DukeHealth

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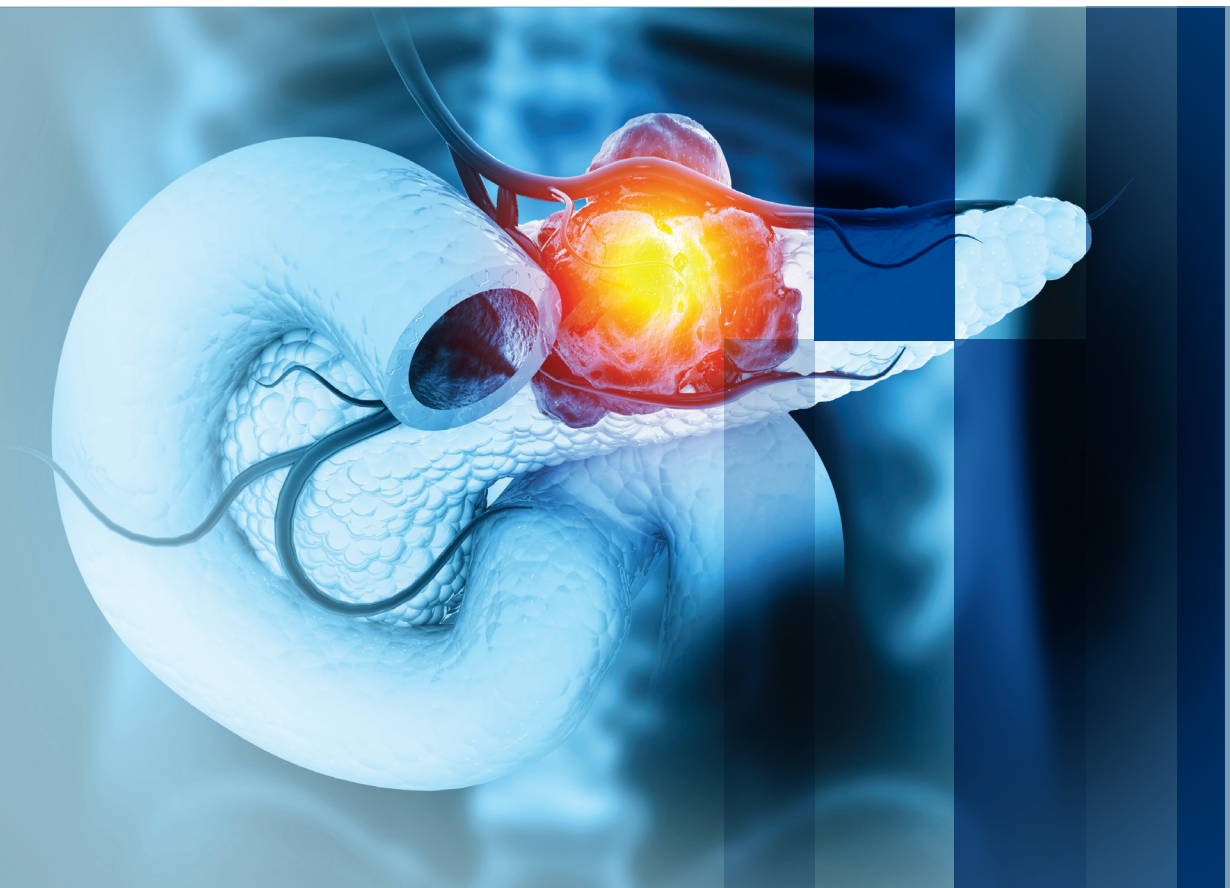
Clinical Practice Today

Integrated Team, Cutting-Edge Trials Expand Pancreatic Cancer Treatment



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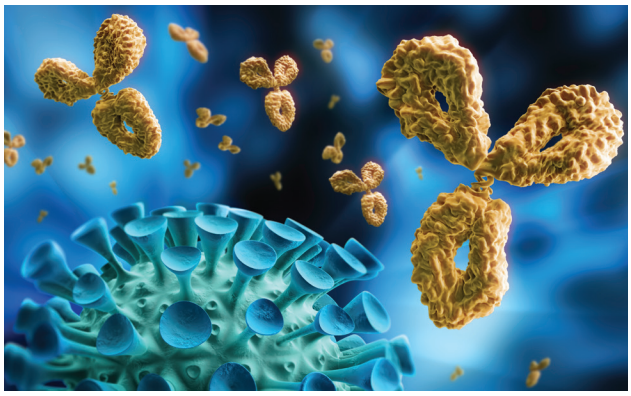

PHOTO CREDIT: peterschreiber.media/iStock.

