Clinical Practice Today

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CASE STUDY
First-of-Its-Kind Surgery for Severe Neurotrophic Keratopathy

A novel approach saves a patient’s eyes

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Cutting Calories Might Slow Biological Aging

Anti-aging serums, wrinkle creams, and surgeries provide the promise of a youthful appearance that can go only skin deep. But a new analysis by researchers at Duke suggests another method may prevent biological aging at a physiological level: calorie restriction.

In the study, conducted by the National Institute on Aging and published online in the May 2017 issue of the *Journals of Gerontology, Series A: Biological Sciences and Medical Sciences*, investigators examined publicly available data from the 2-year Comprehensive Assessment of Long-Term Effects of Reducing Intake of Energy trial. During 2 years of follow-up, on average, the biological age of participants in the calorie-restriction group increased by only 0.2 years compared with 1.4 years for participants who ate a normal diet.

“Ours is the first study to test if caloric restriction can slow measured biological aging in humans in a randomized setting,” says Daniel W. Belsky, PhD, the study’s lead author and assistant professor of medicine at Duke. “Our findings suggest a template for developing and evaluating therapies designed to mimic the effects of caloric restriction to ultimately prevent chronic diseases.”

New Antibody May Reactivate Immune System in Cancer Therapy

Adding an investigational antibody to rituximab may restore the drug’s cancer-killing properties in some patients with rituximab-refractory chronic lymphocytic leukemia (CLL), according to a small, proof-of-concept study by Duke researchers.

The study, published in June 2017 in *PLOS ONE*, is part of ongoing efforts to find a way to resensitize nonresponsive malignant B cells to rituximab, a common first-line CLL therapy to which some people are naturally resistant. With the goal of promoting complement-dependent cytotoxicity, the investigators tested an anti–complement factor H antibody.

“The drug works in part through an immune mechanism that triggers cancer cells to die,” explains senior author Edward F. Patz Jr, MD, a radiologist at Duke. “In some people, this immune mechanism is deactivated. Our antibody basically reacts it.”

The study lays the groundwork for a phase 1 clinical trial slated to begin in late 2018. (*Colored scanning electron micrograph above shows blood cells from a patient with CLL.*)
Health care data can contain social security numbers and other data that may attract hackers who want to misuse that information or sell it. Although small practices may have only a few thousand patient records, hackers may target them to gain entry into larger health care systems and the millions of patient records stored there. Or, alternatively, smaller practices might get swept up in an attack on a larger entity.

In the May 2017 “WannaCry” attack on the UK National Health Service, smaller clinics with older computers running outdated software were particularly hard hit. One month later, physician offices affiliated with the Heritage Valley Health System outside Pittsburg, PA, were hobbled by the Petya malware virus.

A 2016 study from the Ponemon Institute showed that nearly 90% of health care organizations had had a data breach, and in June 2017 a report from the Health Care Cybersecurity Task Force commissioned by Congress declared that health care cybersecurity in the United States is in “critical condition.” This has vast implications for the privacy of personal health information (protected by the Health Insurance Portability and Accountability Act of 1996, or HIPAA) and for the security of financial data for both patients and practices. It also has legal and financial implications for practices that can be fined for HIPAA violations and sued by patients and other health care organizations for privacy infractions. The estimated cost of a health care data breach is more than $350 per record—or $700,000 for a practice with 2,000 patients.

Keeping up with cybersecurity safeguards and regulations can be complicated for well-resourced health systems. It can be even more challenging for independent practices with no central information technology (IT) department.

One important initial step is to conduct a risk assessment—required by HIPAA—to identify weaknesses in policies, procedures, and technology, including electronic health record (EHR) systems. The US Department of Health and Human Services (HHS) offers some tools for practices to undertake this on their own, but it’s still a complex task. “For many physician practices and even smaller hospitals, bringing in outside expertise is almost a given,” says Chuck Kesler, chief information security officer for Duke Health.
Although cybersecurity and malware threats are constantly changing, Kesler says practices can take a few simple steps to reduce their risk.

