Care Management

Simply put, the telehealth model relies on telecommunications equipment to create real-time interactions between patients and subspecialists. Previously, telehealth remained out of reach for many community health centers because it requires that doctors and patients have access to high-speed Internet, a video monitoring system and technological support specialists.

“Far more research and development has been done since we began,” says Gordon. “We can offer a broader variety of solutions now with far more diversity.” Providers can perform patient exams remotely utilizing technology. A digital stethoscope allows a full examination of lung and breath sounds, and remote viewing capabilities provide high resolution sound and images consistent with a thorough bedside examination. “Remotely, the doctor can even see skin better than with the naked eye, which can help diagnose a skin rash or even skin cancer.”

Simultaneously, providers can remotely review, in a split screen, the patient’s electronic medical record including entries by other providers, laboratory data, and radiographic imaging.

The applications are tremendous within subspecialties – tele-dermatology, plastic surgery, radiology, and obstetrics/gynecology, to name a few. “Basically, whatever is out there digitally has a telehealth application,” says Dr. Pennino. Legacy RGH telehealth program already provides consultation services to area hospitals in other specialties like surgery and surgical subspecialties, wound care, bariatric psychology, infectious disease, psychiatry, and nephrology.

In Sync with Affordable Care

Telehealth represents tremendous opportunity to support the 2010 Patient Protection and Affordable Care Act (ACA), says Dr. Szalados. The ACA embodies three broad goals — to increase access to healthcare, uniformly increase the quality of healthcare delivered, and decrease global healthcare expenditures by increasing the efficiency of the care delivered.

“Because rural and critical access hospitals are typically fiscally-challenged by tight financial margins, telehealth provides a solution. Community hospitals are now better able to provide more complex care to increasingly complex inpatients and thereby improve their case-mix and finances.”

Two important goals for U.S. Healthcare Reform include the provision of the best healthcare to every patient whenever needed (patient-centered healthcare); and optimization of the health of populations (population health) through uniform access, early intervention, and effective chronic disease management. “The technology inherent to telehealth is the foundation for reengineering the processes of healthcare delivery through the elements of information and communication,” he adds.



Photo: Lynne Tseng

“Through telehealth, these ICU patients in rural areas can access deeper layers of care with physicians they wouldn’t typically have on-sight.” Dr. Szalados with Kristen Stewart, R-PAC seen here rounding with ICU staff at United Memorial.

The ACA specifically directed the Center for Medicare and Medicaid Innovation (CMI) to develop telehealth, including tele-critical care, tele-stroke, and remote patient monitoring to improve service delivery and care coordination. “Our hope,” says Gordon, “is that a state bill currently under review will pass, which would cover Medicaid patients for telehealth consults. Here in our region, telehealth providers are active through Health Association of New York State (HANYS) to help develop policies regarding best practices and payment policies.

Through the Delivery System Reform Incentive Program with the University of Rochester and RGH, these telehealth providers are working with Health Association of New York State (HANYS) to help develop policies regarding best practices and payment policies. “Our hope is that third-party payers will also join in to support reimbursement,” she says. “Fortunately, our two major insurers here in Rochester already reimburse for telehealth, but we need to do more with population health. We’re also applying for a large government grant that would give us help for high-risk patients.”

Already, many high-risk groups are seeing the benefits of telehealth. Notably, patients with congestive heart failure are being sent home from the hospital within a shorter period of time. “As providers, we’re being asked to put our arms around a bigger patient population, and we’re already seeing better outcomes, and less patient readmitting.”

Addressing Critical Care Needs

Over the past five years, Dr. Szalados’ Surgical Intensive Care Unit (SICU)-based team has provided continuous tele-critical care services to hospitals like Newark Wayne and United Memorial Medical Center in Batavia. As a healthcare attorney, he has also been instrumental in providing national legal representation and program development consultation to

groups and healthcare entities on telehealth implementation.

On any given day, Dr. Szalados and his team sign on to the telehealth system, where they conference with area hospital staff to formally round on critically-ill ICU patients. The team examines patients, reviews labs and radiographs, develops care plans, and even updates family members. Clinical impressions and a care plan are then documented in the remote hospital's EMR. The PA team provides continuous coverage after-hours and rounds again in the evening, with attending intensivists available 24/7 as needed.

"Through telehealth, these ICU patients in rural areas can access deeper layers of care with physicians they wouldn't typically have on-sight."

RGH's SICU has also coordinated the implementation of new initiatives like therapeutic hypothermia protocols for cardiopulmonary arrest resuscitation, ventilator-weaning and sedation protocols, and antibiotic stewardship, successfully with its associated hospitals.

"There are also many instances where the SICU team is involved in, together with the local hospital-based providers, delicate bedside discussions regarding end-of-life care issues specific to ICU patients," he adds. "Overall, such remote interactions have been met with overwhelmingly positive feedback by families and caregivers at the remote hospitals," says Dr. Szalados.

Patients Asking for It

Given our technology-driven world, it's not surprising that patients young and old are coming to expect more individualized, convenient care. Emails, smartphones, and remote monitoring technology are all enhancing patients' ability to communicate with providers. "Simply put, telehealth is a tool, an enabler that creates access to specialty and subspecialty care for an expanding group of patients," says Dr. Pennino. "It's like Skype on steroids," he jokes.

Smartphone applications, for example, are currently being used in any number of applications – from monitoring ambulatory chronically ill patients to working with Olympic athletes in-training. "The only limits to the potential applications of telehealth are imagination and commitment," adds Dr. Szalados.

"By expanded access through telehealth, we can intervene far earlier in a patient's care while keeping our patients in their own communities," says Dr. Pennino. A patient who has experienced congestive heart failure, for example, can be cared for in their own home via computer or iPad. "All that's needed is a broadband connection." By downloading a simple app, patients can take their own pulse and blood pressure and other vital signs. Medication can also be monitored with pharmacy

interaction. "It's very interactive." The same technology can also be used for diabetics.

"It's also an opportunity to enable super sub-specialties to grow and become more sophisticated," says Dr. Pennino. "Most hospitals cannot retain this kind of sub-specialty in-house. What's more, we've seen dramatic reduction rates in readmissions for chronic disease patients when telehealth is employed."

These telehealth leaders say they are increasingly aware that the cost of hospitalization includes not only the financial implications of inpatient care, but also the associated risks like infection and other complications of institutional care.

Hospitalization can also lead to situations where caregivers and family members are potentially removed from the patient's care – negatively impacting recovery, rehabilitation, and post-discharge care. "It's been repeatedly demonstrated that the most important advocates for any patient's care are family members or their local caregiver community," says Dr. Szalados.

With time, he predicts, hospitals will increasingly resemble intensive care units and increasingly greater numbers of patients will be cared for as outpatients wherever possible. "Despite being treated at home, in rehabilitation centers, nursing centers, or rural hospitals, all patients should have equal access to the best healthcare possible at any place and any time."

Wound Care

Wound healing and management, prominent issues within the nursing home setting, represent another promising opportunity for telehealth, says Ms. Gordon. "Patients with wounds are a particular group that benefits from this approach because they are typically far less mobile within the nursing home." Wound care services usually attract the most complex wounds and ulcers, which are often slow to heal and require complex treatment regimens. This usually entails detailed initial assessment with frequent follow-up assessments of wound status and repeated adjustment of therapy.

Fortunately, the availability of reasonably priced photographic equipment like high-resolution cameras enables a quick electronic transfer of high quality digital images to make possible the assessment of wound status by remote experts. Videoconferencing and the Internet enable efficient exchanges of information, images and conversations between patients and wound specialists.

Studies have already shown that when verbal reports supplemented by digital images are shared with wound care nurses providing advice remotely, there is a notable reduction of subsequent face to face consultation time, she adds. "Telehealth can definitely impact decision accuracy and patient satisfaction."

Patients with leg ulcers, for example, are benefiting from



an initial physician face to face assessment, with subsequent follow-up by home care nurses. The majority of images are of sufficient quality to permit assessment by the specialist. “Acceptance is consistently high among patients, nurses and wound experts.”

Traditionally, the costs of patient care including transportation, aides and special vehicles, can all be lessened by the ability to consult via technology. Fewer ER visits and hospitalization mean significant cost reductions in hospital utilization.

What Lies Ahead

Just as we are only beginning to see the potential inherent in the electronic health record, each medical specialty has opportunities with telehealth. Thus far, specialties which have most successfully leveraged health information technology are the consultative specialties like radiology.

Dr. Szalados sees great potential to provide tele-stroke, tele-behavioral, and tele-pathologic consultations, which already are having great success beyond our region. In Berlin, for example, stroke patients have access to mobile ambulance CT scan imaging while they are en route to the hospital; thrombolytic therapy, where indicated, is initiated in the ambulance even prior to hospital arrival.

The U.S. military has successfully leveraged telehealth to facilitate increased remote access to care in the battlefield, field hospitals, local VA systems, and rehabilitation facilities. The Low Activities of Daily Living Monitoring Program (LAMP) represents a tele-rehabilitation program which promotes veteran independence by providing care coordination, assistive technology/adaptive equipment, home environmental

modifications, and home-based rehabilitation.

“Just as the Internet and Bill Gates’ vision of a “computer in every home” (now, the computer in every pocket) allowed easy, widespread, and rapid access to information and communication, telehealth will evolve as a continued transformation of the previously rigid and limited healthcare system into an increasingly patient-centered system.” Telehealth can optimize access, quality, and cost.

“I see tremendous opportunities in the Behavioral Health world,” adds Gordon. Utilizing tele-psychiatry in remote areas provides a positive way to connect with a doctor. She predicts continued expansion with

mobile wound care and collaboration with nursing homes. “Being able to evaluate patients from more remote nursing homes has great potential, especially with our aging population,” she says. “Rounding remotely, the more patients who embrace it amounts to better success rates.” While she recognizes that telehealth will never take the place of face-to-face patient/provider interaction, it comes down to a matter of receiving care when needed as opposed to potentially to no care at all.

Looking forward, more employers will begin embracing telehealth for their employees, she predicts. Early intervention within the workplace, as well as chronic disease management, will help cut down on missed work days and improve productivity. “Already, some employers enable their employees to dial into a doctor and potentially receive a diagnosis for say, strep throat, without even having to leave the building or miss a day of work.”

