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Western New York
PHYSICIAN
THE LOCAL VOICE OF PRACTICE MANAGEMENT AND THE BUSINESS OF MEDICINE

URMC's Stem Cell and Regenerative Medicine Institute

Revolutionizing Treatments for Wide Range of Afflictions

Bradford C. Berk, M.D., Ph.D., and CEO of URMC

Mark Noble, Ph.D

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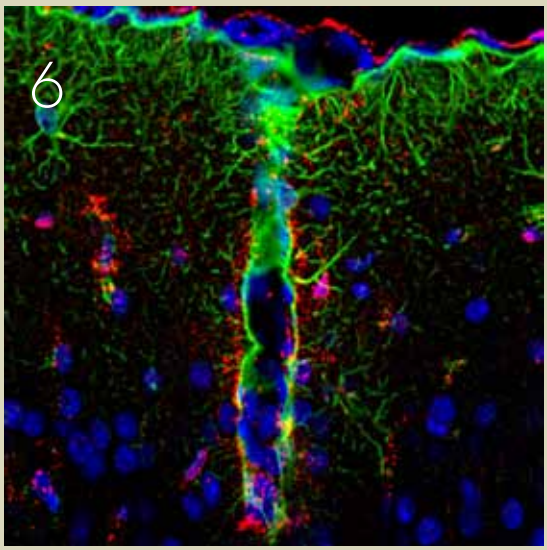

FROM THE PUBLISHER

Welcome to the June Issue

As a native Rochesterian, I know to expect any kind of weather this time of year – but I think it's safe to say summer is officially here – at least by the time this issue arrives in mailboxes. While most of us take it a little slower during these warm summer months – enjoying more time with family and friends and the beautiful outdoors of the Western New York region – medical research and discovery continues on with steady momentum. Nowhere is this more apparent than in the busy research labs at the University of Rochester Medical Center.

Within those labs, intensive stem cell research is leading to medical breakthroughs offering significant promise toward our ability to treat, prevent and reverse disease and injury. We enjoyed the opportunity to sit down with URMC CEO Bradford Berk, MD, PhD, and internationally-renowned research scientists Mark Noble, PhD and Steven Goldman, MD, PhD, who provided a snapshot of recent URMC discoveries on the verge of becoming a reality for countless patients across our region, the country and around the world.

Enjoy supporting clinical articles on Canaloplasty, a newer approach to treating Glaucoma and also how genetic testing can help patients understand their risks for cancer. Also in this issue, our medical legal expert, James Szalados, MD, MBA, Esq discusses liability issues regarding *Communication Barriers in Clinical Care*, and CPA Steven Terrigino brings our attention to fraud in the workplace and offers tips on prevention and strategies for protection.

Whether through an in-depth cover story, a profile or as a contributing author, I thank you for sharing your time and expertise with all of your colleagues through the pages of *Western New York Physician*.

My continued thanks to advertisers! Your presence in the magazine sets you apart – positioning your practice and your business as invested leaders in health care in Western New York. Your continued trust and support ensures that all physicians in our region benefit from this collaborative sharing of information.

All the best,
Andrea

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Genetic Testing Helps Educate Patients About Their Cancer Risk

Patricia A. Somerville, M.D.

Kristie N. Smith, MS, CGC, EWBC

OVER THE PAST SEVERAL YEARS, ADVANCES IN THE FIELD of cancer genetics have given patients and their health care providers the opportunity to determine predisposition to certain cancers, including breast cancer, in order to initiate proper medical management. Although multiple risk factors for breast cancer are known, personal and family history of cancer are key elements impacting cancer risk. In fact, up to 10% of breast cancers and 15% of ovarian cancers are considered hereditary. Many genes associated with hereditary cancer are known, however, the majority of hereditary breast cancer is due to mutations in one of two major breast cancer susceptibility genes: BRCA1 or BRCA2.

Many health care providers, including Elizabeth Wende Breast Care, LLC (EWBC), now offer genetic testing for hereditary cancer. EWBC also has a certified genetic counselor on staff specifically trained in both human genetics and psychosocial counseling. "My goal is to assist patients in understanding complex genetic information," says Kristie N. Smith, MS, Certified Genetic Counselor, EWBC. By obtaining a detailed personal and family history, genetic counselors assess the patient's cancer risk and the chance for a hereditary cancer syndrome. Multiple risk assessment models are available to determine both the risk for breast cancer and the chance of a BRCA mutation, including Tyrer-Cuzick, Gail, Claus and BRCAPRO, among others. Genetic counselors provide education on the benefits, risks and limitations of genetic testing.

"When patients are identified as high risk for breast and ovarian cancer, personalized medical management plans can be developed for the early detection and/or prevention of cancer, ultimately saving lives," adds Ms. Smith. In addition to unaffected patients with a family history of cancer, breast cancer patients may benefit from genetic testing as well. Not only can testing provide information for their family members, it also has implications for their risk of a second cancer. For example, women with breast cancer who are found to carry a BRCA mutation have up to a 64% chance of developing a second primary breast cancer and up to a 13% chance of going on to develop ovarian cancer.

Mutations in BRCA1 or BRCA2 confer up to a 50% risk of breast cancer by the age of 50 and up to an 87% lifetime risk of breast cancer in unaffected women. BRCA mutations are also associated with up to a 44% lifetime risk of ovarian cancer.

The National Comprehensive Cancer Network has developed recommendations for the medical management of BRCA mutation carriers, which are updated annually to reflect new information. The recommendations currently include additional breast cancer surveillance via breast MRI, preventative surgery and/or chemoprevention to lead to the early detection and/or prevention of cancer. In addition, the American Cancer Society recommends annual breast MRI along with mammography for women who have a lifetime risk for breast cancer exceeding 20%.

"If patients decide to undergo genetic testing, they need to understand that a positive test result doesn't mean that cancer is inevitable, just as a negative result doesn't mean they have no risk for developing cancer," explains Dr. Somerville, EWBC. "Testing positive only means a patient has a significantly elevated risk over that of the general population." It is also important to note that not all patients with BRCA mutations will have a

strong family history of breast cancer, though patients with mutations are predisposed to developing cancer at a younger age.

Since BRCA mutations are inherited in an autosomal dominant manner, both women and men can carry these mutations and pass them on to their offspring. The chance for each of their children to inherit the mutation is 50%. This is one reason why health care providers must be diligent in asking patients about both the maternal and paternal history of breast and ovarian cancer. If individuals do not inherit the mutation causing cancer in their family, their risk for cancer is that of the general population and they should follow general screening guidelines. However, if an individual does inherit the familial mutation, his or her risk for cancer is increased significantly.

Risk factors suggestive of hereditary breast and ovarian cancer syndrome include a personal and/or family history of premenopausal breast cancer, male breast cancer, ovarian cancer, multiple relatives on the same side of the family with breast and/or ovarian cancer and being of Ashkenazi Jewish descent. Li-Fraumeni Syndrome, a rare autosomal dominant hereditary disorder, as well as CHEK2 and PALB2 genes, also play a role in the risk of developing breast cancer.