Duke Identifies New Strategy for Immune Response to HIV

Publishing in *Nature Communications*, Duke researchers describe a strategy for engineering pieces of the HIV envelope that stimulate the process in which the immune system makes protective antibodies.

"To achieve this, we have to find the right antibody and then guide it along the way toward key mutations that are really rare," says senior author, Barton Haynes, MD, director of the Duke Human Vaccine Institute. "What we have found is that the immune system does not want to make protective anti-HIV broadly neutralizing antibodies unless it receives some help. This study demonstrates that, with the help of computer simulations, we were able to find the right HIV envelope immunogens to guide the immune system to make the desired antibody types."

Lead author Rory Henderson, PhD, used a computational technique called molecular dynamics simulation to identify how key antibody mutations prevent the virus from escaping neutralization. "A lot of work has been done with what we call priming—getting that gene to start to express and start seeing the antigen," says Henderson. "What we've never been able to do is coax it toward a specific mutation, which is what we would need for a vaccine. Our study showed how we can do that."

Haynes said the finding moves HIV vaccine development closer to fruition by showing that the immune system can indeed be guided to produce antibodies with specific mutations that are needed for antibody function.

Study Reveals Short-Term Safety of Active Monitoring for DCIS

The first study comparing surgery to active monitoring as treatment for ductal carcinoma in situ (DCIS) finds that women who carefully monitor the precancerous cells are no more likely to develop breast cancer after two years than women who undergo surgery to remove them.

The early results of the Comparing an Operation to Monitoring with or without Endocrine Therapy (COMET) study, published in the *Journal of the American Medical Association (JAMA)*, suggest women and their doctors may consider active monitoring as a safe, less-aggressive alternative for treating low-risk DCIS.

"Many women wonder, 'Do I really need to do this to myself?' when they're faced with surgery and possibly radiation to remove DCIS," says E. Shelley Hwang, MD, co-principal investigator and vice-chair of research in Duke's Department of Surgery. "These early results from our study give us reassurance that active monitoring is safe in the short term and that the cancers that are diagnosed during active monitoring are detected at an early stage."

"We noted there were fewer cancers diagnosed in those patients who had active monitoring, and we feel that part of this was due to the hormone-blocking treatment that many of them had," Hwang said. "Although this was optional on the study, over 70% of women combined active monitoring with endocrine therapy, suggesting that this may be an important part of active monitoring in the future for women with DCIS."

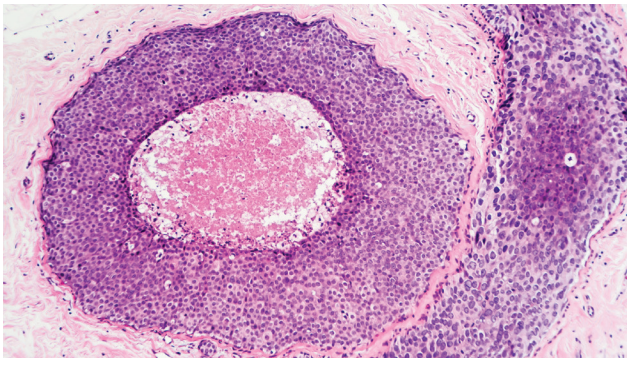

PHOTO CREDIT: rightdx/iStock.

Comprehensive Care for Immigrants and Refugees

By Haifa Kassis, MD

A patient's cultural beliefs and practices surrounding health and food can greatly influence how they communicate about their illnesses and respond to medical recommendations.

Providing comprehensive care for immigrants and refugees requires an understanding of their unique needs, which may include overcoming language barriers, lack of familiarity with the U.S. health care system, and cultural differences. Primary care clinicians can be crucial to this population's health and well-being by focusing on a few key areas.

Planning for the First Patient Visit

The U.S. health care system is complex and difficult to navigate. These difficulties are compounded for recently arrived immigrants and refugees with limited English proficiency. "I start the first visit by welcoming the patient and explaining my role as their primary care doctor, how the U.S. healthcare system works, and how to reach me," says Patricia F. Walker, MD, DTM&H, FASTMH, professor of medicine at the University of Minnesota and staff physician at HealthPartners Travel and Tropical Medicine Center.