**Reduce Phishing Risks:** One of the easiest ways to gain entry to sensitive data is by exploiting social skills or relationships, a tactic called social engineering. The most common example is phishing, in which hackers use an email that appears to be from a trusted person or institution (eg, colleague, bank, IT department) to extract information or gain entry to the system. Some of these are easy to spot, but some are not. Phishing can also occur via text message or phone calls.

Most hospitals and health systems have system-wide email filters that help sift out phishing messages, but independent practices will need to set up some safeguards on their own. Still, Kesler warns, even the best email filtering system can’t catch everything, so make sure staff are aware of common tactics. Be suspicious of attachments and web links, even if they’re from someone you know. Poor grammar, misspelled words, or calls for urgent action are other earmarks of phishing.

**Update Early and Often:** The best way to protect devices is by running security patches as soon as they become available. IT departments may take care of this process for hospital- or health system–owned practices, but standalone practices need to do this on their own. Unfortunately, many smaller practices continue to run out-of-date software on older computers because of the cost and inconvenience associated with upgrading systems. Kesler says many of the ransomware attacks on health care systems could have been avoided by keeping patches current.

**Use Encryption on All Devices:** All sensitive data should be encrypted to make unauthorized access more difficult. This is especially important as devices get smaller, more portable, and easier to steal or lose. Most new laptops come with encryption capabilities built in, but older computers may require third-party software.

**Choose Smart Passwords:** Long passwords—such as 20 characters composed of 4 or more words (with a few scrambled letters, numbers, and special characters)—are more secure than short ones, Kesler says. Even better are password management systems, such as LastPass. These services generate random passwords, store them in the cloud, and automatically populate the password at login. Although even these services could be hacked, Kesler says it’s much safer than keeping a file of passwords on your computer. It’s also safer than using the same password for various websites. He points out that more than 1 billion passwords were stolen in the 2013 data breach at Yahoo, giving hackers insight into the favorite passwords of 1 billion customers—likely including someone in your practice.

**Use Multifactorial Identification (also known as 2-factor or 2-step authentication—which are separate processes):** This approach is gaining favor at banks, health care organizations, and companies that store sensitive information. After entering their password, users enter a code they receive on their smartphone or special key fob. Even if hackers get your password, they won’t be able to log in without that second piece of information.

**Raise Awareness:** Keeping staff informed about common scams can help. The HHS, American Medical Association, state medical societies, and even some hospitals provide training materials and workshops for staff in physician practices.

Despite these preventive measures, practice staff still need to be prepared to respond in case an issue arises. Having cyber liability insurance (often included in practice insurance) is essential. In fact, some health care systems require affiliated practices to show a certificate of insurance before providing access to their EHRs.
A 36-year-old woman was referred to Duke after being diagnosed with triple-negative breast cancer. Because the tumor’s hormone receptor expression was low, hormonal therapy was not indicated, and she started chemoradiotherapy.

The cancer stayed in remission until she began to have severe headaches 5 years later. She presented to the emergency department at Duke Raleigh Hospital. Computed tomography and magnetic resonance imaging (MRI) revealed lung metastases, a small liver lesion, and multiple brain metastases, including a large tumor in her right frontal lobe, which needed to be resected immediately.

Anna R. Terry, MD, the neurosurgeon on call, quickly coordinated a team of operating room staff to help her perform the surgery. Using Brainlab to help localize the tumor and plan the incision, she resected the tumor. Postoperative MRI showed the resection had been successful.

“Although the resection itself is pretty straightforward, it takes a lot of teamwork to make it happen safely,” Terry says. “Being able to quickly pull together a team at any time—day or night—is critical to our ability to help patients like this.”

The next day, the patient consulted with a radiation oncologist to plan treatment and set up follow-up with Paul Kelly Marcom, MD, the medical oncologist who had helped treat her primary breast cancer.

Two weeks later, she began a course of fractionated radiotherapy and stereotactic radiosurgery to treat the smaller brain tumors. Repeat marker assessment of the brain tumor showed low levels of hormone receptor expression. Marcom started her on treatment with ovarian ablation, an aromatase inhibitor, and a cell-cycle inhibitor.

“This case demonstrates the need for improved treatment options for this type of breast cancer—something the Duke breast program is working on,” Marcom notes. “But the receptor expression change makes trying this combination a reasonable option. We will follow her closely and, if it does not work, move to other treatment options.”