"Patients are regularly voicing concern to us regarding their cancer risk and are interested in learning ways to reduce this risk," states Dr. Somerville, EWBC. "By determining if they have a hereditary form of breast or ovarian cancer, patients can make informed decisions regarding the best health care options for themselves and their family members."

Elizabeth Wende Breast Care, LLC, an outpatient breast imaging facility in Rochester, NY, is internationally recognized as a leader in the field of breast imaging, breast disease detection and diagnosis. Services include digital mammography, ultrasonography, breast MRI, multimodality imaging biopsy, bone densitometry, cancer risk assessment and genetic counseling. EWBC has been designated a Breast Imaging Center of Excellence by the American College of Radiology (ACR).

CLINICAL FEATURE

Aggressive Breast Tumors Linked to Vitamin D Deficiency

Luke Peppone, PhD

Low vitamin D levels among women with breast cancer correlate with more aggressive tumors and poorer prognosis, according to a new University of Rochester Medical Center study highlighted this week at the American Society of Breast Surgeons meeting in Washington, D.C.

The study is one of the first to examine vitamin D and breast cancer progression. Previous research has focused on vitamin D deficiency and the risk of cancer development. The URMC epidemiology study associates sub-optimal vitamin D levels with poor scores on every major biological marker that helps physicians predict a patient's breast cancer outcome.

"The magnitude of the findings was quite surprising," said lead researcher Luke J. Peppone, PhD, MPH, research assistant professor of Radiation Oncology at the URMC James P. Wilmot Cancer Center. "Based on these results, doctors should strongly consider monitoring vitamin D levels among breast cancer patients and correcting them as needed."

A growing number of physicians are already monitoring cancer patients and healthy people for vitamin D. Last fall the Institute of Medicine (IOM) announced new daily recommended intakes of vitamin D for nearly all adults and children in the US and Canada. Although the IOM did not specifically address vitamin D and cancer, it reported that 600 IUs daily meets the needs of most people. Higher amounts are often prescribed to cancer patients; sometimes a weekly dose of 50,000 IU is necessary to treat severely deficient people.

COVER STORY

URMC's Stem Cell and Regenerative Medicine Institute

Julie Van Benthuysen

Revolutionizing Treatments for Wide Range of Afflictions

LAB LEADERS: Drs. Chris Proschel, Mark Noble, and Margot Mayer-Proschel (left to right) have worked together as a team since 1990. They played key roles in identifying— and are considered to be among the best in the world at handling—the four known progenitor cells for the various cells found in the central nervous system.

Groundbreaking research in stem cell and regenerative medicine is happening right here in Western New York – paving the way for life-altering treatments for spinal cord injuries and diseases like Parkinson's and Multiple Sclerosis.

The Saunders Building: *The newly opened facility was named in honor of local businessman E. Philip Saunders for his decades of support for research at URMC and will be a hub for accelerating medical research, increasing access to clinical trials for physicians and their patients, and improving patient care and outcomes.*

The University of Rochester Medical Center is leading the charge toward our understanding of development, disease and discovery of new treatments for a vast range of conditions. As antibiotics and vaccinations revolutionized the ability to treat diseases and reduce suffering, discoveries within stem cell biology are poised to provide similar benefits. Established in 2008, the Institute focuses on a host of complex issues – from developing approaches to treating fractures to studies on protecting the body from toxic effects of cancer treatments.

The URMC's expertise in the field began with bone marrow transplant research three decades ago. While stem cell transplantation put Rochester on the map, URMC's efforts since then have attracted the best researchers and scientists to our biotechnology sector. With substantial federal and state funding, particularly from The Empire State Stem Cell Board, the Institute's research into neurological disease, cancer, cardiovascular disease, and bone repair has accelerated substantially.

"Stem cell and regenerative medicine represents one of the scientific foundations of our strategic growth plan in biomedical research," says Bradford C. Berk, M.D., Ph.D., CEO of URMC. "Grants are critical to advancing our understanding of stem cells and bringing these discoveries into new therapies for a host of diseases."

New Facility To Further Accelerate Research

The URMC's new on-campus facility soon under construction will enable scientists to produce human stem cells suitable for testing new therapies – either through cell transplantation or improving existing cells. The Upstate Stem Cell cGMP Facility (USCGF) represents a regional resource coordinated by an advisory committee representing leading medical centers from Buffalo to Albany.

cGMP – current good manufacturing practices – designates that the facility complies with federal regulatory procedures and guidelines for the production and handling of human embryonic, progenitor, and adult stem cells for scientific investigation and experimental human therapies. Significant research addressing neurological, cardiovascular, and musculoskeletal diseases and cancer will be conducted there, and several biotechnology companies will enjoy access. As one of the few on-site facilities of its kind, our region stands to benefit from notable economic development potential.

"We already have a terrific foundation," says Dr. Berk, "but this facility fills a critical gap in our scientific infrastructure that will enable scientists to take their research to the next level and foster more collaboration."

Internationally-Renowned Experts

The URMC is home to a rich and diverse stem cell faculty – 40 strong representing 15 different URMC departments – and collectively supported by more than 230 staff, including multiple Ph.D. students, postdoctoral fellows, M.D./Ph.D. students and technical fellows.

Its scientists are considered worldwide leaders for their groundbreaking efforts, particularly in neuromedicine. Mark Noble, M.D., Ph.D., Director of the Stem Cell and Regenerative Medicine Institute, professor in Biomedical Genetics and a pioneer in stem cell science, focuses on spinal cord repair, multiple developmental maladies, toxicology, and cancer. He has authored numerous scientific articles and is a founding member and scientific advisor to two biotech companies developing stem cell therapies.

Steven Goldman, M.D., Ph.D., Dean Zutes Chair, professor of Neurology, Neurosurgery, and Pediatrics, and chief of Cell and Gene Therapy, is a recognized authority in neural stem cell research, focusing on different disease targets.

The URMC's Center for Musculoskeletal Research, headed by Dr. Regis O'Keefe, is strongly supported by NIH funding and maintains a large number of patent applications with multiple opportunities for translating discoveries into therapies.

Unlocking the Key to Stem Cell Knowledge

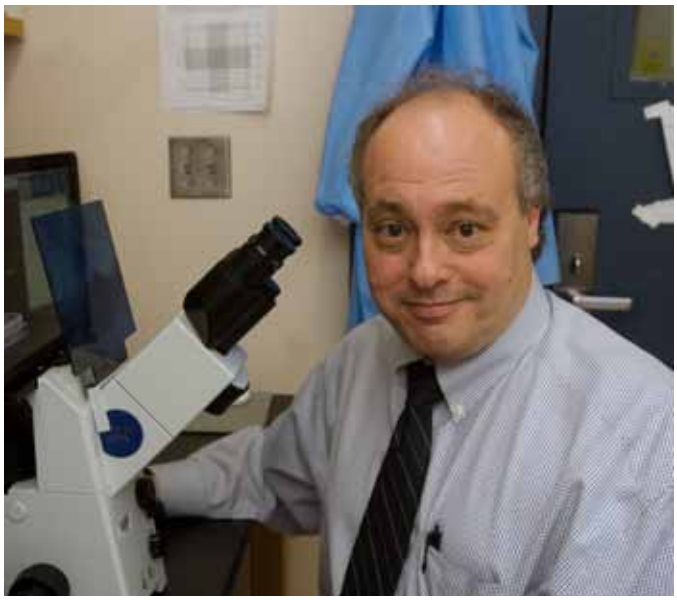
Few recent scientific discoveries have held such great potential as stem cells. URMC researchers are among the few to discover multiple stem cells and work out their complicated lineage to the extent necessary to treat disease effectively.