In most instances, the first visit should be primarily spent on history and not include sensitive examinations. Primary care clinicians may also see patients several times within the first few months depending on their health needs and goals and to build trust and rapport.

PHOTO CREDIT: FatCamera/iStock.

Primary Care Screening and Assessment

Ideally, all immigrants and refugee patients should receive the standard of care for screening and assessments. "Chronic illnesses, like cardiovascular disease and cancer, as well as mental health conditions, have become more common in much of the world and often go untreated," says Martha Carlough, MD, MPH, consulting faculty at Duke Divinity School, professor emeritus of family medicine at UNC-Chapel Hill, and staff physician at Samaritan Health Center.

Clinicians can also consider additional screening and assessments based on where the patient was born and where they lived before coming to the U.S. "Patients might have been exposed to trauma and certain infections during migration and had limited or no access to preventive care or treatment," says Marc Altshuler, MD, professor of family medicine and program director at Thomas Jefferson University Hospital and director of Jefferson's Center for Refugee Health.

Most experts agree that screening for infectious diseases of long latency, such as hepatitis B, HIV, and tuberculosis, is needed in almost all groups of immigrants and refugees, even years after their arrival to the U.S. To help clinicians customize screening for refugees based on their country of origin, the Minnesota Center for Excellence in Refugee Health has developed an online tool called CareRef. Additional information on immigrant and refugee health is available from the CDC and other sources.

Addressing Language Barriers

"All patients should be asked for their preferred language," says Carlough. If the patient prefers to speak a language other than English, medical interpretation services by qualified interpreters should be automatically provided. Face-to-face and video-based medical interpretation services are equally effective, followed by phone interpretation. Asking family members to interpret should be avoided.

Clinicians may design and manage their office in ways that mitigate language barriers. For example, some practices have a multilingual welcome sign to greet patients when they come in. Front desk staff members should also be trained in how to use medical interpretation services and be ready to assist patients who need help with scheduling appointments.

Bridging Cultural Differences (and Avoiding Cultural Assumptions)

A patient's cultural beliefs and practices surrounding health and food can greatly influence how they communicate about their illnesses and respond to medical recommendations. Arthur Kleinman, a psychiatrist and anthropologist, referred to these factors as the patient's explanatory model of illness and created questions to help clinicians understand the patient's self-perception of their health conditions. "Clinicians can begin to understand how their patients think about their medical problems and why they behave the way they do by using Kleinman's questions," suggests Carlough. These open-ended questions can help avoid potentially incorrect assumptions, and include:

- What do you call this problem?
- What do you believe is the cause of this problem?
- How serious is it?
- What do you think this problem does in your body?
- How does it affect your mind?
- What do you fear most about this condition?
- What do you fear most about the treatment?

Caring for immigrants and refugees requires cultural sensitivity and some adjustments, yet "primary care clinicians who see refugees and immigrants in their practice are happier," says Walker. "It is such a privilege to care for them, and they truly open our world up," adds Carlough.

Resources

CareRef tool

CDC website

Local health departments

State refugee health coordinators

Local refugee health clinics

Transplant Still an Option for Patients Over 70

By Jordan McCollum

Historically, patients over the age of 70 were not considered candidates for kidney transplantation. However, age has become a less important contraindication for listing a patient for transplant, according to kidney and pancreas transplant specialist Goni Katz-Greenberg, MD, Duke's associate medical director for kidney transplant.

"A 70-year-old today is not the same as in the 1980s or 1990s. They're usually stronger and more robust," says Katz-Greenberg, who presented on this topic at the June 2024 American Transplant Congress. "Data show the largest growing population for patients with end-stage kidney disease is 65 and over."

The Organ Procurement & Transplantation Network reports that from 2000 to 2024, kidney transplants among patients over 65 increased sixfold, more than triple the growth in other age groups. Similarly, Duke increased kidney transplants in this age bracket each year since 2022. Duke also performed the most overall kidney transplants in North Carolina in 2024, with the highest one-year conditional survival rate.

Evaluating Older Patients for Transplant

Older patients require the same type of transplant evaluation as younger patients. "In particular, we pay closer attention to heart studies and CT to make sure they have adequate cardiac function and there are no prohibitive calcifications around their vessels," Katz-Greenberg says.