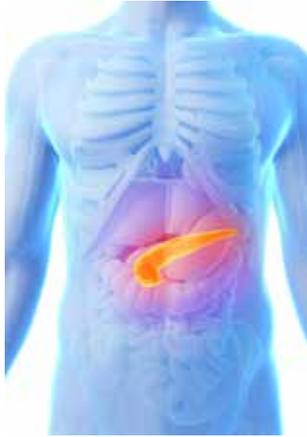
Another opportunity exists for those employers who provide on-site daycare to their employees. Pediatricians can link into the daycare via telehealth and alert parents to a potential issue. A child might get diagnosed with an ear infection, so when the child is picked up they can already bypass the need to go to the pediatrician and instead head right to the pharmacy to pick up a prescription.

“Our recent reports on patient satisfaction with telehealth are very encouraging,” says Dr. Pennino. “The undistracted nature of the interface quite simply strengthens the doctor/patient relationship and improves quality of care and communication in every respect.”

Pancreatic Cancer: Advances in Treatment Approaches



Sheema Chawla, MD
Lipson Cancer Center



Pancreatic cancer is a challenge for modern medicine. Despite best efforts, the 5-year survival rate remains at about 5%. The incidence and death rate are roughly equal, underscoring the nasty nature of this disease. While smoking, heavy intake of alcohol, obesity, diabetes, chronic pancreatitis and genetic factors increase the risk of this disease, the majority of patients have no identifiable risk factors.

Making the diagnosis

Pancreatic cancer rarely presents in the early stages. It has a high mortality, mainly due to spread at presentation, and it is therefore resistant to most treatment options. There is currently no screening program for the detection of pancreatic cancer, unlike cervical and breast cancer. People with pancreatic cysts, age above of 50 years who have new onset diabetes, two or more first-degree relatives (parents, sibling, child) with pancreatic cancer, history of a genetic syndrome associated with pancreatic cancer may undergo investigations in absence of symptoms.

What is new in screening?

Scientists are learning more about some of the changes in DNA that cause cells in the pancreas to become cancerous. Inherited changes in genes such as BRCA2, p16, and the genes responsible for hereditary non-polyposis colorectal cancer (HNPCC) can increase a person's risk of developing pancreatic cancer. Researchers are now looking at how these and other genes may be altered in pancreatic cancers that do not seem to be inherited. They have discovered that pancreatic cancer does not form suddenly. It develops over many years in a series of steps known as pancreatic intraepithelial neoplasia or PanIN. Researchers are using this information to develop tests for detecting acquired (not inherited) gene changes in pancreatic cancer precancerous conditions. One of the most common DNA changes in these conditions affects the KRAS oncogene, which affects regulation of cell growth. New diagnostic tests are often able to recognize this change in samples of pancreatic juice collected during pancreatic duct examination.

Clinical features

These are notoriously vague and early diagnosis remains a major problem. The symptoms of painless jaundice, pain, weight loss and new onset diabetes should alert early investigation, especially in patients with relevant risk factors. The presence of clinical signs on examination frequently represents advanced and inoperable disease. Diabetes mellitus is a presenting feature in up to 10% of cases, thus one should be clinically suspicious when treating elderly patients with new-onset diabetes.

Investigations

Patients presenting with suspicious symptoms would undergo routine blood tests followed by imaging. CA19-9, a blood marker for pancreatic cancer is not used in the diagnosis but for follow up. Ultrasonography can offer an initial non-invasive evaluation of tumors; however, it is by no means accurate and can be incorrect in a third of cases. CT scan of the chest, abdomen and pelvis is the standard imaging modality and also assists in staging of the disease. Magnetic resonance cholangiopancreatography offers better imaging of the biliary tree, pancreatic ducts and vascular invasion. In patients presenting with jaundice, endoscopic retrograde cholangiopancreatography (ERCP) enables pathological sampling and offers palliative biliary stenting for patients with unresectable tumor or who are not fit for surgery. Endoscopic ultrasound has been shown to be more sensitive and specific compared with CT in diagnosis, particularly for small tumors. It is important prior to treatment that a biopsy is taken to confirm the histological diagnosis of the pancreatic cancer.

Management

Patients can also be staged clinically, based on how operable the disease is:

- **Resectable disease:** absence of extrapancreatic disease without evidence of direct invasion of the blood vessels. Surgery to remove pancreatic cancer (most often a Whipple procedure) is a long and complex operation that can be hard both for the surgeon and the patient. A newer approach now used at some major medical centers is to do the operation laparoscopically. For this approach, the surgeon makes several small incisions in the belly instead of one large one. Long, thin surgical instruments and a tiny video camera are then inserted through these cuts to do the operation. One advantage of this surgery is that people often recover from it more quickly. But this is still a difficult operation and surgeons are looking to see how it compares to the standard operation

and which patients might be helped the most by it. Chemotherapy (chemo) given post operatively (known as adjuvant treatment) might help some patients live longer.

- Borderline resectable disease: absence of extrapancreatic disease with some blood vessel invasion. These cancers are often treated first with chemotherapy (neoadjuvant chemotherapy), sometimes along with radiation. Imaging tests (and sometimes laparoscopy) are then done to make sure the cancer hasn't grown too much to be removed. As long as it hasn't, surgery is then done to remove it. This might be followed by more chemotherapy.
- Locally advanced/unresectable disease: absence of extrapancreatic disease, frank invasion of blood vessels. Standard approach is chemo and/or chemoradiation.
- Metastatic disease: any disease involving distant sites or metastasis. These patients are treated with chemo alone or best supportive care.

Palliation

Other treatments might also be used to help prevent or relieve symptoms from these cancers. For example, radiation therapy or some type of nerve block might be used to help relieve cancer pain, or a stent might be placed during an endoscopy to help keep the bile duct open.

Chemotherapy

Many clinical trials are testing new combinations of chemotherapy drugs for pancreatic cancer. Studies have looked to see if combining gemcitabine (GEM) with other drugs would help patients live longer. For example, adding capecitabine (Xeloda) to gemcitabine seems to help some patients. The combination of gemcitabine, irinotecan, and celecoxib (an arthritis drug) also shows promise.

Other targeted therapies: Many drugs targeting other aspects of cancer cells are now being studied for use in pancreatic cancer. Some of these drugs, such as sunitinib (Sutent), have several different targets.

Other studies are testing the best ways to combine chemotherapy with radiation therapy or newer targeted therapies.

What is new in systemic therapy of pancreatic cancer?

As researchers have learned more about what makes pancreatic cancer cells different from normal cells, they have developed newer drugs that should be able to exploit these differences by attacking only specific targets. These targeted therapies may prove to be useful along with, or instead of current treatments. In general, they seem to have fewer side effects than traditional chemo drugs. Looking for new targets to attack on cancers is an active area of research.

One of these are Growth factor inhibitors. One example is epidermal growth factor receptor (EGFR) blocker like erlotinib (Tarceva), which is already approved for use along with gemcitabine. Others are anti-angiogenesis blockers that are used to block the growth of new vessels which supply nutrition to cancer cells. Yet other group of drugs that target the tumor stroma. The stroma is supporting tissue that seems to form a barrier that helps protect the cancer cells from the effects of chemo drugs. Researchers are now looking at drugs that attack

the stroma directly to help break it down. This might allow chemo or other drugs to be more effective. Some of these types of drugs are now in clinical trials.

Immune therapy

Immune therapies attempt to boost a person's immune system or give them ready-made components of an immune system to attack cancer cells. Some studies of these treatments have shown promising results.

Monoclonal antibodies: One form of immune therapy uses injections of man-made monoclonal antibodies. Toxins or radioactive atoms can be attached to these antibodies, which bring them directly to the tumor cells.

Cancer vaccines: Several types of vaccines for boosting the body's immune response to pancreatic cancer cells are being tested in clinical trials. Unlike vaccines against infections like measles or mumps, these vaccines are designed to help treat, not prevent, pancreatic cancer.

Drugs that target immune system checkpoints: The immune system normally keeps itself from attacking other normal cells in the body by using "checkpoints" – molecules on immune cells that need to be turned on to start an immune response.

One possible advantage of these types of treatments is that they seem to have very limited side effects. At this time, all above treatments are available only in clinical trials.

Radiation therapy

Role of radiation in pancreatic cancer is controversial. It is usually given in combination with chemotherapy or for palliation of symptoms. Newer and most way of delivering radiation is intensity modulated radiotherapy in 25-30 daily treatments where goal is to use highly conformal radiation while minimizing side effects to surrounding critical structures. Some current studies are looking at intraoperative radiation therapy (in which a single large dose of radiation is given to the pancreas in the operating room at the time of surgery) and proton beam radiation (which uses a special type of radiation that might do less damage to nearby normal cells). Also, research is going on in field of stereotactic body radiotherapy in single or 3-5 sessions of highly focused external beam radiotherapy for treatment of inoperable cancers.

Summary and Conclusions

Pancreatic cancer is a complex and highly lethal disease that is best treated in the multidisciplinary setting. Although it is natural for health care providers to focus on prolonging life, helping a patient and their family through the difficult transitions that come all too often with pancreatic cancer are equally important. Doctors are encouraged to include a palliative care expert as part of their multidisciplinary team. Although the survival statistics are currently bleak, there are a number of bright spots on the horizon, including individualized therapies and the prevention of an invasive pancreatic cancer by improvements in the management of cystic lesions of the pancreas.

Sources:

1. American Cancer Society
2. GP Clinical review: Management of pancreatic cancer. April 2012
3. CA Can J 2013; 63:318-348

Virtual Colonoscopy

About

Virtual colonoscopy is the latest development in colon cancer detection. Since its introduction in 1994, ongoing research has led to significant advances in the accuracy and usefulness of this non-invasive procedure and offers benefits in a number of situations where traditional colonoscopy is contraindicated. The procedure utilizes sophisticated imaging techniques to generate a 3-D reconstruction of the inner surface of the colon, which can then be evaluated for abnormalities by specially trained radiologists.