Nearly a decade ago, scientists discovered and isolated human embryonic stem cells, considered the master cells of biology holding the potential to generate any type of cell in the body. While adult stem cells have proven to be enormously useful in research and may prove to be ideal for transplantation or other clinical treatments, their numbers are limited, they're often difficult to isolate and cannot renew themselves as readily as other types of stem cell. Embryonic stem cells represent a potentially inexhaustible supply of cells and give rise to tissue-specific stem cells, which in turn produce progenitor cells, the final step before the emergence of the body's mature cells.

"The strength of embryonic cells is actually their curse," says Dr. Goldman. "They can generate all the major cell types, but we don't yet have sufficient understanding of the biology of these processes to make them become what we would like them to."

The stem cell biology teams headed by doctors Goldman and Noble are developing means of replacing the support cells of the brain and spinal cord. Although many neurological conditions are not yet fully understood, some are candidates for stem cell therapies because they are caused by the loss or degeneration of a single identifiable type of cell.

A class of neurological diseases called myelin disorders signifies one example. Myelin – the fatty substance that covers nearly all the body's nerve cells – helps signals in the nervous system move from one point to another. In traumatic injuries,



Steven Goldman, M.D., Ph.D., is a recognized authority in in neural stem cell research.

neurodegenerative diseases like multiple sclerosis and cerebral palsy and rare childhood neurological diseases called pediatric leukodystrophies, myelin breaks down, interfering with the body's signaling system. Normal myelination during development can also be compromised by iron or thyroid hormone deficiency and exposure to environmental toxicants.

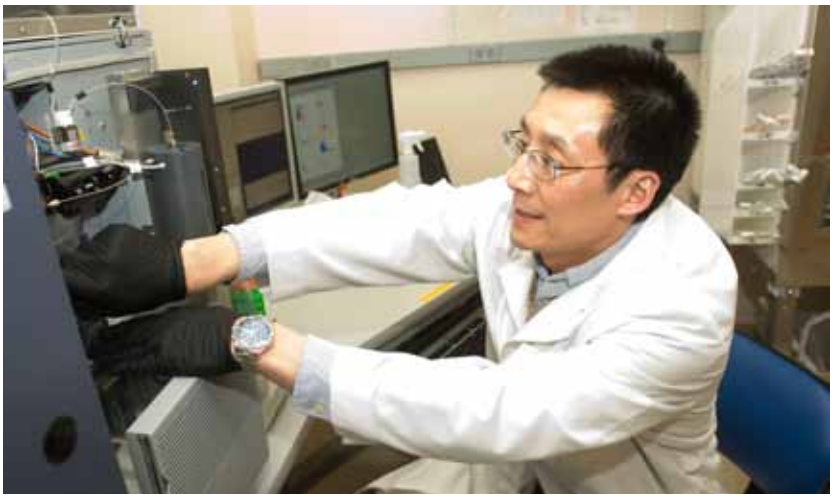
Dr. Goldman's team set about finding a way to replace myelin, turning to oligodendrocyte precursors – cells found in the adult and developing fetal brain responsible for producing a subset of tissues in the central nervous system that includes myelin.

"These cells infiltrate exactly those brain regions where one would normally expect oligodendrocytes to be present," says Dr. Goldman. "As they spread, they create myelin, which wraps around and ensheaths the nerve cells."

Through this research, the origins of Vanishing White Matter Disease have been uncovered, with clinical trials beginning within the next two years. Should they prove safe and effective,

the use of stem cell-derived cells for treating myelin diseases should proceed. "Individually these are uncommon diseases, but collectively they're not."

This work has spawned new ways of thinking about early human development, suggesting that a substantial amount of what are considered developmental diseases likely originate in precursor cell malfunction. "Using our knowledge of stem cell lineage – what it does and what it was made for – we can apply it to a disease paradigm," adds Dr. Noble.



Su Wang, MD, Ph.D, assistant professor of Neurology, working at the BD FACS Aria – a piece of novel equipment which sorts fluorescently-activated cells.

Scientists have also used neural stem cells and their derivatives to replace the precise types of cells lost in patients with Parkinson's and Huntington's diseases, two prototypic neurodegenerative diseases. Huntington's may be a near-term target of stem cell-based therapy. Recruitment of stem cells and precursor cells also could be enhanced by combining stem cell medicine with gene therapy.

Collaborating on Bone and Spinal Cord Injury Repair

Through the URMC, the Center for Musculoskeletal Research is moving towards the use of stem cell transplantation for repair of bone fractures and cartilage damage. Dr. Noble's research team was the first to isolate the precursor cells that give rise to oligodendrocytes, to develop the means of growing large numbers of these precursor cells to repair a damaged spinal cord by transplantation of such cells. "By transplanting a very specific type of astrocyte – the most numerous cell in the central nervous system – our team has obtained striking levels of repair in animal models of human genetic disorders where normal myelination doesn't occur," he says.

"This study is a critical step toward developing improved therapies for spinal cord injury, both in providing very effective human astrocytes and in demonstrating that it's essential to first create the most beneficial cell type in tissue culture before transplantation." The scientists are now moving forward with testing transplanted human astrocytes in different injury models resembling severe, complex human spinal cord injuries at early and late stages after injury.

"Diseases of the brain and spinal cord present an especially daunting challenge for cell-based strategies of repair, he says, given the multiplicity of cell types in the central nervous system and the precise manner with which they must interact."

Researchers are also exploring through clinical trial the use of an already FDA-approved drug that increases the population of bone stem cells to expedite bone repair, particularly in elderly patients with osteoporosis. A Rochester-based biotechnology company that employs a stem cell technology for cartilage repair, ligament and tendon healing and spinal fusion has emerged from the team's work.

Great Strides in Cancer Research

Stem cells hold tremendous promise in cancer research. Studies suggest that cancers often use a similar strategy for growth as is used by the normal body, with stem cells playing a vital role. Leading researchers at the University's Wilmot Cancer Center, led by Craig Jordan, Ph.D., are exploring the idea that mutations at the stem cell level fuel cancer and tumor formation, which might explain why cancer often cannot be entirely wiped out by modern therapy because no current treatment reaches the stem cell, or the origin of the disease. Their goal is to investigate pathways and molecular networks that control cancer stem cells, in hopes of creating a new generation of therapies.

"When we employ a therapy that may be useful in killing off the majority of cancer cells, if the cancer stem cells remain the tumor just regrows," says Dr. Noble. The challenge is to figure out how to kill these cancer stem cells without destroying normal stem cells and causing unacceptable levels of harm to the rest of the body.