"We also take special note of 'frailty measurements,'" she adds. These frailty measures include the sit-to-stand test, the six-minute walk test, and the hand-grip test. "Although age is associated with frailty, when I think of some of our senior transplant recipients, the last thing you'd say is that they're frail," says Katz-Greenberg.

Not all centers accept patients over 70. However, Katz-Greenberg has seen successful outcomes among her patients at Duke. "Patients in this age category tend to do well with transplant," she says.

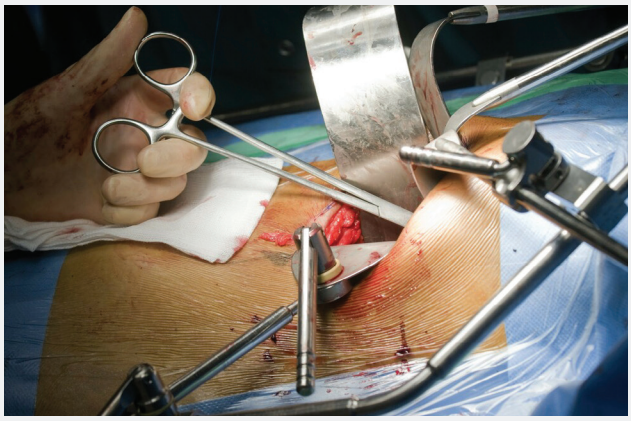

PHOTO CREDIT: Arno Massee/Science Source.

Living Donation Speeds Transplant

With limited available organs, all kidney transplant recipients face a wait. "If a 70-year-old patient just starting dialysis comes to us, they could be waiting a long time," says Katz-Greenberg. "If they have a living donor, we can do a transplant now. We encourage physicians to urge patients to find a living donor."

Across all age groups, living donation can hasten transplant. Even if a willing donor lives too far away or is not a match, options like paired donor exchange, remote donation, and voucher donation shorten patients' wait times and help others awaiting lifesaving care.

"We want physicians to know patients over 70 have options," Katz-Greenberg says. "Nationwide, transplant among seniors has increased, and we're making efforts to do that at Duke, as well."

To refer a patient for transplant, visit:

How To Navigate Visits from Drug Representatives

By Emily Paulsen

PHOTO CREDIT: Perawit Boonchu/iStock.

Visits from drug representatives can be time-consuming and fraught with ethical questions. Understanding guidelines and laws regarding visits from drug reps can help physicians navigate the implications of these interactions.

Visits from drug reps have "always been a high-risk touchpoint," says Hillary Stemple, JD, health care attorney and partner with ArentFox Schiff in Washington, DC, as they may brush up against laws and regulations including anti-kickback statutes, the False Claims Act, health care fraud laws, and patient privacy protections like HIPAA. However, by following certain guardrails, it's possible to mitigate risk, she says.

Check available guidelines. The Department of Health and Human Services Office of Inspector General and the American Medical Association offer guidance addressing physicians' relationships with drug companies. Physicians should also review internal policies where they practice. Any meals provided by manufacturers should be "modest" by local standards, Stemple says. A plate of sandwiches during an educational presentation may comply, but a steak dinner at a "special occasion" restaurant would cross the line, she says.

To avoid gray areas, some hospitals and practices opt to prohibit all meals and visits from industry to providers, including product samples and educational visits.

Protect patient privacy at all times. Drug manufacturers and their sales are not considered "covered entities" under HIPAA, and under no circumstances should sales reps be given access to anything that could identify a patient, Stemple says.

Beware of veering into "expense relief." If a rep offers to help with prior authorizations or make phone calls on your or your patient's behalf, this can raise not only privacy questions, but it may also be considered a kickback. "It's something of value to the physician practice that they would otherwise have to pay for," adds Stemple.

Consider implications of consulting or speaking engagements. Manufacturers must report all payments (including meals or consulting fees) to physicians and other providers in the Open Payments database established by the Sunshine Act. Higher-than-average payments to a specific provider may raise questions from patients, employers, or others. Providers have an opportunity to review information from the previous year. Stemple advises physicians to review it carefully and dispute any amount that appears in error.

Regardless of whether a drug representative has promoted the product at the practice, Stemple says, it's important for physicians to prescribe the best medication for each patient's needs.