The patient tolerated the treatments well and experienced no serious adverse effects. Now, 3 months later, she’s back to her usual activities.

“Historically, the prognosis for someone with widely metastatic disease that has spread to the brain was often not great,” Terry says. “However, with the broad range of treatment options we have at Duke, I am optimistic she will continue to do well for quite a while.” (MRI above shows the patient before frontal craniotomy for tumor resection.)
Tips for Infection Control in Physician Offices
By Daphne Swancutt

Recently, there has been increased attention on the importance of infection control practices in hospitals to optimize patient safety. But, these practices also need to be applied across the continuum of care—including at physician offices. “In any setting, there’s a risk of infection,” says Gina Pugliese, RN, MS, vice president emeritus of the Premier Safety Institute. “But, typically, there’s not as much quality control in physician offices as it relates to prevention and control practices.”

In its recently updated report (www.cdc.gov/hicpac/pdf/core-practices.pdf), the Centers for Disease Control and Prevention (CDC) along with the Healthcare Infection Control Practices Advisory Committee recommend the following core practices for preventing and controlling infection in your office.

Hand hygiene. Make sure that there is easy access to supplies and that staff moving from examination rooms to other areas are washing their hands frequently.

Environmental surfaces and medical equipment. Regularly clean and disinfect frequently touched surfaces, and promptly clean and decontaminate blood spills or other potentially infectious material. Make sure to regularly disinfect and sterilize reusable medical equipment.

Injection and medication safety. Among the most significant challenges of preventing and controlling infection are unsafe injection practices, Pugliese says. “The lack of knowledge and oversight contributes to the risk of outbreak in many small, nonacute settings like physician offices.” Avoid the following scenarios:
- Using a single syringe to administer medication to more than 1 patient
- Reinserting a used needle into a medication vial and then reusing the vial for another patient
- Preparing medications near contaminated supplies or equipment

Minimizing potential exposure. Use proper respiratory hygiene and cough etiquette to reduce the risk of spreading respiratory infection. Provide tissues, masks, and hand hygiene supplies to staff and patients, and display instructional signs or handouts. When feasible, move your patients with respiratory infection symptoms out of waiting areas and into examination rooms as soon as possible.

Occupational health. Make sure your staff are vaccinated against preventable diseases, says Pugliese. In addition, the CDC recommends implementing sick leave policies that encourage staff to stay home when they have symptoms of acute infectious illnesses.

Of note, the risk of spreading infection increases as patients move among various health care settings. “Doctors need to know who their patients are and where they’re coming from,” Pugliese says.
New Hypertension Guidelines: Do They Add Clarity?

By Tim Pittman

New hypertension guidelines issued jointly by the American College of Physicians (ACP) and the American Academy of Family Physicians (AAFP) recommend treating persistent systolic blood pressure at or above 150 mm Hg with a goal of less than 150 mm Hg—a change from guidance by the American Heart Association (AHA), American College of Cardiology (ACC), and the Centers for Disease Control and Prevention (CDC).

Issued in March 2017, the new ACP and AAFP guidelines recommend treatment in patients aged 60 years or older with hypertension and urge reducing blood pressure to a target of less than 150 mm Hg to lower the risks of stroke, cardiac events, and death. The 2 organizations rate the recommendation as strong with high-quality evidence. These guidelines closely align with key recommendations released in 2014 by the Eighth Joint National Committee.

Conversely, the AHA, ACC, and CDC recommendations identify high blood pressure as 140/90 mm Hg or higher and advise lifestyle improvements—diet, exercise, and weight management—before adding medication to maintain blood pressure below 140/90 mm Hg. Both the American Society of Hypertension and the American Diabetes Association have issued separate guidelines.

Conflicting guidelines are common among expert panels, says Michael A. Blazing, MD, a Duke cardiologist and specialist in cardiovascular disease prevention and rehabilitation, who monitors the recommendations.

Each recommendation is “an evolution of the risk-benefit equation,” he explains, describing the data as “somewhat rudimentary” regarding risk and benefit for specific populations.