The Center recently created a Cancer Stem Cell Research Program, one of the nation's firsts, which includes a set of labs led by a scientific team from across URMC departments. Re-

searchers will investigate the clinical relevance of stem cells involved in acute leukemia. Another project will investigate how stem cells contribute to breast development, from the embryonic stage through puberty and pregnancy, how pregnancy alters breast stem cells and whether these changes have any affect on breast cancer.

"Such work opens the possibility of stopping cancer at its roots, as well as improving the care of patients who already have the disease," says Dr. Noble.

URMC scientists are also researching how drugs commonly used to treat cancer can actually damage the brain and how environmental toxicants affect brain development. This work has led to early identification of drug candidates that may prevent chemotherapy's adverse neurological side effects. Because stem cells and other precursor cells are so often the target of such damage, says Dr. Noble, the use of such cells to rapidly identify potential harmful outcomes may prove to be one of the great contributions of stem cell biology to medical science.

"Some of these drugs appear to be quite promising in respect to brain tumor treatment," he adds. "If animal studies are successful, transition to clinical studies can happen much faster."

Dr. Goldman and Janna Bates – a technician in his lab where she is staining cells.

Bradford C. Berk, M.D., Ph.D., and CEO of URMC shares insight on URMC's strategic plan for growth in biomedical research. Continued grant and funding support arms URMC with the critical resources necessary to advance understanding of stem cells and bring these discoveries into new therapies for a host of diseases.

Endless Potential

The possibilities for stem cell biology extend to other health conditions, including research involving the use of certain stem cells for repairing and regenerating tissues damaged by pulmonary emphysema. The Armed Forces Institute for Degenerative Medicine has also recognized the vast opportunity to improve treatment for wounded personnel. "The military is very interested in addressing the combination of bio-engineered prosthesis with stem cell repair for injured soldiers," says Dr. Berk.

With national and state initiatives enabling research universities like URMC to act more nimbly, scientists hope to cross the finish line to new treatments faster. Already the Institute stands ahead of most research institutions and bio-tech companies in this arena.

The challenge is to accelerate the process of translating the knowledge of stem cell biology into successful new treatments, recognizing a number of major steps must occur before clinical trials can even begin. "We're not ready for prime time yet," adds Dr. Noble. "The FDA process takes time."

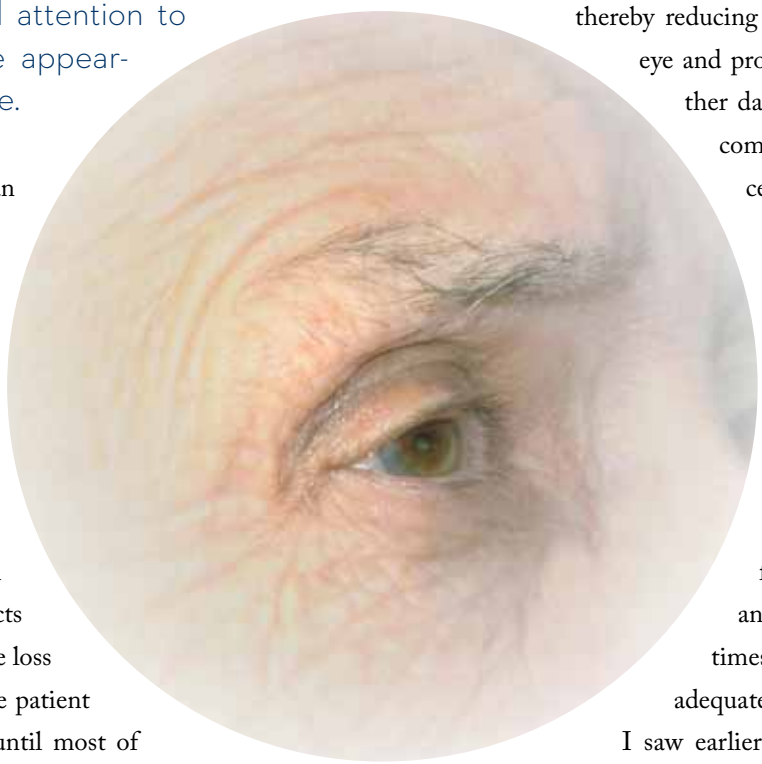
The URMC's aggregation of talent has clearly positioned the Institute to be an international leader. "Our goal is to see Rochester develop over the next decade into the major American referral center for stem cell-based treatment of neurological disease."

Canaloplasty

A Newer Approach to Treating Glaucoma

Richard Seeger, MD

Combine an aging demographic with a disease that increases significantly with increasing age will cause a marked increase in it's prevalence. Just such a convergence of factors is happening with the eye disease, glaucoma. Add in the reality that most people have no symptoms from glaucoma until the late stages, and the need for regular screening exams becomes even more imperative. Anyone over age 65 should have a thorough eye exam every two years at the minimum, with careful attention to eye pressure and the appearance of the optic nerve.



But what exactly do we mean by the term glaucoma? In the simplest way to define it, glaucoma iscaused by increased intraocular pressure exerting damage on the optic nerve, in the back of the eye. Known as the "sneak thief of sight", glaucoma usually has no pain associated with it, and it affects the peripheral vision first. The loss is subtle and gradual, and the patient does not notice the deficit until most of the vision is irretrievably lost. During the eye exam, the Doctor will test the eye pressure to see if it is elevated. While some glaucoma patients will have a normal reading at any random point of testing, some patients will have elevated eye pressure without glaucoma, as the optic nerve is able to withstand that patient's level of pressure. As important, if not more so, is the exam of the optic nerve. With progressive damage, the surface of the nerve will change, with ever-greater excavation, known as "cupping". In glaucoma, the individual nerve fibers that comprise the optic nerve atrophy, leading to a gradual loss of ability of the nerve to send visual sensations to the brain and structural change in the nerve itself.

Once the Doctor makes the diagnosis, treatment usually begins with eye drop therapy and/ or lasertherapy. The goal is to reduce intraocular fluid production and increase outflow, thereby reducing the pressure head inside the eye and protect the optic nerve from further damage. For most patients, this combined approach is very successful and affords an excellent prognosis for retained vision for the rest of the patient's life. For some, however, medical and laser therapy is not powerful enough to reach the desired pressure level. Too, the patient may develop intolerable side effects to the medicine. Compliance issues and cost are sometimes significant impairments to adequate treatment as well. A patient I saw earlier this week for the first time comes to mind. A pleasant woman in her ninth decade of life, she presents with legal blindness in one eye and deterioration in the other. She cannot recall when her last eye exam occurred and there is a vague history of taking one eye medication. Always having been independent, her family has

not been allowed to monitor her medical conditions. She spends her time moving from state to state, staying with family, never having any physician in charge of her medical care. In such a scenario, especially as the patient begins to lose their insight, it is not surprising that conditions such as glaucoma can erode the body's function, even to thepoint of profound loss.