Resources

HHS OIG Physician Relationships With Vendors

AMA Code of Medical Ethics' Opinions on Physicians' Relationships with Drug Companies and Duty to Assist in Containing Drug Costs

Duke To Offer New Treatment for Early-Stage Alzheimer's Disease

By Nicole Jablonski

The Duke Memory Disorders Clinic in the Department of Neurology will soon offer a recently FDA-approved drug to treat early symptomatic Alzheimer's disease. This drug, donanemab, is the second anti-amyloid therapy available to patients, after the FDA approval of lecanemab in 2023.

"This new class of drugs is promising. We know that amyloid and tau proteins are a marker of Alzheimer's disease progression. These drugs encourage the microglia to remove the amyloid from the brain, slowing cognitive decline," says Kim G. Johnson, MD, Duke geriatric psychiatrist and chief of the Memory Disorders Division in Neurology.

Donanemab and lecanemab are administered by intravenous (IV) infusion, a new delivery method for Alzheimer's disease treatments. Before anti-amyloids, drugs to slow cognitive loss were in pill form, with the last new treatment for cognitive loss developed over 20 years ago. "Previous treatments don't affect disease pathology; they just increase neurotransmitters in the brain. Anti-amyloids are a big deal because they modify the disease," says Johnson.

Lecanemab and donanemab are equally effective. "Clinical trials show they slow cognitive loss between 20% and 30% over 18 months of treatment," says Johnson.

Inclusion and Exclusion Criteria

Lecanemab and donanemab are for patients diagnosed with mild cognitive loss. "We require a mini cognitive status test to determine a patient's initial eligibility," says Johnson. "This is something primary care providers and family practitioners can support with, as patients often report early signs of cognitive loss to them first."

Research shows that patients get the most impactful results if they start anti-amyloid therapy earlier in the Alzheimer's disease process. Patients with mild cognitive impairment—when these proteins are just starting to increase—benefit most from the drugs. "The donanemab and lecanemab trials both showed patients with lower tau, indicating earlier-stage disease, had a greater rate of cognitive slowing than those with higher tau," says Johnson.

At Duke, patients diagnosed with later-stage or more advanced Alzheimer's disease are referred to geriatric medicine providers to manage long-term care. Patients with suspected early-stage disease are referred to neurology for extensive evaluation, which includes genetic testing for the *APOE4* gene, imaging tests such as MRI and amyloid PET, and a spinal tap to determine if amyloid and tau proteins are present in the cerebrospinal fluid.

"This testing allows us to confirm the patient's diagnosis and risk-stratify to determine if anti-amyloid treatment is the best choice for patients," says Johnson. "We are very upfront with patients about their risk profile. It's our job to educate patients and their families so they can make wise decisions."

To refer a patient, log into Duke MedLink or call 919-668-7600.

Choosing a Medical Waste Disposal Vendor

By Frank Celia

Medical waste disposal is not one of the flashier aspects of running a medical practice; however, choosing the right vendor can affect a practice's bottom line and environmental goals.

Before reaching out to potential vendors, practice managers can familiarize themselves with their state's requirements regarding regulated medical waste (RMW). Although many matters in health care are dictated by federal law, medical waste disposal is one area in which state laws and regulations have a bigger impact. The Healthcare Environmental Resource Center has a state-by-state RMW resource locator that physicians can use to find the appropriate requirements.

Once a practice knows its state's requirements, it should work up a "simple self-waste audit" to determine what streams need to be processed, says Zach Hetrick, director of new business development at Reduction In Motion, an environmental consulting firm based in Fallston, MD. A common mistake he sees, especially among smaller practices, is overclassifying RMW, which leads to unnecessary fees. A primary care practice that performs little wound care may not need to classify every discarded glove, mask, or gown as RMW, he cautions.

Practices should then solicit bids via a formal or semi-formal request for proposal (RFP) process, he says. An RFP allows the practice to tell the vendor what it needs, rather than the other way around. RFPs should include an itemized list of services, as opposed to an open-ended contract with an opaque, flat fee. Over time, open-ended contracts tend to go up in price, Hetrick warns.

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"Ninety-nine percent of all clinics out there should only have on-call service," he adds, "meaning they don't have regular pickup times." On-call service often requires a dedicated waste storage room, which can be a higher upfront expense, but is less costly in the long run, Hetrick notes.

Before the vendor's contract starts, Hetrick suggests doing a walkthrough with the vendor to determine the layout and logistics of the job. If the vendor shows up one day and cannot enter the practice because of a locked door, for example, it may still charge the practice for that pickup.