“The research to date has come to a general consensus that 150 mm Hg is the upper limit to begin treatment and 130 to 140 mm Hg is a valid lower limit,” Blazing says. “The question is how to design future interventions that are appropriate for treating populations to get to a safe number.”

Because trial data are available on patients who have experienced stroke or have diabetes mellitus, guidance for those patients is more precise. Blazing advocates using electronic health records (EHRs) to improve precision for all patients.

“We need to design the next set of studies seeking specific populations that can be identified by EHR and look at how we can apply a treatment algorithm in that situation,” Blazing says. (Angiogram above shows an aneurysm of the aortic arch [dark] in a patient with arterial hypertension.)
To improve population health, primary care providers (PCPs) can partner with allies in public health and the community, but clinicians often don’t know where to begin. That’s where the Practical Playbook comes in—and it has little to do with football.

The Practical Playbook is a joint effort between Duke Community and Family Medicine, the de Beaumont Foundation, and the Centers for Disease Control and Prevention to define concrete methods for integrating primary care and population health.

“People thought it was crazy. Make coordination of health care with public health like a playbook? But the name stuck,” says J. Lloyd Michener, MD, chairman of the Duke Department of Community and Family Medicine and the principal investigator for the Practical Playbook.

Launched in 2014, the Practical Playbook’s website (www.practicalplaybook.org) walks clinicians, public health officials, and other stakeholders through the nitty-gritty basics of selecting a health outcome to improve, finding partners to collaborate with, reaching out to the community, and aligning stakeholder goals.

The website includes numerous Practical Playbook success stories from around the country. One example involved the goal of reducing hospital admissions for childhood asthma in Durham, NC, and surrounding areas. “We saw asthma hospital admissions drop by 68% over about 2 years,” Michener says.

The Practical Playbook’s principals are now considered so important that major professional medical societies and many public health departments are heavily promoting the Practical Playbook to health care providers.

Karen Smith, MD, a solo family physician in rural Hoke County, NC, used the Practical Playbook to address obesity among her patients. Although she ran into some roadblocks, her efforts opened up communication with other physicians in the area, the local health department, and even the county commissioners. “The Practical Playbook literally goes through step by step what it is we should be doing,” she says.

Michener offers a final suggestion for health care providers: “Talk to your public health director—there’s a good probability there’s already a project under way. Just learn what others are doing and see how you might be able to help.”
A novel approach saves a patient’s eyes.

After years of undergoing laser treatment and surgeries for recurrent retinal detachment, a 61-year-old man sustained significant damage to his oculomotor nerves. Ultimately, the nerve damage caused him to lose corneal sensation, and he developed neurotrophic keratopathy.

To stop the condition from progressing and prevent infection, a local corneal specialist tried a series of nonsurgical treatments. Still, the epithelial defect persisted. If a more aggressive approach was not identified soon, the patient could develop a serious infection and lose one or both of his eyes.

The corneal specialist learned about a new reinnervation surgery being offered at the Duke Eye Center by orbital and oculofacial plastic and reconstructive surgeon Ilya Leyngold, MD. He referred the patient immediately.

Historically, treatments for neurotrophic keratopathy have been designed to protect the cornea and prevent infection, rather than being curative or targeting the loss of sensation itself. Recently, clinicians have introduced corneal neurotization, a procedure in which a healthy sensory nerve is transferred to the cornea.

In the latest iteration of the surgery—performed by only a handful of surgeons across the world—reinnervation is conducted through a small eyelid incision using an autologous sural nerve graft. Although this approach is significantly less invasive than the original technique, which required a bicoronal scalp incision, the surgery requires a multidisciplinary team and is associated with a risk of donor-site morbidity.

To avoid these limitations, Leyngold had further modified the surgery by using deceased-donor nerve grafts to transfer the supratrochlear nerve to the patient’s cornea. The use of a deceased-donor nerve graft instead of an autologous graft from the patient’s leg allows the surgery to be even less invasive and eliminates the risk of donor-site morbidity.
“It’s not a novel concept,” Leyngold explains, “but it’s a novel approach in that—to my knowledge—no one else has used a deceased-donor nerve graft for this indication.”