When more conservative approaches fail, surgical interventions become essential. The surgical standard for decades has been the Trabeculectomy. A trap door of partial thickness scleral tissue is created, allowing for the controlled egress of intraocular fluid. The fluid collects underneath the conjunctiva forming a "bleb". The fluid in turn is absorbed by the blood vessels on the outside of the globe. This alternative drainage pathway effectively lowers eye pressure without the need for medication. This surgical approach has saved the vision of many thousands of patients, but there are drawbacks to the surgery as well. Some patients are not candidates for the procedure and complications with the bleb can cause significant problems, such as infection. Alternative approaches include the use of a drainage tube, which directs intraocular fluid to a plate around which a bleb forms. More recently, a new approach, called Canaloplasty has been developed, which avoids the need for a bleb and its inherent limitations. In this novel approach, the surgeon meticulously dissects to the level of the drainage canal with the intent of improving its function. A tiny catheter is inserted into Schlemm's canal, dilating it, and allowing passage of a 9-0 permanent suture to cinch it open. In turn a porous window in the corneal tissue is created, increasing flow to the natural drainage canal. In this way, outflow of fluid via the original outflow channels is increased significantly, without creating an artificial system or the need of an external bleb. The tissue of the eye remains less violated and it returns to a more natural state. I have found this procedure to be safe and effective for theright patient population and look forward to offering it in the future to this growing population of patients in need.

"a new approach, called Canaloplasty has been developed, which avoids the need for a bleb and its inherent limitations"

2011 EDITORIAL CALENDAR JULY–DECEMBER

JULY
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AUGUST
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DECEMBER
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Invited experts offer perspective on the impact of healthcare reform – what it means, what it might cost, and the impact to the healthcare system and patients in western New York.

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Electronic Health Records
Area experts and practitioners share valuable expertise in managing the implementation process, avoiding pitfalls and guiding your practice into the through the transition.

Protecting Your Practice from Fraud

Steven M. Terrigino, CPA

"An ounce of prevention is worth a pound of cure" ~ Ben Franklin

What are the chances that your practice may be a victim of employee theft? The U.S. Chamber of Commerce has estimated that 75% of all employees steal at least once and that half of these steal repeatedly. The Chamber also reported one of every three business failures is the direct result of employee theft. FBI reports employee theft as the fastest growing crime in the United States. Hopefully, when you are done reading this article, your risk can be mitigated by the suggestions I offer.

Employee theft can generally take two forms, tangible and intangible. Tangible theft means physically taking something such as cash or supplies while intangible theft may mean the misappropriation of time.

Without proper procedures in place, cash can be easy to misappropriate, especially in physician practices. Commonly, a practice has one office manager solely responsible for the accounting, and recording of transactions, especially cash. The best means to prevent theft is a segregation of duties amongst multiple individuals. However, this is generally impractical in most practices, due to the limited number of employees as well as cost.

We have been engaged by many practices to review the internal controls in place with respect to protecting their assets and managing a practice. Below are some of the suggestions I make to my clients on a regular basis as to how they may mitigate risk of cash pilferage. The managing partner or a designated partner in the practice should perform the following functions:

1. Open and review your bank statements

The best means of protecting your cash is to know where it is going. Every month you should physically open your bank statements and review them, especially the cancelled checks. Specifically, you should review the cancelled checks to verify the vendors being paid are actual vendors of the practice and the signatures on the checks are that of the authorized individual, preferably the managing partner. The bank statements should be reviewed to make sure monies being transferred are going to the proper accounts and not personal accounts of a third party. Finally, ensure the bank statements and cash accounts are being reconciled on a monthly basis.

2. Sign all of the checks

While it may be practical to have the office manager prepare checks for payment, you should sign all of the checks before they are issued. Each check should be accompanied by an invoice. The invoices should be reviewed for propriety. There have been documented cases where one check was issued to a vendor and included payment for multiple bills. This has been done, for example, with utility bills or credit cards being remitted for payment due to the commonality of vendors. This can go easily undetected without having the invoices to review.

3. Count cash drawers on an unannounced basis

A few times a year it may be advantageous to count the cash drawers of employees on a surprise basis. The cash in the drawers should then be reconciled to the encounter forms and the respective co-pay amount. Often times smaller amounts of cash can be pilfered without anyone every noticing. Moreover, at the end of everyday the encounter forms should be reconciled with the collection of cash as well. Many of my practices use triplicate forms and the cash is reconciled with the physician's copies of the forms. This verifies that all patients have been accounted for, in the event an encounter form was destroyed. The deployment of the surprise counts also sends a message to the staff that practice management is monitoring procedures on a regular basis. In and of itself, this acts as a deterrent as well. Your accountant may be engaged to perform these counts.

4. Monitor use of credit cards

Many credit cards offer incentives that can certainly be beneficial for a practice. For example, if a practice purchases large amounts of medical supplies on a regular basis the incentive on that particular card may be airline miles. Just like bank statements, the credit card statements should be opened by one of the practices' partners. The charges should be reviewed to verify they have been properly authorized and specifically relate to the practice.

5. Monitor use of time

As I mentioned earlier, the other means by which employees may steal is through time. If employees are paid hourly and manually submit their time, it is very easy to not report the proper hours one worked, albeit if they arrive late or leave early. The best way to mitigate this is through the use of a time clock. Other examples of employee misuse of time can be when employees are on the internet or ever popular social networking pages during work hours. A lot of websites can be blocked by your computer network administrator.

In conclusion, the above simply offers a cursory perspective on how to best protect your practice. No one method or combination of methods will be a guarantee employees will not take advantage of the system. The suggestions merely offer a basic means by which to protect your assets, monitor operations and as a result, perhaps deter employees from attempting to circumvent controls. As a base line, the use of them is highly encouraged to mitigate risk. I recommend having a comprehensive internal controls review of your practice to make sure all areas within the organization have been addressed and the best controls available are in place. A comprehensive review would cover several functional areas from cash, accounts receivable, human resource management to information technology, just to name a few. Remember Ben Franklin's sage advice, an ounce of prevention may be worth a pound of cure.

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Advertiser Index

What is My Liability?

Communication Barriers in Clinical Care

James E. Szalados, MD, MBA, Esq.

Issue

Effective communication, as an interchange of information, is critical to the process and outcome of clinical medical care. The exchange of accurate information in the clinical setting is an important patient safety issue since treatment plans are based upon data obtained through complaints and medical histories; and subsequently, patients' consent to, and compliance with prescribed therapy. It is also well recognized that medicine is, in part, an art, based respect and trust, which in turn is based in effective communication. Some examples of potential barriers to effective communication include diversity in language, disability, beliefs, and culture.

Perhaps the most commonly recognized challenge to effective communication is language. According to US Census data, at least 14% of the US population primarily speaks a language other than English and this number is increasing. However, patients with disabilities, such as deaf and mute persons also present communication challenges.

The responsibility, and thus the liability for, a failure to accommodate patients with communication barriers who present for treatment, is increasingly being shifted to hospitals, medical offices, and providers. Legal liability for a failure to provide for effective communication to non-English speaking patients, or patients with disabilities, is potentially far reaching, ranging from violations of Medicare's Conditions of Participation, federal and state statutes, informed consent laws, and even potentially constituting professional misconduct.