Ray Tan, MD

Dr. Raymond Tan is Chief, Department of Medical Imaging at Highland Hospital, the first hospital in the area to perform Virtual Colonography. As a pioneer in this specialized imaging area, Dr. Tan led Highland Hospital through a Pilot Study for the ACR study group and his team continues to lead the way in CT colonography volumes.

As a pioneer in virtual colonoscopy, what advances have you witnessed?

Virtual Colonoscopy, which is a non-invasive, image-based method of evaluating the colon for colon cancer and for the polyps that are known to grow into colon cancer, has steadily matured as a technology over the past decade. We have improved first in the technology that allows us to identify lesions in the colon, now with CT scanners that can image at sub-millimeter resolution to create truly stunning images of the colon. In addition, now CT scanners deliver a much lower dose of radiation for the same scan such that we are now at a radiation dosage of approximately 30% of what it was just a few years ago. It is important to note that the risk of not screening for colorectal cancer is much greater than the radiation risk of a low dose CT scan. One issue that has persisted nationally for colon cancer is that the overall screening rate of the population remains low. Currently, of the eligible screening population which is adults over the age of 50 years, approximately only 60% have received any type of colon cancer screening examination. Virtual colonoscopy is now widely recognized as one of those modalities.

How accurate and reliable is this form of imaging and is the quality and consistency of reporting similar to that of a traditional colonoscopy?

There have been numerous randomized double blinded studies in the United States as well as in Europe and Asia that have established virtual colonoscopy both as a safe and reliable means for screening for colon cancer. The detection rate for primary colon cancers is now essentially the same at virtual colonoscopy as it is for traditional optical colonoscopy. For the detection of polyps, the most recent data shows that for polyps greater than 5 millimeters in size, virtual colonoscopy also has equivalent detection to optical colonoscopy. For lesions smaller than 5 millimeters, the sensitivity of virtual colonoscopy does decrease significantly to approximately 50%. It is important to note however that polyps of this size rarely, if ever pose any risk to develop colon cancer in the near term. It is for this reason that the screening interval for virtual colonoscopy is at this time shorter than that of optical

colonoscopy with a 5 year time interval. It is important, as with any specialized field, to be certain that the radiologists performing the examination, as well as the support staff, have the proper training and experience to perform these examinations at the highest level.

When is a virtual colonoscopy the appropriate choice? Eligible Patients? Indications and contraindications?

The American Cancer Society estimates over 136,000 new cases of colon and rectal cancer in 2014. Furthermore, colorectal cancer is expected to cause over 50,000 deaths in 2014. This remains a prevalent disease in the population with an estimated lifetime risk of approximately 1 in 20 (5%). Given this, the recommendation is that beginning at age 50 both men and women with an average risk for developing colorectal cancer should undergo screening. Virtual colonoscopy is one of these options, which is recommended in at a 5 year interval. Alternatively, traditional colonoscopy can be considered at every 10 years. Other testing modalities include fecal occult blood testing, fecal immunochemical testing, and stool DNA testing. Double contrast barium enemas remain on the official recommendations for several national societies, however in my opinion, these offer too high of a radiation dose and furthermore, have too low of sensitivity, with approximately 50% overall sensitivity for colon cancer and colon polyps, to be considered a viable alternative except in rare situations and in localities where access to other modalities maybe more limited. There are people who have a higher risk for colon cancer than the general population, and for these individuals screening may be indicated before age 50. These categories include: having a personal history of colon cancer or adenomatous polyps, inflammatory bowel disease, such as Crohn's disease or ulcerative colitis, a strong family history of colon cancer or colon polyps and a known family history of hereditary colon cancer syndrome, such as familial adenomatous polyposis and Lynch syndromes. Relative contraindications to virtual colonoscopy include recent surgery on the colon and active inflammation in the colon. Generally speaking, virtual colonoscopy can be attempted in these patients at a later point when the active issue has defervesced.

Insurance coverage is an important concern for patients. Is this approach recognized as a viable alternative to traditional colonoscopy?

22 states mandate full insurance coverage for virtual colonoscopy. New York State is not one of them. In our area, typically insur-

ance coverage is extended to patients who have had an incomplete colonoscopy at some point in the past. Most commonly this occurs because of complex anatomy, known strictures, and difficulties with anesthesia. There are certain specific exemptions extended to individuals with specific medical contraindications such as cardiovascular risk factors, respiratory risk factors and bleeding diatheses. These are handled on a case by case basis by insurance providers in our area. At the present time, Medicare does not cover virtual colonoscopy as a screening test, but usually does cover evaluation of an abnormality when there is a preceding incomplete colonoscopy in the past. Nevertheless, virtual colonoscopy is recognized as a viable screening modality by major organizations including the American Cancer Society, the American College of Gastroenterology and the American College of Radiology.

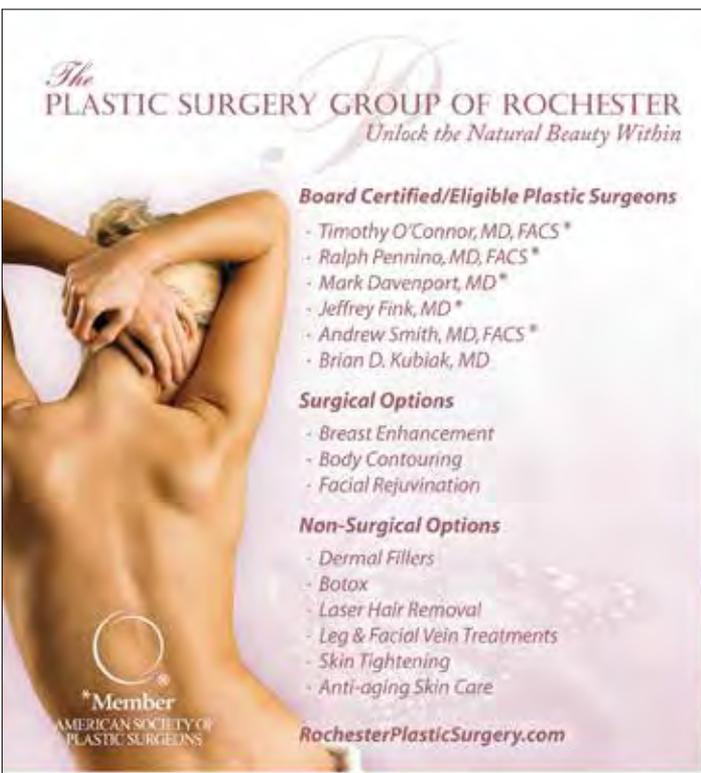
What are the benefits and risks?

There are many benefits to undergoing virtual colonoscopy. Virtual colonoscopy is performed with patient fully awake and without sedation or anesthesia. Thus, there is no need to take significant time off from work. The examination can be performed in approximately 20 minutes and the scan itself takes approximately 15 seconds. Several studies have shown that patients preferred virtual colonoscopy to traditional colonoscopy and reported a greater degree of comfort during the procedure. There is also a decreased risk of complications. While complications from traditional colonoscopy and flexible sigmoidoscopy are rare, complications from virtual colonoscopy are even rarer. Once the examination is completed, the patient can immediately

resume their regular activities. For this reason President Obama opted to undergo virtual colonoscopy for primary screening in 2010. He was able to do this with ease, did not have to transfer his Presidential powers during the process, and could resume his schedule right after. From an economic standpoint, virtual colonoscopy is less expensive than optical colonoscopy.

What advances are on the horizon?

As we look to the future, I fully expect that virtual colonoscopy will continue to improve from a technical standpoint. Sensitivities for even very small lesions in the less than 5 millimeter range will continue to increase. In my 10 plus years of performing these examinations, every year our ability to find smaller and smaller lesions accurately has improved. This test will be further established as a safe, effective and convenient way to screen for colon carcinoma. In addition, as CT scan technology continues to improve, radiation doses continue to be reduced further adding to long term patient safety. At Highland Hospital, we have the most up-to-date “ultra” low dose CT technology. Research continues in computer assisted detection (CAD) where algorithms assist the radiologist in identifying potential abnormalities. One of the most exciting things on the horizon for virtual colonoscopy is the so called “prep-less” scan. This technology basically uses computer subtraction to visually remove bowel content from the colon. So there is no need for bowel cleansing regimens. There has been exciting work performed in this area, and certainly this is anticipated to be a tremendous improvement in patient comfort.



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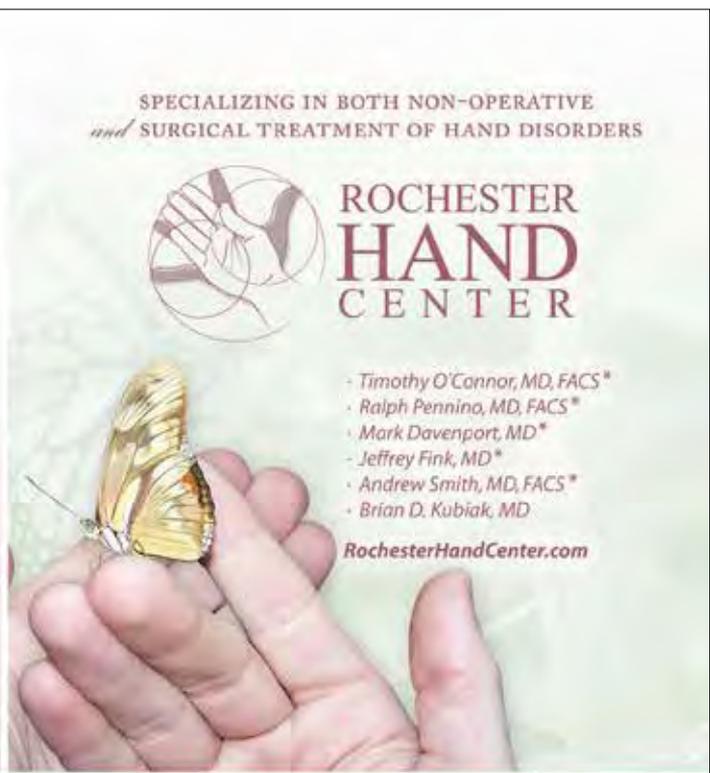
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Implantable Diagnostic Technology Advances

Prototype of Raland Therapeutics' CytoComm Living Biosensor System

The University of Rochester has received a second patent for an implantable biosensor that can provide physicians with real time information on their patients' health. The technology is licensed to Fairport-based Raland Therapeutics.