Practices that prioritize environmental sustainability may issue RFPs that call for reusable instruments rather than disposable ones. Practices should also consider their options for how waste is processed. Treating with ozone gas is the most eco-friendly method, followed by autoclaving and incineration. When choosing among the three, be mindful of the distance the waste must travel to be treated, Hetrick notes, because the carbon emissions may outweigh the environmental benefits.

State-by-State RMW Resource Locator

Duke leads with research, commitment to increase cure rates

Integrated Team, Cutting-Edge Trials Expand Pancreatic Cancer Treatment

By Nicole Jablonski

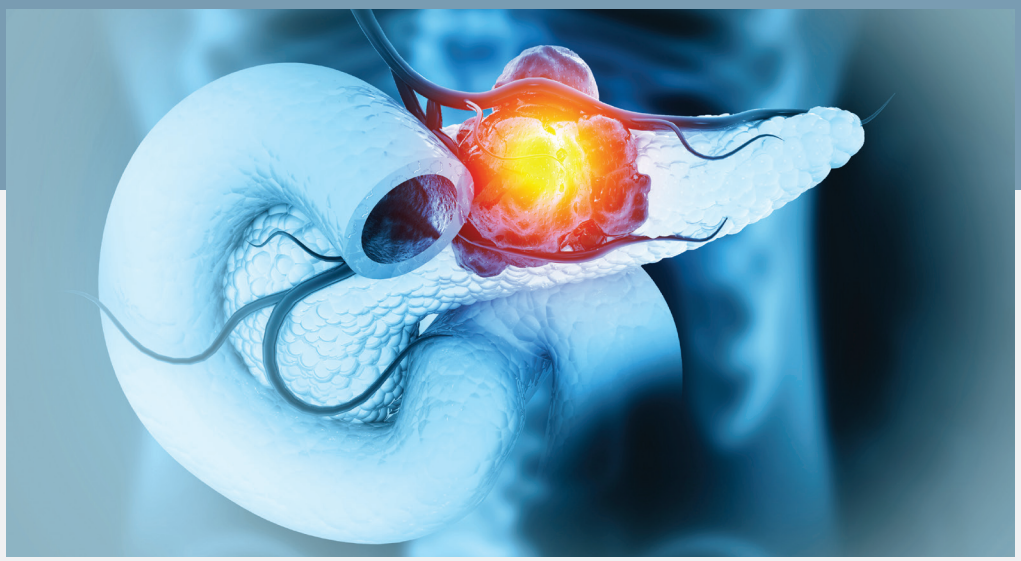

PHOTO CREDIT: Mohammed Haneefa Nizamudeen/iStock.

200

pancreatic resections performed by Duke per year

The Duke Cancer Institute (DCI) Pancreatic Cancer Program is building a legacy of hope and innovation with a mission to improve the cure rates of one of the most aggressive cancers. "Our surgical team performs over 200 pancreatic resections a year with exceptional surgical outcomes," says Daniel P. Nussbaum, MD, surgical oncologist. "But improving cure rates for pancreatic cancer requires more than the standard approaches available at most institutions. It takes an integrated team to offer cutting-edge, personalized treatment options."

Multidisciplinary Approach to Care

"Currently, about 90% of patients who have surgery to remove localized pancreatic cancer will face recurrence at some point, many within just a few years of their initial treatment," says Nussbaum. "While we plan each patient's treatment with a hope for a cure, this disease requires a dedicated team thinking ahead about how to prevent or delay recurrence and to have treatment options available to offer when it does," says Nussbaum.

When detected at an early stage, pancreatic cancer treatment typically involves surgical resection combined with chemotherapy. Subspecialist support is also required to manage potential gastrointestinal and metabolic issues that can arise during treatment and recovery. "One of the best things about Duke is that we provide the highest level of multidisciplinary care for patients with pancreatic cancer and other complex gastrointestinal cancers," says Niharika B. Mettu, MD, PhD, gastrointestinal medical oncologist.

DCI's pancreatic cancer team includes surgeons, medical oncologists, gastroenterologists, radiation oncologists, radiologists, interventional radiologists, and exceptional inpatient and outpatient nurses and advanced practice providers. "We also have close relationships with our dietitians, medical family therapists, social workers, psychiatrists, and palliative care team to ensure every patient has the ancillary care they need," says Mettu.