The US Department of Health and Human Services (DHHS) mandates that physicians who accept Medicare and Medicaid reimbursement are obligated to provide foreign language interpreters for all 'Limited English Proficiency (LEP)' patients. The DHHS mandate is enforced by the Offices Civil Rights (OCR) at the federal level and by the Office of Professional Medical Conduct of the Department of Health at the state level in New York. For healthcare facilities, the Hill-Burton Act requires that facilities which receive federal funds must undertake to provide a perpetual "community service" under which such facilities are required to make their services "available to all persons" and the OCR has now determined that this requirement extends to all patients with communication challenges. The Emergency Medical Treatment and Active Labor Act (EMTALA) requires that federally funded hospitals provide adequate medical screening and stabilization prior to transfer. Informed consent is mandated prior to transfer, and, of course, informed consent presupposes effective communication. NY Public Health Law § 2803-c also codifies patients' rights to informed consent or informed refusal to medical treatment. Moreover, NY Codes, Rules and Regulations § 405.7 specifically defines effective communication as a 'Patient Right' explicitly stating that if a patient does not understand his or her care plan, then the hospital must provide the necessary assistance, including an interpreter or signer.

The federal Rehabilitation Act and the Americans with Dis-

abilities Act (ADA) also each address the obligation of health-care providers to deaf and mute persons. The Rehabilitation Act guarantees that persons with disabilities will receive "meaningful access" to programs and activities receiving federal financial assistance; explicitly mandating effective communication as a prerequisite to meaningful access to health services. The ADA actually defines "discrimination" as "a failure to take the steps necessary to ensure that no individual with a disability is excluded, denied services, segregated or otherwise treated differently than other individuals because of the absence of auxiliary aids and services;" noting that auxiliary aids and services include the provision of qualified sign language interpreters. It is noteworthy that NY laws reference and echo both the ADA and Title VI of the Civil Rights Act which expand the competency requirement to provide effective communication to persons with disabilities.

The ADA defines a "qualified interpreter" as "one who is able to interpret effectively, accurately, and impartially both receptively and expressively, using any necessary specialized vocabulary."

A common question is: 'who can function as an interpreter?' The ADA defines a "qualified interpreter" as "one who is able to interpret effectively, accurately, and impartially both receptively and expressively, using any necessary specialized vocabulary." The reliability of the information delivered by non-professional translators is subject to scrutiny. The complete and accurate conveyance of information is medically and legally critical in situations where information forming the basis for therapeutic decisions is discussed. Translation by family members poses inherent risks since family members may lack fluency in medical terminology and may misinterpret important information; they may filter, downplay, or withhold important information based on potential sensitivities or cultural roles; and finally, it is not inconceivable that family translators might even color the information conveyed to reflect their own preferences – nullifying the principles of

autonomy in which the process of informed consent is based.

In-house hospital language banks utilize multilingual employees as volunteer interpreters. The key advantages of in-house employee interpreters include low cost, access and availability, and established confidentiality relationships. Similar to family translators, employee interpreters may also lack complete fluency either in the language or dialect, or misunderstand medical terms. The reliability of the information conveyed is seldom verifiable. Institutions and providers may also elect to use pre-translated forms, documents, and health education materials; although, these do not obviate the need for translators to answer questions and provide supplemental information. Professional translators are probably optimal since they minimize translation errors, preserve confidentiality, minimize bias, and preserve traditional family roles during the healthcare encounter. Telephone interpretation, also referred to as 'remote consecutive interpretation' represents another option; for example, the AT&T Language Line Service is available at all times and accesses interpreters for more than 140 languages. Whenever outside contactors are employed, HIPAA compliant relationship contracts are necessary to preserve confidentiality.

The American Medical Association (AMA) has noted that "a health care professional or facility is not required to provide an interpreter when it would present an undue burden." An undue burden might be posed by the expenses or difficulties involved in retaining interpreter services. Factors courts have used in determining the "undue burden" threshold include: the practice's or facility's operating income, the frequency of need, the population served, and eligibility for tax credits. The simple question of whether the cost of retaining an interpreter exceeds the reimbursement is not regarded as an undue burden by the courts.

In summary, the increasing diversity of the US population and the increased regulation and scrutiny of medical practice now requires that physicians, practices, and hospitals be able to overcome communication challenges which may interfere with the delivery of safe, effective, and patient-centered medical care.

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.

Healthcare IT 2000

by Kent Crosier

What Healthcare IT solutions are you looking to implement this year? I am sure EMR is on the list but there are other IT solutions out there that can bring HUGE benefits to your practice.

As the Healthcare world changes, ALL practices will need to invest in technology other than EMR at some point. The benefits of these technologies are tremendous and will provide your practice with improved productivity, reduced costs, improved patient care, etc. The most challenging part is to figure out where to start and how to get the most bang for your buck. As difficult as this may be, my suggestion is to start somewhere and start now! Make the investment and benefits will come!

Benefits to Healthcare through Technology

Information technology in the field of heath care allows complete management of the medical information and the safe exchange of information between the health care consumers and the providers. Information technology has brought about a big revolution in the heath care industry. Some of the benefits of information technology in health care industry include:

- Improved quality of health care
- Prevention of medical errors
- Reduction in the health care costs
- Increase in the administrative efficiencies
- Decrease in the amount of paperwork
- Increased access to affordable health care options

The introduction of information technology to the health care system has created an efficient platform to better manage health information and patients histories. The documents need not be filed in the form of papers and can be completed on the computer and given to the patient. There are less chances of loss of documents and patient information.

Healthcare Trends to Watch for

With a major push toward healthcare reform and the appropriation of nearly $20 billion in federal stimulus funds as part of ARRA (The American Reinvestment and Recovery Act), 2010 was an action-packed year for the healthcare industry, particularly healthcare IT. 2011 promises to be even more dynamic as healthcare organizations prepare for upcoming industry changes and position themselves to take advantage of government incentives. The following are 10 trends I feel will drive the healthcare IT market this year:

1. Cost Containment Is Paramount

The United States currently spends more than $2.5 trillion annually on healthcare, and this figure is expected to jump to $4 trillion by 2015 if nothing is done to control escalating costs. The Obama administration will begin to scrutinize healthcare spending at every level and reward hospitals that are the most cost-effective. Healthcare institutions will respond not only by implementing new systems like EHR technology, but will also look to implement systems and processes that allow them to maximize their existing spend by eliminating waste. Spend analysis, workforce management, and revenue cycle management technologies will all be instrumental in helping hospitals cut costs, maximize human resources, reduce overtime, and expedite claims resolution and payment.

2. Storage And Business Continuity Concerns Abound

Nearly 30% of the data stored on the world's computers today are medical images, and this figure continues to increase. Healthcare institutions consistently need to upgrade their storage systems to accommodate for their ever-increasing stream of patient data. Furthermore, healthcare facilities need to ensure this data is always available to provide continual uptime and a consistent quality of care. Finally, this data needs to be easily replicated and restored in the event of disaster because patient records can't be replaced.

3. Physician Groups Join Healthcare Systems

The percent of hospitals employing physicians has nearly doubled since 1994. Expect this trend to continue in 2011 as physicians seek to join forces with healthcare systems in an effort to quickly enhance their technological capabilities. For example, selecting and implementing an EHR is an undertaking many private practices have yet to engage in.