The technology was created at the University of Rochester Medical Center by Spencer Rosero, M.D., a heart rhythm specialist, and consists of a "living chip" that can detect subtle biological changes in the body that could provide physicians with advance warning of health problems.

The device – which Raland Therapeutics is developing under the name CytoComm Living Biosensor System – contains live cells that are engineered to detect specific biochemicals found in the body. The cells "respond" when they come into contact with these chemicals and glow when exposed to a light source. This fluorescence is detected by the device's photonics sensors which in turn give off a wireless signal that is picked up by an external sensor.

While the technology has many potential applications, one of the first uses of the device will be in the area of chemotherapy toxicity. The target dose of chemotherapy varies from patient to patient, with the goal of administering enough of the drugs to effectively treat the cancer without triggering toxic side effects. Currently, the process of determining doses of chemotherapy drugs is obtained by measuring the patient's height, weight, and liver and kidney function, among other factors.

By sensing the levels of the medication and other markers present in a patient's body in real time, the CytoComm technology would enable doctors to more precisely tailor a course of chemotherapy to the patient, eliminate dramatic swings in the administration of medication, prevent toxic overdoses, and enable physicians to more consistently deliver "just the right" level of treatment.

The company is also developing a version of the implantable sensor for use in laboratory studies involving animals.

Earlier this month the University of Rochester was awarded its second patent for the technology. The first patent, issued in 2011, covered the housing of live

cells. The most recent patent covers the detection of changes in the cells using photonics technology. A third patent is pending.

Raland Therapeutics is one of 11 the finalists for 43North, the world's largest business idea competition. The finalists, trimmed down from a field of more than 6,900 applications, will pitch their ideas to a panel of judges at Shea's Performing Arts Center in Buffalo on October 30. Each finalist will win a portion of 43North's \$5 million in cash prizes, which include a top award of \$1 million. The 43North finalist team that receives the most tweets using their assigned hashtag (Raland Therapeutics' is #43North10) will win an additional \$10,000.

URMC Joins NIH Network Dedicated to Finding New Treatments for Rheumatoid Arthritis, Lupus

The University of Rochester Medical Center is one of 11 research groups across the country chosen by the National Institutes of Health to join the NIH Accelerating Medicines Partnership in Rheumatoid Arthritis and Lupus Network. The new program is a partnership between the NIH, biopharmaceutical companies, advocacy organizations and academic scientists to more rapidly identify promising drug targets and develop much-needed new treatments for patients with these conditions.

"These awards represent the first phase of an unparalleled approach to identify pathways that are critical to disease progression in rheumatoid arthritis and lupus," said NIH Director Francis S. Collins, M.D., Ph.D. in an announcement from the NIH. "Insights gained from this effort hold the promise of enhancing quality of life for patients and family members impacted by these and other devastating autoimmune diseases."

URMC's research team, led by Jennifer H. Anolik, MD, PhD, will focus on rheumatoid arthritis, an autoimmune disease that occurs when immune cells mistakenly attack healthy joints. They will collect joint tissue and analyze where and how immune cells communicate with bone cells, a process that they believe is critical in initiating the inflammation and resulting joint destruction characteristic of the disorder. Understanding this cell "crosstalk" may uncover new ways to stop

or slow the cascade of events that leads to inflammation.

Rochester's data will be pooled with findings from the other 10 research teams with the goal of generating a comprehensive understanding of how tissue damage occurs in rheumatoid arthritis and lupus. Like rheumatoid arthritis, lupus strikes when immune cells go after parts of the body they are meant to protect. Based on this information, Network members will determine the most promising targets for the development of new diagnostic tools and therapies.

"To advance the field in drug development and find better treatments research teams have to work together," said Anolik, an associate professor of Allergy, Immunology and Rheumatology. "As scientists, we tend to think in our own box, to focus on one cell that we believe is important in human disease. But human disease is so much more complicated than that. To go to the next level we need to integrate all sources of data."

Anolik, who treats rheumatoid arthritis and lupus patients at UR Medicine's Rheumatology Clinic, says the need for new therapies is great. While there are some effective treatments for rheumatoid arthritis, the majority of patients don't fully respond to the drugs and joint damage worsens as they are moved from one treatment to the next. The situation is dire for lupus patients; there are very few approved drugs that are variably effective and associated with many side effects.

Christopher T. Ritchlin, MD, MPH, professor and chief of the division of Allergy, Immunology and Rheumatology says Anolik's team was selected for this highly competitive award based on the novelty of their translational research proposal coupled with the close collaboration between Orthopaedics and Rheumatology in a superb research environment.

"We believe the NIH recognized the unique nature of our Center for Musculoskeletal Research, where scientists and clinicians from many disciplines work together to address unmet needs for patients with systemic musculoskeletal and autoimmune disorders," added Ritchlin.

UR Medicine Introduces New Laser Cataract Surgery



Christian Klein, MD

Bob Luce is enjoying the beauty of our changing seasons with greater joy than he has in years. The retired math teacher recently had refractive laser cataract surgery that has opened up “a new world” for him.

He was one of the first patients in Rochester to undergo cataract surgery using a femtosecond laser at UR Medicine’s Flaum Eye Institute, the first regional center to acquire the Catalys® laser system to treat cataracts.

The new technology offers ophthalmologists greater precision and reproducibility than the traditional, manual technique for restoration of vision for people facing a progressive decline in their eyesight from cataracts. The new system combines state-of-the-art femtosecond laser, advanced 3D imaging and sophisticated software allowing surgeons to customize treatment planning for removal of the cataract.

This is a tremendous advance because it largely eliminates incisions previously requiring a blade while limiting the amount of disruptive energy introduced into the eye during surgery. This decreases potential damage to nearby ocular tissues, the most important of which is the innermost layer of the cornea.

The procedure is safe, relatively easy to perform and results in less intraocular inflammation for patients. It’s truly amazing to watch the procedures, because incisions and lens softening are visualized in real time and appear to materialize out of thin air.

What is a cataract?

A cataract is a clouding of the protein-based lens in the eye. Everyone eventually develops them

as we grow older. By the age of 80, more than half of all Americans either have a visually significant cataract or have already had surgery to remove them.

Common symptoms of cataracts include blurry vision, poor night vision, sensitivity to lights and glare, and frequent changes in corrective lenses or contacts. They are the leading cause of reversible blindness in the United States.

The gold standard treatment for cataracts has been surgical removal, which for decades was done manually. The availability of femtosecond laser surgery allows doctors to achieve more reproducible results with less inflammation for our patients.



Femtosecond laser system can be used to remove cataracts at the Flaum Eye Institute. The high-tech procedure offers greater precision, reduces inflammation and improves outcomes.

The level of precision afforded by the laser is far better than anything we can consistently achieve manually, even in experienced hands.

Patients are the best advocates for the surgery. After undergoing the new laser cataract surgery, Luce praised its simplicity, but more importantly, the improvement in his vision. He has repeatedly said that colors are brighter and more vibrant than they have been in years while the clarity of his vision has improved to a level not experienced in many decades.

About laser cataract surgery

Every eye has a distinct size and shape and the new laser system has 3D imaging technology that allows surgeons to build a 3D map of each eye and customize the treatment plan.

The surgeon programs the laser to create an opening in the capsule that houses the cataract. The goal in this step is to create an opening that is as perfectly circular and centered as possible as well as being the proper size to “fit” the artificial lens being implanted. This opening allows the surgeon to access and remove the cataract.

The next step is to use the laser to soften the cataract and break it into tiny pieces. These pieces are removed with minimal ultrasound energy. (In the traditional, manual approach, a mechanical instrument and ultrasound energy are used.)

If needed, surgeons can use the femtosecond laser to make additional corneal incision, often called limbal relaxing incisions (LRIs), to reduce astigmatism.

The optical system is finely calibrated and can be unforgiving. A quarter diopter (a measure of focus) here or there can really impact the patient’s quality of vision. As surgeons, we all want the most predictable, accurate technology to provide consistent and positive results.

Restoring vision

There are a variety of artificial lenses available to potentially minimize or, in some cases, eliminate the need for prescription eyeglasses after surgery. Patients are encouraged to discuss all options with their eye surgeon.

Traditional lenses can correct near- or far-sightedness, as well as some forms of astigmatism. Premium lenses, such as multifocal, accommodating or toric lenses, can be used to improve the range of focus as well as treat varying degrees of

astigmatism. These premium lenses are often not covered by insurers, thus requiring an out-of-pocket expense.

The implanted lenses are not necessarily a complete solution to vision restoration. Our eyes continue to change with age and prescription glasses or contact lenses may be needed as time goes on.

Several of my colleagues at Flaum Eye Institute also perform this high-tech surgery: Shobha A. Boghani, MBBS, Holly Hindman, MD, Scott McRae, MD, David Shiple MD, Shakeel



Amateur photographer Bob Luce recently had cataracts removed using a new laser surgery technique at UR Medicine’s Flaum Eye Institute. His vision improved dramatically and colors are much more vibrant, he says

Shareef, MD, and Regina Smolyak, MD.

The Flaum Eye Institute is a leader in ophthalmologic care and research in Upstate New York. Clinicians and scientists collaborate to restore vision and improve therapies for tomorrow. The institute is based on the campus of the University of Rochester Medical Center and has a second office in Geneva, serving the Finger Lakes region.

For more information about cataract surgery, go to www.cataract.urmc.edu or call 585-273-3937.

Collaborative Care is the Best Treatment for Lymphedema

By Deanna Hayden, PT; Leigh E. Vigneri, PT, MLD/CDT, CMP, Cert. MDT; and Robin Rice, PT, MLD/CDT

Although millions of patients are diagnosed with lymphedema every year in the United States, we have found that many physicians and caregivers may be unfamiliar with the causes and treatments available for this condition. By working together in a collaborative approach, physicians and both physical and occupational therapists can often bring lasting relief to lymphedema patients.