When the patient arrived at Duke, Leyngold had already performed 4 such surgeries. However, he worried that the procedure might not be as successful in a patient who had a significant amount of scarring on the surface of his eyes from prior eye surgeries.

But the procedure went well, and, after reinnervating the patient’s cornea, Leyngold performed tarsorrhaphy to protect the patient’s eye while the nerves were growing. By 1 month postsurgery, the epithelial abrasion had healed, and his sclera was white and quiet. He had also regained sensitivity in several quadrants.

Three months later, once Leyngold was confident that the patient had regained sensitivity throughout his eye, Leyngold reopened the eyelid. “With the amount of scarring in his eye, I was not initially optimistic that this would work well,” Leyngold says. “But we ended up being able to save his eye, which shows that this procedure can work for other patients with a similar amount of scarring. It’s really encouraging.”

Leyngold anticipates the treatment will have multiple additional applications: “My hope is that, because this approach involves less surgery, less downtime, and potentially fewer complications, we might be able to increase the number of patients we can help, maybe someday offering this procedure to people who have only partial loss of corneal sensation or other chronic ocular conditions like dry eye.”
A recent interim report from the Commission on Combating Drug Addiction and the Opioid Crisis states the challenge of America’s opioid crisis bluntly: “With approximately 142 Americans dying every day, America is enduring a death toll equal to September 11th every 3 weeks.” Thus, physicians and other health care professionals have crucial roles to play in taking steps to curb the opioid epidemic.

“This may be a new and uncomfortable role for some,” says Mara Laderman, MSPH, director of innovation for Cambridge, MA–based Institute for Healthcare Improvement (IHI). “But, it is essential for turning the tide.”

Laderman and IHI recommend the following steps to help address the prescription opioid crisis.

**Evaluate your prescribing practices.** Limit the supply of prescription opioids in circulation by reducing the dose and quantity. This may mean offering nonopioid alternatives for pain and working with payers on reimbursement. In addition, access your state’s prescription drug monitoring program (PDMP) before prescribing opioids to check for concerning activity (eg, early refills).

**Raise risk awareness.** It’s important to educate your patients and their families and caregivers about the risks of prescription opioids, including identifying patients at greatest risk of addiction. For instance, patients may seek “quicker fixes” through illicit drugs such as heroin. Laderman says it’s essential to elevate the risk of prescription opioids to that of these nonprescription drugs.

**Recognize opioid use disorder.** Review the diagnostic criteria in the DSM-5 for opioid use disorder and learn to recognize these signs. Work with patients to manage and taper opioid use and provide ongoing and comprehensive addiction treatment. This may include medication-assisted treatment and behavioral health support. With additional regulatory changes and increased funding options, Laderman says that more providers can be trained to treat this chronic condition, similar to how they’ve been trained to treat other chronic disorders.

**Work with your community.** Collaborating with community organizations that are also working to alleviate the opioid crisis can create a collective firewall against opioid abuse. Identify these groups, and be open to new approaches that include forming partnerships with law enforcement and providing health care expertise within your community. “Communities need to take a systems-based approach that simultaneously addresses multiple parts of the complex pathway of opioid misuse, dependence, addiction, and recovery,” says Laderman.
A 19-year-old woman presented at Duke with avascular necrosis of the talus bone in both ankles. As a leukemia survivor, she had significant bone damage due to long-term prednisone use. She experienced increasingly severe pain in her ankles, with swelling, loss of motion, and difficulty walking.

Several medical institutions recommended ankle fusion surgery. However, this procedure has a high nonunion rate and risked limiting her range of motion in both the ankle and subtalar joints. Following research by her family, she reached out to Duke orthopaedic surgeon Selene G. Parekh, MD, for a new solution.

Parekh recommended an innovative procedure—creation of a custom, 3-dimensional (3-D)–printed total talus replacement—to restore her mobility and relieve pain.

Through 3-D printing, Parekh says, a total talus replacement can be customized to a patient’s anatomy. “When replacing a bone, it needs to be perfectly size-matched and positioned, which can only be achieved with 3-D printing,” he notes.

To perform the procedure on her left ankle, Parekh made an incision in front of the ankle—similar to those made for total ankle replacements—and removed the entire talus bone. He then inserted a size-matched, 3-D–printed total talus replacement made from cobalt-chromium.