Benefits of Technology in Healthcare

The marriage between medicine and technology has reshaped healthcare and revolutionized the medical profession. Some of the major benefits are:

Secure environment:

Technology allows physicians and patients to interact in a secure and comfortable environment to discuss sensitive issues.

Flexibility:

Physicians can answer routine and less critical queries at a convenient time.

Cost- and time-saving:

Physicians can follow-up, provide advice, and re-direct patients to resources on the Internet. This saves cost and time by reducing office visits.

Source: Healthcare Technology Online

Source: dart creations

Source: the pulse beat

Body Cool, Inc.

Practical, Cost-Effective Way to Initiate Hypothermia in the Field

Al Kinel, MBA

Out-of-hospital cardiac arrest (OOHCA) is a common, lethal public health problem affecting up to 325,000 people in the U.S. each year, and is the third-leading cause of death[1]. People that survive the initial cardiac arrest and stroke event oftentimes struggle when dealing with return of spontaneous circulation (ROSC). In fact, less than half of victims who experience ROSC survive to leave the hospital alive. Cardiac arrest causes the release of toxic compounds directly linked to brain injury.The cause of death for most patients with ROSC who die within one month of the cardiac arrest or stroke is anoxic brain injury. Survival with good neurologic recovery is achieved in only 11–48% of resuscitated patients, and the balance either die during their hospital stay, or remain alive with severe neurologic deficits [2] (Becker et al., 1993; de Vreede-Swagemakers et al., 1997).

Despite advances in prevention and nearly 40 years of prehospital advanced life support treatment including external chest compression with ventilation, and defibrillation, most patients resuscitated remain unconscious in the field. Therapeutic Hypothermia (TH) is a controlled lowering of the body temperature which is believed to reduce the release of toxic compounds, thus reducing brain injury. Inducing therapeutic hypothermia in selected patients surviving out-of- hospital sudden cardiac arrest has a major impact on long-term neurologically intact survival rates.

Research Proves the Value of Field-Based Hypothermia

Several studies published in the New England Journal of Medicine in 2002 have confirmed improved outcomes after ventricular fibrillation with external cooling to 32–34°C. In one trial of 275 patients by the Hypothermia after Cardiac Arrest Study Group, external cooling with a specialized blanket did not begin until after hospitalization, and the target temperature was achieved at a median of 8h. Cooling was associated with an increased percentage of patients discharged alive without severe neurologic deficits, from 39% to 55%, for an absolute difference of 16%. In the other trial of 77 patients (Bernard et al), external cooling was initiated in the field with paramedics applying cold packs, and was continued in the hospital, and target temperatures were achieved 120min after return of spontaneous circulation. Again cooling was associated with an increased likelihood of discharge alive without severe neurologic deficits, from 26% to 49%, for an absolute difference of 23% and may prove to be

one of the most important clinical advancements in the science of resuscitation[3]. The conclusion drawn is that the earlier that hypothermia is achieved, the better the chances for survival.

A recent pilot study by a group in Seattle examined the safety, efficacy, and feasibility of using a rapid infusion of normal saline at 4°C by paramedics in the field following ROSC in 125 patients who suffered cardiac arrest from VF, asystole, or pulseless electrical activity[4]. Awakening and successful discharge from the hospital trended toward improvement in patients randomized to in-field cooling, suggesting a potential benefit for early cooling in VF patients.

New Protocols to Induce Hypothermia Arrive

Several EMS organizations within the US began to initiate hypothermia in the field, and published results of improved outcomes. Both the International Liaison Committee on Resuscitation (ILCOR) and the American Heart Association have endorsed the use of field-based hypothermia, however a number of factors had delayed its adoption in both the hospital and pre-hospital environment. That is now changing.

"Cardiac arrest is won or lost at the scene" says Dr. Jeremy Cushman, Regional EMS Medical Director for Monroe and Livingston Counties. "Early activation of the 911 system, early high quality and uninterrupted CPR, and early defibrillation are essential to achieving return of circulation. If we win that first battle and achieve ROSC at the scene, therapeutic hypothermia gives us a chance at winning the second battle and getting that patient to walk out of the hospital." The Monroe-Livingston County area was one of the first in the state to enact a protocol allowing EMS personnel to initiate hypothermia after ROSC by using topical cooling packs placed in the axilla, groin, and around the neck and administering intravenous chilled saline if available.

Problems With Topical Cooling Methods

Regardless of whether the EMS personnel use ice-packs or cold-packs to topically cool the body, there are challenges applying ice packs in areas of high blood flow:

- Ice packs cannot be directly applied to the skin
- Challenges ensuring that packs are placed in the ideal locations, and remain securely in place
- Ice packs do not stay cold because the cold dissipates too quickly

Local Startup Body-Cool to Offer Innovative Way to Initiate Hypothermia in the Field

A local company, started by Michael Amalfi, Dick Crossed, and partially funded by Tom Golisano, is developing a product to make it easier, safer, and more effective to topically cool patients that have experienced ROSC while en-route to the hospital. Body-Cool will soon introduce the Body-Cool Harness, a disposable unit designed to place cold in the areas that have the most blood flow, secure the cold, ensure maximum transfer of cold, and prolong the effectiveness of cold time-period. The one-size fits all harness is made of materials that surround cold packs with a top layer of breathable micro mesh fabric to aid the thermal transference but keeps the cold pack from having direct contact with the patient's skin. Beneath the cold pack is an insulation fabric which hinders thermal transference.

Michael Amalfi provides his view on the venture,"I am excited about the prospects to save lives and to create a company, based in Rochester, while advancing the reputation of our community as an incubator of medical device companies and creating local jobs".

The Body-Cool harness can be stored in an ambulance, hospital, or near an automated external defibrillator (AED). The Body-Cool harness was developed with significant input from EMS personnel, emergency medicine physicians, and cardiologists, and has been well-received by those who have been briefed or are testing the product. Currently awaiting FDA approval, it is anticipated that the Body-Cool harness will be available this year.

1. American Heart Association Policy Statement, 2010

2. Becker L.B. Smith D.W. Rhodes K.V. "Incidence of cardiac arrest: a neglected factor in evaluating survival rates." Ann Emerg Med. 1993;22:86–91. [PubMed]

3. Bernard S.A. Gray T.W. Buist M.D. Jones B.M. Silvester W. Gutteridge G. Smith K. "Treatment of comatose survivors of out-of-hospital cardiac arrest with induced hypothermia." N Engl J Med. 2002;346:557–63. [PubMed]

4. Kim F. Olsufka M. Longstreth W.T., Jr. Maynard C. Carlbom D. Deem S. Kudenchuk P. Copass M.K. Cobb L.A. "Pilot randomized clinical trial of prehospital induction of mild hypothermia in out-of-hospital cardiac arrest patients with a rapid infusion of 4 degrees C normal saline." Circulation. 2007;115:3064–70. [PubMed]

URMC Urology Team Introduces Breakthrough Surgery for Kidney Cancer

Minimally invasive procedure integrates fluorescent imaging and robotic surgical system

Dragan Golijanin, MD

JAMES P. WILMOT CANCER CENTER SURGEONS HAVE BECOME the first in the nation to use a new, infrared imaging technique combined with robot-assisted surgery to remove kidney cancer. The team, led by Dragan Golijanin, MD, has successfully performed robotic laparoscopic partial nephrectomies on patients at Strong Memorial Hospital using the new technology.