As its name suggests, lymphedema is an accumulation of lymphatic fluid that causes localized swelling, usually in the extremities. The lymphatic system includes a network of lymph vessels and nodes that carry lymph fluid – rich in large protein molecules – back to the heart. That fluid is filtered as it flows through the nodes, trapping bacteria and other foreign substances which are then destroyed by lymphocytes that are responsible for fighting infections and cancers. Obstructing the lymphatic flow causes the fluid to accumulate and become stagnant in the tissues of the limb closest to the obstruction. This creates a favorable environment for bacterial growth, which can lead to frequent infections.

Lymphedema is most commonly linked to cancer treatments; this is known as secondary lymphedema, in which swelling often occurs following surgery or radiation. Secondary lymphedema can also result from any trauma, injury or surgery to the lymphatic system – it can develop immediately, or anywhere from months to years after the surgery or injury. Another type, primary lymphedema, can develop at birth or in puberty or adulthood; it typically affects the lower extremities in women.

The primary symptom for either kind of lymphedema is swelling, most commonly in the arm or leg but also sometimes in the neck, chest wall/breast, face, abdomen, back and genitals. Pitting edema, characterized by indentations in the skin after the skin is depressed for a few seconds, may be present. Affected areas may also show evidence of tightness, pain, a feeling of heaviness and changes in skin texture.

Although not curable, lymphedema can be effectively managed to increase patient comfort and reduce the likelihood of potentially harmful secondary infections. Following a diagnosis, physical and occupational therapy treatments can help reduce the size of the limb: Manual lymph drainage, developed by Dr. Emil Vodder in the 1930s, is a gentle massage of the connective tissue that assists in the movement of stagnant fluid through the vessels and stimulates the development of collateral channels through which the lymph can begin to flow.

Clinical treatments must be followed by daily self-care responsibilities. An experienced physical or occupational therapist can train the patient and/or a partner to continue effective massage

techniques at home, along with compression of the extremity to prevent the re-accumulation of stagnant lymph fluid while reducing pressure on the skin tissue. Compression is typically accomplished with bandaging or the use of medical garments; continued daily use of these compression resources may be necessary. Limb swelling can be further reduced by a regular regimen of aerobic, stretching, and strengthening exercises, all performed by the patient while wearing compression bandages or garments. Swimming, walking, bicycling and yoga can also be beneficial for the lymphedema patient.

It is particularly important for the patient to observe a strict compression regimen when traveling by airplane, as the decrease in cabin pressure can put stress on the lymphatic and circulatory systems and exacerbate swelling. Housework, yard work, and exercise can also aggravate fluid accumulation, making compression safeguards important during those activities as well.

Effective lymphedema management depends heavily on patient and family education. Skin care, massage and compression use are all key in decreasing the risk of exacerbation of lymphedema. However, early diagnosis and a comprehensive treatment plan can help patients return to their regular activities, free of discomfort and long-term risks.

The authors are licensed physical therapists with Rochester Regional Health System.

Proactive Care

Prevention is the best “cure” for lymphedema. At-risk patients should observe these precautions:

- Perform **daily skin checks** to look for cuts, abrasions, insect bites, hangnails or torn cuticles on the affected limb. Any skin lesions are potential sources of infection and should be cleaned and covered. Any signs of infection should be reported promptly to the primary care physician.
- Maintain **good skin hygiene** – keep the skin meticulously clean and completely dry, particularly in skin creases and between fingers and toes.
- Patients should use an **electric shaver** for hair removal to prevent cutting the skin, and take care not to cut their cuticles during manicures or pedicures.
- **Avoid carrying heavy objects**, as straining the affected limb can exacerbate swelling.
- **Avoid extreme temperature changes.** Do not use hot tubs, whirlpools, saunas or steam baths. When bathing or washing dishes, use warm water instead of very hot water.
- **Always wear sun protection** when outdoors.

“Face Time” for the Heart Diagnoses Cardiac Disease

URMC Press

To the careful observer, a person's face has long provided insight into what is going on beneath the surface. Now, with the assistance of a web camera and software algorithms, the face can also reveal whether or not an individual is experiencing atrial fibrillation, a treatable but potentially dangerous heart condition.

A pilot project, the results of which were published online today in the journal *Heart Rhythm*, demonstrates that subtle changes in skin color can be used to detect the uneven blood flow caused by atrial fibrillation. The technology was developed in a partnership between the University of Rochester School of Medicine and Dentistry and Xerox.

“This technology holds the potential to identify and diagnose cardiac disease using contactless video monitoring,” Jean-Philippe Couderc, PhD, with the University of Rochester Medical Center’s Heart Research Follow-up Program. “This is a very simple concept, but one that could enable more people with atrial fibrillation to get the care they need.”

Atrial fibrillation is an irregular or sometimes rapid heart rate that commonly causes poor blood flow to the body. This occurs when erratic cardiac electrical activity causes the upper and lower chambers of the heart to beat out of sync. More than three million Americans suffer from the disease.

While the condition can be readily diagnosed, in many people it goes undetected, either because it comes and goes, or because the symptoms – fatigue and weakness – are too general to warrant concern. Consequently, it is estimated that 30 percent of people with atrial fibrillation do not know they have the condition.

Furthermore, while atrial fibrillation is treatable if detected – both by medication and through a procedure that essentially resets the heart’s electrical activity – many individuals with the condition will experience a reoccurrence. If untreated, the condition places individuals at a significantly higher risk for blood clots and stroke.

The technology described in the study employs a software algorithm developed by Xerox that scans the face and can detect changes in skin color that are imperceptible to the naked eye. All this requires is that the subject remain still for 15 seconds.

Sensors in digital cameras are designed to record three colors: red, green, and blue. Hemoglobin – a component of blood –

“absorbs” more of the green spectrum of light and this subtle change can be detected by the camera’s sensor. It turns out that the face is the ideal place to detect this phenomenon, because the skin is thinner than other parts of the body and blood vessels are closer to the surface.

Study participants were simultaneously hooked up to an electrocardiogram (ECG) so results from the facial scan could be compared to the actual electrical activity of the heart.

The researchers found that the color changes detected by video monitoring corresponded with an individual’s heart rate as detected on an ECG. Essentially, the irregular electrical activity of the heart found in people with atrial fibrillation could be identified by “observing” the pulses of blood flowing through the veins on the face as it absorbed or reflected green light with each heartbeat.

The study found that the video monitoring technique – which researchers have dubbed videoplethymography – had an error rate of 20 percent, comparable to the 17 to 29 percent error rate associated with automated ECG measurements.

While the pilot study was only conducted on 11 people and intended to demonstrate that the technology was feasible, the researchers are now in the process of evaluating the technology on a larger study population, including those without atrial fibrillation.

Couderc contends that these new studies – coupled with the application of image stabilizing technology and the ongoing improvement in the resolution of cameras – will lower the error rate. “This study was intended to be a proof of concept and, as is the case with many new technologies, we believe that we can significantly improve its accuracy and the usability,” said Couderc.

Like many other personal health technologies that have emerged in recent years, the authors see this as a way to diagnose or monitor people at risk for atrial fibrillation and alert them and/or their physicians when the condition is detected. The contactless nature of the technology and the proliferation of web cameras could even eventually allow the screening to occur without interrupting the user. For example, the program could run in the background while someone is reading their email on their tablet, computer, or smart phone.

Additional authors include Derick Peterson, Xiaojuan Xia, and Burr Hall with the University of Rochester, and Survi Kyal, Lalit Mestha, and Beilei Xu with Xerox. The study was funded by Xerox and the Center for Emerging and Innovative Sciences, a New York State-support Center for Advanced Technology.

Cash Balance Plans for Professional Firms: Understanding a Hybrid Approach

A Safe Harbor from Rising Tides of Uncertainty



James Esposito, QPC

Much has been written in today's retirement planning industry about the sheer growth of cash balance plans, a type of qualified defined benefit (DB) plan. Between 2011 and 2012, plan adoption surged to 22%, compared to only 1% for the ubiquitous 401(k) plan. Today, these make up roughly 25% of all U.S. defined benefit plans, compared to only 3% in 2001.

Among their many benefits, cash balance plans, as qualified DB plans, offer participants an account balance, the vested portion of which can be distributed as a lump sum upon retirement, or upon separation from a business. Employees may more readily understand and appreciate a benefit defined as an account balance, vs. a vaguely-defined monthly retirement benefit payable in the future—based upon average compensation and service. Further, pairing a cash balance plan with a 401(k) plan (a “hybrid” approach), and using techniques such as New Comparability, allow an employer to craft differing benefit levels for different participant groups, while still satisfying complex non-discrimination requirements.

Sheer popularity of cash balance plans among successful professional firms such as physicians' offices may stem from a few reasons: a growing expectation that income taxes and health care expenses will continue to rise, as well as a desire for owners to protect assets from creditors, amid an increasingly litigious business climate. Today, this is especially timely, with the Congressional Budget Office (CBO)'s Aug. 2014 update, where individual income taxes as a percentage of GDP will continue to trend upward over the next decade, as a result of inflationary pressures.

In an increasingly unknowable and changing environment, professional firms like physicians' offices might consider the potential impact of such tax increases, as well as gain a better understanding of the many tax-sheltered savings benefits that cash balance plans offer; in particular – the aforementioned “hybrid” approach. Recently-released guidance by the IRS and Treasury Department in September 2014 on hybrid plans, has finalized the allowable interest crediting rate definitions that can be used in a cash balance plan to include a maximum fixed interest rate of 6%. Furthermore, the new regulation, effective

Jan. 1, 2016, enables interest credit rate definitions that can help sponsors of cash balance plans reduce funding volatility and share risk with participants.

Aside from the rising tide in income taxes—perhaps among the most unknowable issues for those planning ahead for retirement is the continued rise of health care costs. Although difficult to quantify over the long-term, and largely dependent on various individual characteristics, such costs are expected to be significant. The Employee Benefits Research Institute projects that a married couple age 65 with median drug expenses is estimated to need approximately

\$151,000 to have a 50% chance of meeting their retirement health care costs and approximately \$255,000 to have a 90% chance.¹ Paired with a portable Health Savings Account, assets in qualified high deductible retirement health plans are likely the chief source to address these costs. Subsequently, the need for increased retirement savings is a very likely reality and a priority for owners of small to mid-sized, closely-held professional firms.