Unlike fusion surgery, there is no risk of the bone not healing properly, and the talus replacement has a much faster recovery time. Patients are required to wear a cast for 3 weeks without bearing weight on it, then wear a boot for 3 weeks and walk on it, followed by a return to wearing their own shoes and undergoing physical therapy for 6 to 12 weeks to regain motion and strength.

“When I saw the patient 7 weeks after surgery, she was doing great,” Parekh says. “She has returned to doing things that teenagers do. Patients who have undergone this surgery feel as if they’ve restored their quality of life. They experience significant pain relief (upward of 85%) and have a more normal walking pattern.” The patient is considering having the same procedure performed on her right ankle later this year.

“At Duke, we are harnessing new technology to save limbs and provide solutions for patients who didn’t have any good solutions before,” says Parekh, who has performed about 20 surgeries of this kind to date. (X-ray above shows the talus bone highlighted in yellow.)
A 45-year-old woman with a history of cystinuria and chronic kidney stones presented to an urgent care center with persistent cough and a skin infection. Physicians suspected medical toxicity and dehydration and adjusted her prescriptions. Laboratory results indicated renal insufficiency.

The patient’s cough and skin condition showed improvement at a follow-up visit, but her renal function remained lower than normal, and she had hematuria and proteinuria. The patient, who was taking angiotensin-converting enzyme inhibitors for hypertension and had experienced an allergic reaction, was referred to the Duke Division of Nephrology.

After securing a detailed record of the patient’s medical history and conducting microscopic urinalysis, a nephrologist ordered kidney biopsy, which confirmed the presence of glomerular basement membrane antibodies—a definitive marker of Goodpasture syndrome (GPS).

The decision to biopsy the kidney was an unusual choice at an early juncture in the case, but it proved to be the diagnostic key, says John P. Middleton, MD, the lead nephrologist on the case and director of the Division of Nephrology’s site-based clinical research.

“Most patients don’t get biopsies early in the treatment process because that is usually not seen as clinically significant,” says Middleton. “But given the other factors in this case, we decided to go forward with the procedure, and it proved to be the key.”

The patient’s hematuria and proteinuria levels could have been interpreted as a urinary tract infection, Middleton explains, but both were central to his differential diagnosis.

“Because of the active urine sediment and the lab results, we initially believed the situation was likely to be an unusual presentation of a common disorder.”

Middleton and Jessica Morris, MD, a Duke nephrology fellow also working with the patient, say the patient interviews about her long medical history informed the diagnosis and treatment approach.

“Because of the active urine sediment and the lab results, we initially believed the situation was likely to be an unusual presentation of a common disorder—more kidney stones or additional..."
allergies to medication or perhaps a straightforward urinary tract infection,” Middleton says. “It wasn’t like we looked into a microscope and diagnosed GPS.”

Ongoing laboratory tests continued to indicate limited renal function as well as high levels of creatinine. Middleton began to suspect an underlying, undiagnosed condition.

“Early on, we were able to see her kidney function declining before our eyes,” he says. Indeed, the patient’s advanced-stage GPS was acute enough to trigger antibody formation. The patient was prescribed oral cyclophosphamide and initiated regular plasmapheresis therapy.

The case was also unusual, Middleton notes, because the patient experienced no GPS-related lung involvement common to the syndrome. “In medicine, it’s much, much more common to see a weird presentation of a common disease than a rare presentation of a rare disease,” he says.

“In an academic center, we see just a few cases of this syndrome a year—a handful or less,” he adds. “One of the reasons Goodpasture syndrome is so difficult to diagnose is because it is so rare. You don’t have large randomized trials with 1,000-plus patients. You just have to go with your experience in similar cases with clinical trends from lab data.”

After a hospital stay of more than 40 days, the patient’s acute kidney function decline was halted. However, because of the effects of GPS, she is being treated for advanced chronic kidney disease. A few months after leaving the hospital, she was assessed and placed on the transplant list.

Such complex cases are managed most effectively in an academic medical center where multispecialty consultations can occur simultaneously, Middleton says. “These situations require the expertise of many for a good outcome.”

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