Golijanin, an assistant professor in URMC's Department of Urology and at the Wilmot Cancer Center, spearheaded the research behind the development of the new technique, which illuminates tissues and organs in a completely different way.

Golijanin's study found the novel technology, for which URMC has pending patent applications, to be safe and effective. The FDA granted approval for the procedure based entirely on the work of Golijanin and fellow Urology surgeons Guan Wu, MD, and Hani Rashid, MD.

Kidney cancer, or renal cell carcinoma, is diagnosed in more than 58,000 people a year in the United States and was responsible for more than 13,000 kidney cancer specific deaths in 2010. Surgery is usually the first, and in many cases, only course of treatment. For small tumors (less than 5 cm) robot-assisted laparoscopic partial nephrectomy is an emerging technique that has gained acceptance. Partial nephrectomy removes the cancer while preserving as much healthy, unaffected kidney tissue, and kidney function, as possible for the patient. However, robotic surgery carries a long learning curve for surgeons, who are challenged to remove tumors with adequate margins while preserving healthy tissue amid a complex vascular supply within the kidney.

Until now, the best existing technology required the surgeon in the operating room to toggle between two systems – a console with "arms" to control the robotic instruments, and the imaging system that provided views of the surgical site. Typically before an operation begins, the patient is injected with a dye that fluoresces green when exposed to infrared light, which defines and illuminates the operative area in detail for two to five minutes at a time. The challenge for the doctor has been to move relatively quickly between the instrument console and a projection of the images that are often displayed across the room – similar to watching two different TV screens.

> "This combination of new and existing technology offers great potential"

"This can be cumbersome and time-consuming, especially in more challenging cases," said Golijanin.

The new technology, developed with Intuitive, of Sunnyvale, Calif., integrates the fluorescent imaging system and the surgical console into one system. The multimodal imaging allows the surgeon to turn his or her attention back and forth from different types of images to the surgical tools, without stepping away from the console. Existing da Vinci systems can be upgraded with the new imaging technology.

"This combination of new and existing technology offers great potential and opens the door to being able to provide the option of minimally invasive surgery to a greater percentage of patients, and to preserve kidney function in a greater percentage of patients," said Golijanin. "Through further study we'll fine tune the process to determine the optimal dosing of the infrared dye, the exact timing of the intravenous injection, and determine whether this new imaging technology actually improves outcomes, both in terms of cancer prognosis and the preservation of kidney function. By simplifying the imaging process, it will also assist young urologists and decrease the number of cases needed to master robotic laparoscopic partial nephrectomy.

Results from Dr. Golijanin's study showed that in 11 patients, the kidney tumors and surrounding renal arteries were clearly identified, and malignant tissue was differentiated from normal tissue. Surgeons expect the new system will serve as an adjunct to existing imaging, allowing them to achieve better resection margins around the cancer with fewer bleeding complications, Golijanin said.

WHAT'S NEW IN Area Healthcare

URMC Heart Expert Elected President of American College of Cardiology Chapter


Leway Chen, MD, MPH

University of Rochester Medical Center cardiologist **Leway Chen, M.D., M.P.H.**, was recently elected to the Board of Governors for the **American College of Cardiology**. During his three-year term, Chen will serve as president of the **New York Cardiological Society** and then president of the ACC's New York Chapter.

In the elected roles, Chen represents cardiologists throughout Upstate New York, with significant focus on the impact of health care reform on patient care and reimbursement rates.

Chen is an associate professor Medicine and director of the **URMC Program in Heart Failure and Transplantation**. He joined the Medical Center in 1999 and has helped build the program into a tremendous resource for the region.

He is a Fellow in the **American College of Cardiology and American College of Physicians**. He is also a member of the **American Heart Association, Heart Failure Society of America** and the **International Society of Heart and Lung Transplantation**. He has chaired a number of professional conference sessions and serves as secretary of the **New York Cardiothoracic Transplant Consortium**.

Geneva General Hospital Recertified as Stroke Center of Excellence

The New York State Department of Health has recertified **Geneva General Hospital** as a **Stroke Center of Excellence.** Geneva General Hospital is one of 119 hospitals in New York that has achieved this distinction, and was the first to do so in the Finger Lakes region. This award is based on the efforts of a multi-disciplinary team who have developed systems and procedures to deliver the highest standard of care for stroke patients.

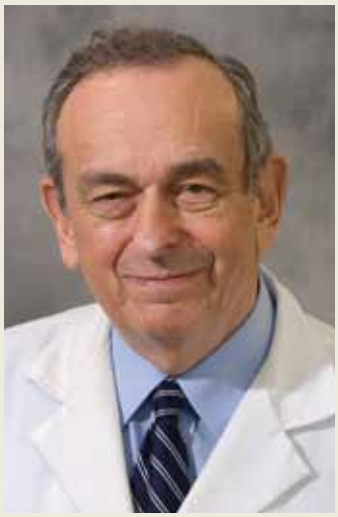
Geneva General is the only hospital in the region to be recognized by both the Department of Health and Joint Commission for its stroke care. Geneva General Hospital also received the **American Heart Association / American Stroke Association's** *Get With The Guidelines℠ Gold Plus Performance Achievement Award.*

The ability to provide the complete continuum of stroke care within specific time frames is a key element of this recognition. Geneva General has been working with the emergency medical community to coordinate timely transport and educate the public on the importance of receiving treatment within three hours of the onset of stroke symptoms.

Once a patient arrives at the ER, a set of diagnostic tests is performed. If a patient meets certain medical criteria, they may receive a special injection called **Thrombolytic Therapy**, also known as "clot busting" medication. This treatment is the hallmark of the Stroke Center designation, because it breaks down the blood clots that cause certain types of strokes and has been proven to reduce the debilitating effects of strokes.

Because the specialized medication must be administered within three hours of the onset of stroke symptoms, there is real value to our rural communities in having high quality stroke care provided right here at Geneva General Hospital.

Moss Awarded Heart Rhythm Society's Top Honor for Exceptional Contributions to Field


Arthur J. Moss, MD

Arthur J. Moss, MD, professor of Cardiology at **URMC** and world-renowned expert on electrical disturbances of the heart, received the **Heart Rhythm Society's Distinguished Scientist Award**. The award is given annually to an individual who has made major contributions to the understanding and treatment of heart rhythm disorders.

Over a career spanning five decades, Moss has made some of the most important and long-lasting discoveries in the treatment and prevention of cardiac arrhythmias, irregular rhythms that are associated with increased hospitalizations and death; sudden cardiac death; heart failure; and Long QT syndrome, a rare, inherited disorder that makes the heart particularly susceptible to arrhythmias.

"Very few individuals have made such enormous advances in the field of electrophysiology as Dr. Moss. He has truly transformed the care of hundreds of thousands of individuals and added importantly to the scientific body of knowledge," said **Paul J. Wang, MD**, head of **Cardiac Electrophysiology at Stanford University**.

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