Benefits of a Hybrid Plan Approach

In general, companies that only offer a 401(k) plan typically provide employer contributions to participants averaging roughly 2.6% of pay. Conversely, using a hybrid approach, after adopting a cash balance plan alongside the \$401(k), employer contributions tend to approach 6% of pay or more. When census demographics are ideal, it is not uncommon for an employer sponsoring a Cash Balance and \$401(k) Plan combination arrangement to provide a substantially meaningful benefit for rank and file employees of between 7% - 10% of pay. Even more beneficial, the percentage of pay allocations for owners and key principals can often approach 70% or more.

This combination arrangement is particularly appealing to the middle-aged business owner, who after 20-30 years of pouring every available dollar back into the business, is now quickly approaching retirement, without sufficient savings to maintain a current standard of living. In a standalone 401(k) plan, owners can achieve allocations totaling only \$52,000-\$57,500 (as

indexed for 2014). Adding the cash balance plan component, can allow potential total allocations of more than \$160,000 for individuals age 45 and older. The chart below summarizes the maximum allowable allocations by age in a combination arrangement.

Age	Cash Balance Plan ⁱⁱ	\$401(k) Profit Sharing Plan ⁱⁱⁱ	Total Both Plans ^{iv}
45	\$112,056	\$52,000	\$164,056
50	\$143,680	\$57,500	\$201,180
55	\$184,304	\$57,500	\$241,804
60	\$236,495	\$57,500	\$293,995
65	\$244,112	\$57,500	\$301,612

While cash balance plans broadly appeal to businesses of all sizes and types, they are not ideal for every employer. Before making a decision, business owners should consider the following questions:

- Do you want to greatly increase your tax-deductible retirement savings?
- Do you want to control the cost of benefits for employees?
- Are you and your key executives much older, on average, than your rank and file employees?
- Is your business's income and profitability consistently stable and high?
- Can you make a commitment to increase plan contributions for the foreseeable future?

The above are just a few of the key questions for business owners considering the many benefits of a hybrid approach. Risks in today's environment can potentially impact retirement savings as owners prepare for retirement. As a result, owners should consider retirement plan solutions that allow the flexibility of key benefits at both the employer and employee level.

For more information on cash balance plans, please contact Manning & Napier at: info@manning-napier.com.

ⁱ "Amount of Savings Needed for Health Expenses for People Eligible for Medicare: More Rare Good News", Employee Benefit Research Institute, Notes, October 2013.

ⁱⁱ This column illustrates the maximum amount that can be distributed as a lump sum to a participant that has earned income of \$260,000, is fully vested and has one year of plan participation. It uses the 2014 Applicable Mortality Table at 5% for the monthly benefit and 5.5% for lump sum distributions; and a normal retirement age assumption of 65.

ⁱⁱⁱ For 2014, the maximum defined contribution plan annual addition for an individual is the lesser of 100% of compensation or \$52,000 (\$57,500 if catch-up deferrals apply). A \$5,500 catch-up deferral is allowed for any participant who attains age 50 during the plan year and either makes salary deferrals up to the maximum of \$17,500 or reaches another regulatory or plan-imposed allocation limit. This amount assumes that maximum allowable salary deferrals have been made, and that the Cash balance plan is covered by the Pension Benefit Guaranty Corporation.

^{iv} Required Minimum Distributions must be made by April 1 of the year following the year in which age 70½ is attained; unless still an active non-owner employee.

Approved SMA-ART004 (11/14)

James Esposito is a Qualified Plans Consultant for Manning & Napier. In this capacity, he assists employers with the technical design of existing and new qualified retirement plans to better address their goals and objectives. James also provides employers with plan document and governance reviews to ensure overall compliance with an increasingly complex body of rules and regulations. Prior to joining Manning & Napier in 2011, James spent 12 years as the Marketing Director for Security Administrators, Inc., an actuarial firm in Binghamton, NY. He has authored numerous articles and white papers concerning qualified plan design and maximizing benefits for owners of closely held businesses. James has been working in the qualified plans arena for over 15 years, performing defined benefit and defined contribution plan administration and consulting.

James earned his BA in Mathematics from the State University of New York at Buffalo. He is a 10+ year member in good standing of the American Society of Pension Professionals and Actuaries (ASPPA), through which he holds the designation of Qualified Pension Administrator (QPA).

What is My Liability?

Preceptorship and Proctoring

Issue

The process of clinical learning involves observation, supervised performance, and peer review. Similarly, the process of credentialing a provider for a newly acquired skill requires the credentialing body of a healthcare facility to review that provider's respective formal training, and, to document reasonable procedural competence for that specific skill, a process which then continues through subsequent peer review. The process of credentialing providers for procedural competence is generally outlined in the policies and bylaws of the medical staff. In the event that members of a medical staff are unable to assess a provider's procedural competence (as may occur with a newly developed procedure or technique, for example) or, if there are real or perceived conflicts of interest precluding in-house peer review, the medical staff may need to consult an outside expert to help fulfill credentialing and/or peer review functions.

The process whereby a more skilled observer is present during a procedure is either (1) a preceptorship, whereby the preceptor is an instructor or teacher and is therefore responsible for the actions of the trainee; or, (2) a proctorship, whereby the proctor is not teaching, and has assumed limited responsibility for the assessment and documentation of the skills and knowledge of another, presumably already-trained, provider. While there is no question that a preceptor is fully liable for the actions of his or her trainee; the issue of a proctor's liability for the actions of the operating provider remains more complex. Concerns for proctors mostly focus on what liability, if any, is borne by the presumably most skilled and competent surgeon, in the event that the proctored proceduralist either manifests gross incompetence or encounters an unforeseen catastrophic complication.

A proctor may arguably have an ethical duty to the patient; however, the issue of whether or not there is a legal duty remains circumstance-specific. Many proctoring guidelines recommend intervention by the proctor in the event of a complication or



James E. Szalados, MD, MBA, Esq.

emergency, citing ethical obligations and traditionally accepted medical notions regarding the best interests of the patient. There are no precedents for legal challenges to a proctor's decision choosing to intervene when witnessing malpractice and, in general, laws do not specify what immunity, if any, is conferred on a proctoring physician for intervening on a patient's behalf. Good Samaritan laws vary by state. Theoretically Good Samaritan laws should immunize proctoring physicians when they exercise an ethical responsibility to aid patients in emergencies. The legal criteria to invoke Good Samaritan protection require that the physician (1) acted in good faith, (2) was delivering emergency medical care, and (3) had no preexisting duty to treat the patient. Good faith refers to the willingness of a physician to respond to an emergency when there is no duty to do so is evidence of good faith. Medical emergencies have been defined to represent an "exigency of so pressing a character that some kind of action must be taken". However, unexpected events in the operating room are not necessarily emergencies. In the California case of *Bryant v. Bakshandeh* (226 Cal.App.3d 1241(1991)), a urologist was consulted after a patient was asleep but the operation had not started. Following multiple attempts by the surgeon insert a Foley catheter a urologist was called and was also unable to pass the catheter; the operation was then aborted but the patient developed complications from the attempted catheterization. The urologist invoked the Good Samaritan statute as a defense, but the argument failed since the 'emergency' could not be established.

On the other hand, and in general, proctors are not subject to legal liability, unless they have established a professional relationship with the patient. Only two states, California and Ohio, have formally addressed the liability of proctors in the operating room and therefore binding precedents are limited. Liability in negligence must be predicated in a legal duty to the patient; absent a legal duty, there can be no breach, and therefore there can be no liability. Proctors has been held to not be liable under negligence theory even if they witness gross malpractice and choose not to intervene; this principle is best illustrated in the California case of *Clarke v. Hoek* (California 174 Cal. App. 3d 208 (1985)). In *Clarke*, a proctoring orthopedic surgeon witnessed malpractice and chose not to intervene; the trial court dismissed on summary judgment finding that the surgeon had no legal duty to intervene. The case went to appeal wherein the

plaintiff's expert witness claimed that it was a violation of the standard of care to not intervene, but the Appellate court sustained the summary judgment. The California appellate court determined that the 'duty to treat' was not a matter of standard of care but rather an issue of law and that "absent a special relationship giving rise to a duty to act, a person is under no duty to take affirmative action to assist or protect another, no matter how great the danger in which the other is placed, or how easily he could be rescued."

The Ohio courts reached a similar conclusion in the case of *Zablocki v. Wilkin* (Ohio Com. Pl. 2003) where the plaintiff suffered a fractured right ankle and was referred to the care of Dr. Wilkins who was just recently credentialed for podiatric surgery and was required to have a proctor in attendance for his first five surgeries. Dr. Walkovich was appointed by the hospital to serve as Dr. Wilkin's proctor; he was not paid for his proctoring services, did not scrub in, and was not present for the entire procedure however he admitted to discussing the proposed procedure with Dr. Wilkin before the surgery. Dr. Walkovich testified that his "sole function as a proctor was to observe another doctor for purposes of determining if that doctor has demonstrated the skills necessary to justify an extension of privileges." Zablocki later filed a medical malpractice action against both surgeons, in which she alleged, inter alia, that Dr. Walkovich failed to properly supervise the procedure. The court dismissed the action as a matter of law, stating that a "physician who, on behalf of a hospital and without compensation, acts as a proctor in observing a surgical operation for the sole and express purpose of assessing and reporting on the competence of a candidate for membership of a hospital medical staff" does not owe a duty to a patient to "intervene in that surgery in order to prevent malpractice by the proctored surgeon."

Therefore, in order for a proctor to minimize his or her legal risk, he or she must avoid behaviors which may imply a physician-patient relationship that may arguably impose a duty of care. A physician-patient relationship could arise if the patient is led to believe that the proctor will be 'supervising' the procedure, if the proctor is named as member of the operating team on the consent form, if the proctor meets with the patient and suggests that he or she will be assisting in the procedure, or, if the proctor actively participates in the procedure either by offering medical advice or procedural assistance. If the proctor 'crosses the line' from observer to 'participant' then an argument for co-defendant liability can be more convincingly made. Suggestions of active involvement even indirectly can lead to vicarious liability, active intervention may create liability as a surgical assistant, and offering advice may create liability as a consultant. Insulation from liability may be bolstered where the proctor does not scrub and remains outside the sterile field, is absent for portions of the procedure, and is appointed to serve.

In the event that a proctor does, without invitation, intervene on behalf of a patient, such action may still be subject to potential collateral liabilities that are not predicated in a theory of negligence, such as violation of the peer review process, bias, battery, unauthorized practice, or defamation of character. In many instances, proctors retained specifically for the purpose

of demonstrating competency in support of medical staff credentialing are neither licensed to practice in the state or credentialed to perform that procedure within the institution in which the proctoring occurs; in such cases, the active involvement of the proctor in the procedure is unlicensed practice of medicine.

Since the proctoring process exists to meet institutional credentialing requirements, proctors should review the medical staff policies and bylaws beforehand so as to best adhere to institutional proctoring guidelines and expectation and to best protect the interests of all parties. The act of proctoring represents an objective evaluation of another physician's clinical competence by the proctor, who is in fact a representative of, and is responsible to the facility's medical staff. Proctors may further insulate themselves from liability through contractual assignment of obligations and liabilities. On the other hand when the proctor and the individual being proctored practice in the same state or institution, the boundaries between proctor and colleague are more likely to blur; in such instances formal written protocols should be developed and strictly adhered to, careful records maintained, and counsel should be consulted to maximize the protections afforded by relevant peer-review immunity statutes. Even in cases where the proctor and proctored are members of the same medical staff, a contractual assignment of obligations and liabilities may have value in liability protection.

In summary, physicians who chose or are called upon to provide proctoring services should carefully review the proctoring agreements which outline the scope of their responsibilities. Prospective proctors should consider expressly limiting their liability through contractual language clearly defining their role. The potential issue of whether the medical staff has an affirmative duty to indemnify a proctor is one that should be explored contractually. Proctors are well advised to seek legal guidance before proctoring. Finally, it is important that proctors carefully weigh the potential implications of any active clinical involvement which they undertake while proctoring.

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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MEDICAL PRACTICE AUDITS

Risk Analysis and Prevention

by Michael J. Schoppmann, Esq.

In today's medicine, financially intrusive records requests can originate from various entities, and in different ways. One of the "ways," or mechanisms, by which records may be requested is through the issuance of subpoenas involving civil or criminal matters. Some subpoenas may give the physician an opportunity to respond while others may go as far as search warrants in the case of criminal matters and do not allow for the physician to react or oppose them. In addressing the ways of insurance companies, another source of such requests, it is crucial to understand the Insurer's rights to medical records. The Amended HIPAA Privacy Rule gives health plans broad authority ("regulatory permission") to obtain information without the patient's consent. As a result, it is left to physicians to assert their rights (however limited) and to take any and all measures necessary to be certain they understand, and manage as needed, both the timing and the scope of every records request.

Given the extensive number of entities from which an audit can be generated, the risks involved could range from an insurance payment dispute to full blown investigations by state agencies including the Medicaid Inspector General and the State's Insurance Frauds Bureau (and local prosecutors) to numerous Federal agencies such as the Internal Revenue Service, the Office of Inspector General, Medicare Intermediaries, United States Attorneys, and/or the Federal Bureau of Investigation. These agencies are empowered and directed under an ever growing set of laws including the Federal False Claims Act, the State False Claims Act, the Federal Anti-Kickback Statute, and the Federal Stark Laws. It is worth noting that even though they are separate institutions, and that some are private whereas others public, the fact remains that these entities—Insurance, Law Enforcement, Medicare and Medicaid—all closely coordinate with each other.

As a physician who may be the potential subject of an audit, in risk managing the "ways" of these entities, it is of extreme importance to understand and assert your rights, and the rights of your practice. To do so, implementing the following procedures without exception is key:

- Involve yourself in your practice and each records request.
- Take great care in speaking to anyone.
- Never give anything to anyone without knowing if they have the authority to ask for it and if you are producing what is correct in that context.
- Never let anyone into your office (with certain very severe legal exceptions).
- Make certain you only act under the guidance and protection of experienced health care counsel.

Risk management of financial audits must also be aggressively continued throughout the measures deployed in preparing your actual response. Once you are the recipient of such a request, the manner in which it is handled may have far reaching implications. The following measures should be taken in bolstering your resistance to further risk.

Scrutinize the request itself. The request must be carefully reviewed. Is the request legally appropriate? What records are specifically being requested? What information supports the billing and coding submitted by the practice for the date of service? Are the records organized, complete and self-explanatory? Has the practice made a copy of what is produced? Are the records set to be delivered with a return receipt?

Analyze the records actually being requested. Once the records have been provided, there remains another set of measures to deploy – not simply awaiting the records review results. Each practice, subject to a records request should analyze the records actually being requested. Is there a common theme to them? Are there common billing, coding and/or documentation issues? If so, does the practice stand in compliance with the policies and protocols governing those records and/or patients? If not, should remedial measures be deployed, and if so how? A records request is, in essence, a warning to the practice and the physicians that there may well be an issue that needs to be addressed and ignoring that warning will only serve to escalate the severity of the audit response.

Carefully consider settlement. If there is an adverse audit

result, the question then becomes whether to challenge that result or to “settle” the matter at that stage. Settling an audit involves potential implications including contractual, civil, criminal, administrative, licensure, privileges and many more. If a demand for repayment is being made, the practice and physicians must decide if the practice, or they as individuals, are able to pay the demanded amount and if so, how (i.e., lump sum, over a period of time, etc.)? Will the repayment be shared equally between the owner-physicians or will there be an allocation based upon each physician’s error rate?

Carefully consider challenging the decision. If you are not prepared or able to pay, are you prepared to fight the decision? Can you risk jeopardizing your participating contractual status? How strong are the legal, coding and medical underpinnings of the practice’s challenge? What will the costs be associated with such a challenge? How long will the challenge take? Is there an alternative pathway such as a compromised repayment amount? How does any compromised repayment amount

balance against the anticipated costs/losses to the practice? No practice should resolve any audit repayment demand without first carefully weighing all of these questions (and their answers).

In conclusion, the best way to risk manage an audit is to develop, implement and routinely revisit risk management/compliance tools such as having routine compliance audits conducted (under the protection of legal counsel) in order to analyze the adequacy of documentation, provide routine evaluations of business relationships, scrutinize the practice’s billing departments/outside companies, etc. In doing so, physicians and their practices can dramatically decrease their ultimate risk - being subject to audit.

Kern Augustine Conroy & Schoppmann, P.C., Attorneys to Health Professionals, DrLaw.com, is solely devoted to the representation and defense of physicians and other health care professionals. Mr. Schoppmann may be contacted at 1-800-445-0954 or via email at MSchoppmann@DrLaw.com.

LEGAL NEWS

EBOLA PREPAREDNESS FOR THE NON-HOSPITALIST

Question: I don’t work in the hospital; what measures should I take to protect myself and my staff in my private office?

Answer: The United States Centers for Disease Control and Prevention (the “CDC”) is urging physicians in stand-alone clinics and private offices to take any and all recommended measures to protect themselves, their employees and their patients from the potential for exposure. There have already been two Ebola scares, one at an urgent care center in Texas and one at a physician’s office in Boston, which make it clear this is not just an illness for which the emergency departments and hospitals should be prepared. In response, the CDC has issued a checklist for practitioners to use when evaluating a patient they suspect may have Ebola. The checklist can be found here: <http://ow.ly/D7mLq>. Additionally, the CDC has put together general guidance for proactive preparedness including, in pertinent part, a general review and overhaul of infection control policies and procedures. The Health Care Provider Preparedness Checklist for Ebola Virus Disease can be downloaded here: <http://ow.ly/D7mVQ>. It is also highly recommended that physicians purchase and keep on-hand Personal Protective Equipment (or “PPE”) even if they are not otherwise required by regulation to have such PPE in their office. Finally, you should know where to report any potential infection or exposure on the state, local and federal level. On the federal level, the CDC should be immediately notified of any suspected cases. A list of state epidemiologists can be found here: <http://ow.ly/D7n2i>.

HIPAA Privacy Guidance Issued

Question: Since the validity of same-sex marriages is determined on a state-by-state basis under state law, how is the definition of “spouse” interpreted under the Federal HIPAA Privacy Rule?

Answer: The United States Department of Health and Human Services Office for Civil Rights (the “Department”), has recently issued guidance to address the application of the case United States v. Windsor to HIPAA and same-sex marriages. Last year, in United States v. Windsor, the United States Supreme Court held that Section 3 of the Defense of Marriage Act, which stated that federal law would only recognize opposite-sex marriages, was unconstitutional. Therefore, the term “spouse” in the HIPAA Privacy Rule includes individuals in a legally valid same-sex marriage sanctioned by a state, territory or foreign jurisdiction. This applies regardless of whether the location where the services are rendered recognizes the marriage.

This is important to remember; as Covered Entities (as defined by HIPAA) are permitted to share an individual’s protected health information with family members under certain enumerated circumstances.

The Department has stated it will issue further guidance or initiate rulemaking to address same-sex spouses as “personal representatives” under the HIPAA Privacy Rule. We will monitor this rule making and issue updates as it progresses.

The most recent guidance may be found in its entirety at: <http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/samesexmarriage/hhs-windsorhipaaguidance.pdf>. If you have any questions, 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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ROCHESTER REGIONAL HEALTH SYSTEM

Rochester Regional Health System Unveils New Brand, Mission, Vision, Values

New identity elements emphasize a focus on highly collaborative, patient-centered care



Rochester Regional Health System (Rochester Regional) today unveiled a new logo and introduced its vision, mission and values that underscore the System's innovative leadership and commitment to preserve health and enhance the lives of a growing regional community of patients, residents and clients. These new branding and identity elements are being introduced this week to the Health System's more than 14,000 physicians, nurses, caregivers and support staff through department celebrations and new banners and posters displayed throughout its main campuses and regional affiliates. Rochester Regional Health System is the result of the alliance formalized in July between Rochester General and Unity health systems. Clifton Springs Hospital & Clinic and United Memorial Medical Center in Batavia will join the System later this year.

The new logo was designed to express the vibrancy, promise and unmatched capability of Rochester Regional to bring together a full continuum of integrated, nationally-recognized health care services and solutions that can conveniently and consistently help individuals get healthy and stay healthy, regardless of where they live in the region.

"As a fully integrated system – both clinically and operationally, Rochester Regional is uniquely qualified to lead efforts to improve patient and population health, improve the care experience and reduce cost," explained Rochester Regional Health System Co-CEO,

Mark Clement. "When individuals see this new logo throughout the region, they can be confident that the providers and facilities represented by this brand offer the highest quality care, personal attention and service to help them enjoy better, healthier lives."

The values – Quality, Compassion, Respect, Collaboration and Foresight – were defined with input from employees across the system as their shared commitment to the community and to each other.

The mission statement – To enhance lives and preserve health by enabling access to a comprehensive, fully integrated network of the highest quality and most affordable care, delivered with kindness, integrity, and respect – incorporates the shared philosophies that made the partnership between Rochester General and Unity such an ideal fit, according to Co-CEO Warren Hern.

"Culturally, Unity and Rochester General have always had much in common, especially a passionately held mutual commitment to patient-focused care," Hern said. "As we continue on our journey of integration, our complementary clinical strengths and wide-ranging regional locations will allow us to provide even more patients with comprehensive care of the highest quality and value."

UCVA Cardiovascular to Join Rochester Regional Health System

UCVA Cardiovascular Practice will join Rochester Regional Health System on January 1, 2015. The two organizations finalized their agreement on October 31, which will bring 15 cardiologists and 110 employees from four office locations into the newly formed health system.

UCVA has been serving the Greater Rochester and Southern tier areas for more than 20 years, with offices in Greece, Brighton,

Dansville and Geneseo as well as providing cardiology services at Unity Hospital for many years. While UCVA will become an integral part of the highly regarded Sands Constellation Heart Institute (SCHI) of Rochester Regional, their patients will experience a seamless transition with little change in day-to-day operations.

"We are excited about the opportunity to become a part of the staff at the acclaimed Heart Institute," said Maurice E. Varon, MD, Managing Partner UCVA. "All of us at UCVA are committed to continuing to provide the highest quality of care our patients expect, and joining Rochester Regional will ensure our ability to provide seamless and exceptional service long term."

"Bringing the talents and patient-first focus of the UCVA team into Rochester Regional will further position our cardiac team as the best in the Northeast," said Ronald Kirshner, M.D., Chief of the Sands Constellation Heart Institute at Rochester Regional Health System. "Our system-wide affiliations, our physicians and staff, and our award-winning quality together ensure our patients experience the best cardiac care available."

Rochester Regional's Rochester General Hospital (RGH) has earned national recognition for excellence in cardiac specialties and continues its affiliation as a Cleveland Clinic Heart Surgery Program. Home to the fourth largest cardiac center in New York State, RGH has been recognized nine times as one of the nation's Top 100 Cardiovascular Hospitals. According to the 2014 report from CareChex®, a division of Comparison Medical Analytics, RGH ranks first in New York for Cardiac Care and Heart Attack Treatment and #2 in New York for Overall Medical Care.

Rochester Regional Health System Unveils

New Brand, Mission, Vision, Values



The nationally-recognized Rochester General Breast Center is opening a second office - located in the Linden Oaks Medical Complex/20 Hagen Drive in

Rochester.

The new office – housed in the Lipson Cancer Center at Linden Oaks – will open September 2d. Parking is free with easy access to the building. Appointments are now available (585 922 4715).

Both Drs. Lori Medeiros and Joel Yellin will see patients at the Linden Oaks office at various times during weekday hours.

The Rochester General Breast Center has been designated as a Breast Center of Excellence with a reputation for kind, compassionate care and the support of a nurse navigator.

URMC

Clinton Morrison to Lead Pediatric Plastic Surgery Team



Clinton S. Morrison, MD, a plastic surgeon who recently completed his fellowship at Seattle Children's Hospital, has been named the new Plastic Surgery Team Director for the Pediatric

Cleft and Craniofacial Anomalies Center at UR Medicine's Golisano Children's Hospital.

Morrison, who joined the children's hospital earlier this month, will lead the multidisciplinary team in their treatment of cleft lip, cleft palate, and other craniofacial anomalies.

"Clinton came with a tremendous academic track record and a sterling reputation as a surgeon," said Howard N. Langstein, MD, chief of the Division of Plastic and Reconstructive Surgery. "We were thrilled with the opportunity to bring him to Rochester."

A native of Louisville, Ky., Morrison graduated from the University of Louisville School of Medicine and completed his residency in the plastic surgery program at Rhode Island Hospital.

NEWARK WAYNE COMMUNITY HOSPITAL

Cynthia Martinez-Capolino, MD, Appointed Chief of Emergency Medicine at Newark-Wayne Community Hospital



Cynthia Martinez-Capolino, MD, a board-certified Emergency Medicine physician, has been appointed chief of Emergency Medicine at Newark-Wayne Commu-

nity Hospital. As chief, she will oversee the medical services for the over 24,000 patient visits in Newark-Wayne's Emergency Department annually. She has been a physician in the Emergency Department at Newark-Wayne since 2012 and was appointed medical director of the Stroke program, which she spearheaded in 2012. Under her leadership, the hospital received a Bronze Stroke Quality Achievement Award from the American Heart/American Stroke Association for its treatment of Stroke patients earlier this year.

Dr. Martinez-Capolino attended the University of Rochester School of Medicine. She completed her residency training in Emergency Medicine/Internal Medicine at Henry Ford Hospital in Detroit, Michigan. In addition, she has completed fellowships in Primary Care and Infectious Disease. Previously, she worked at the Emergency Physician's Group in Michigan and at the Henry Ford Medical Group in Detroit.

"Our goals are to provide the best care possible for every patient," said Rob Cercek, Regional President of Operations, Rochester Regional Health System. "Dr. Martinez has demonstrated her commitment to providing quality, patient-focused care to every patient so I am pleased that she will be leading our Emergency Medicine team."

Rochester Regional Nephrologists to See Patients at Newark-Wayne Community Hospital

Nephrologists (specialists in kidney disease and hypertension) from Rochester General Hospital's Department of Medicine, John



Hix, MD, Marvin Grieff, MD and Jonathan Bress, MD, are now seeing outpatients at Newark-Wayne Community Hospital. The practice is located at The Department of Surgery/Telehealth Outpatient Physicians' Office on the 2nd floor at Newark-Wayne. The physicians are currently scheduled to see outpatients at Newark-Wayne every Tuesday morning.

ACM MEDICAL LABORATORY

Dr. Mary Williamson Brings the Latest Laboratory Testing Guidance to the Healthcare Provider Community with Wallach's Interpretation of Diagnostic Tests

ACM Medical Laboratory, a division of Rochester Regional Health system, is proud to announce that Dr. Mary Williamson, Vice President, Scientific Affairs and Laboratory Operations, has led the effort to publish a revised and updated version of the well-known Wallach's Interpretation of Diagnostic Tests textbook. In this tenth edition from Lippincott Williams & Wilkins, Dr. Williamson worked with Dr. L. Michael Snyder as Senior Editors to release the latest in testing guidance to give healthcare providers continued

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confidence in ordering the right test at the right time.

This textbook is considered a leading resource for clinical laboratory medicine and is geared for primary care physicians, physician's assistants, nurse practitioners, and medical and nursing students as a guide to improve laboratory utilization by making it simpler to select and interpret the most useful laboratory tests for specific disease states. The book has been published in 2014 in several languages with more than 30,000 copies distributed worldwide.

Dr. Williamson serves as the primary scientific intermediary for ACM's Clinical Trials and Medical Diagnostic businesses, responsible for defining client testing requirements, aligning technical capabilities and resources globally to meet our clients' needs, and ongoing development of ACM's diagnostic test offerings. Dr. Williamson acts as the scientific liaison with our partner and reference laboratories, and leads the effort to harmonize and

standardize processes and key metrics across all global ACM laboratory operations.

"We are very proud of the work Dr. Williamson has done as this publication truly serves as the 'bible' of lab testing for our industry. It is an invaluable resource for the provider community to keep abreast of the latest advancements in lab testing. All of our laboratory professionals have it on their shelves!" said Angela Panzarella, President of ACM Medical Laboratory. "Mary's work with ACM has truly harmonized our processes and platforms, while setting the strategic direction for our labs worldwide."

FINGER LAKES HEALTH

Finger Lakes Health Appoints New Dialysis Program Director

Finger Lakes Health is proud to announce the appointment of Mandy Bishop to Dialysis Manager. Bishop has been with Finger Lakes Health since 2000 and held the position of Home Dialysis Coordinator for the past 8 years.

Bishop graduated with her AAS degree from Finger Lakes Community College and is pursuing her BSN at Western Governors University.

"The Dialysis Center at Geneva General Hospital ensures that patients are not only taken care of clinically, but that they and their families receive the support they need to adjust to this life-changing experience. We are very pleased to have Mandy serve in this leadership capacity. Her experience in dialysis will be a great benefit to the patients and their families who need this vital service." said Frank Korich, Vice President & Site Administrator.

Dialysis is an on-going treatment that patients need to continue on a routine basis. The goal is to have patients feel as good as they can, so they can lead as normal a life as possible. That includes continuing to work, going to school, and being able to travel. The Center accepts referrals for permanent patients and transient visitors.

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We are Committed to Improving the Financial Wellness of Those We Serve

- Investment Management
- Retirement Planning
- Trust Services
- Estate & Tax Planning

LEADING-EDGE STROKE TREATMENT

With Stroke, Time Isn't On Your Side. Dr. Bryan Gargano Is. With stroke, every minute counts. At Rochester General – the region's first Primary Stroke Center, and one of upstate New York's busiest stroke hospitals – that proven experience helps Dr. Gargano's team shave precious minutes off the national standards for stroke care. Their exceptional teamwork drives extraordinary results.

Certified Primary
Stroke Centers
Rochester General Hospital
Unity Hospital
Newark-Wayne
Community Hospital



Remind Your Patients: In case of stroke, don't panic. Think F.A.S.T. – Facial droop, Arm weakness, Speech difficulties and Time – and call 911. Learn more at rochesterregionalhealth.org/stroke.