Recognizing that patients often come to Duke from a distance, the team has prioritized protocols that may let patients receive their standard chemotherapy locally to limit the travel burden and allow patients to continue treatment with their current oncologists.

A Mission To Improve Cure Rates

Pancreatic cancer outcomes, even for patients diagnosed with early-stage disease, have remained bleak because the disease often recurs quickly and metastasizes to other locations. Treatment plans require a proactive approach, often testing novel therapies within a clinical trial setting. "Clinical trials help us find new, potentially impactful treatments that can also benefit patients today," says Nussbaum. "We're growing our clinical trial portfolio with studies uniquely tailored to improve cure rates for the most diverse patients."

Clinical Trials Aiming To Reduce Recurrence and Improve Survival

The team currently leads three innovative protocols for patients with localized pancreatic cancer, and several others are expected to open this year. The first trial tests if a single dose of chemotherapy delivered directly to the liver one week before surgical resection can prevent or delay liver metastasis. "Liver metastases drive survival outcomes in most patients with pancreatic cancer. It's the most common site for metastatic spread or recurrence, and patients who develop liver metastases have worse survival outcomes than those who develop spread to other sites, such as the lungs," says Nussbaum.

The second is a multisite trial based on promising phase 1 results from Memorial Sloan Kettering, which tests if a personalized mRNA vaccine prevents recurrence following surgery. During the phase 1 trial, 50% of patients given the vaccine experienced a robust immune response, and none of the patients demonstrating this response had recurrence at 18 months. This study is now being tested at the highest level as a randomized trial.

The third trial uses the Pancreatic Cancer Program's unique partnership with the NIH to offer T cell therapy to patients with earlier-stage disease. This is the first time this treatment has been employed to test its ability to improve recurrence and cure rates. "The idea is to start intervening earlier in the disease by engaging the patient's immune system to target their own tumor cells," says Nussbaum.

Genomic and Molecularly Personalized Therapies

By the end of this year, the team anticipates two new perioperative trials to open testing targeted therapies for patients with specific genomic or molecular features, including those whose tumors overexpress Claudin 18.2 (over 50% of patients) and those whose tumors exhibit loss of the gene *MTAP* (approximately 20% of patients).

The team is also exploring therapy targeting *KRAS* in pancreatic cancer, because over 90% of pancreatic tumors have mutations in this gene. "We want to study *KRAS*-targeted treatments that may suppress this mutation and tumor activity," says Mettu, director of experimental therapeutics at Duke. These molecularly and genomically targeted trials may lead to more personalized care for patients. "It's important to know that there is hope during every stage of a pancreatic cancer journey, which evolves throughout treatment. Hope pervades everything."

For patient referrals, call 866-385-3123 (1-866-DUKE-123) or email OncologyReferral@Duke.edu.

Taking Time Off and Avoiding Burnout in Private Practice

By Meredith Lidard Kleeman

Even when physicians take time off, many still check email and electronic health records. A 2023 study published in *JAMA Network Open* found that 70% of physicians worked while on vacation, which was directly associated with higher rates of burnout.

Many physicians don't realize how common burnout has become, says Bryan Sexton, PhD, director of the Duke Center for the Advancement of Well-Being Science (CAWS). Currently, the burnout rate among physicians sits at around 50%, after reaching a high of 62% during the COVID-19 pandemic.

Vacations can greatly reduce stress and improve well-being, but research shows that frequent, shorter breaks are more beneficial than a single, extended trip. "When you take a three-week vacation, the amount of work that builds and the anxiety it creates about reentry disproportionately hurt the recovery efforts," Sexton says.

In addition to taking more frequent, shorter paid time off, physicians can implement regular well-being practices to put a little gas back in their tanks. CAWS has developed a series of bite-sized, evidence-based interventions designed for busy healthcare workers. Below, Sexton shares two popular strategies with documented restorative effects.

Improve sleep habits. "Everything you do in life is easier when you have a good night's sleep," Sexton says. "When people have a long history of abusing their own personal sleep time just to get stuff done, reintroducing ways to fall asleep earlier is remarkable."

"3-2-1 Method" To Improve Sleep Quality

- 3 hours before bedtime, stop eating
- 2 hours before bedtime, stop drinking
- 1 hour before bedtime, dim the lights

PHOTO CREDIT: aquaArts studio/iStock.

Cultivate awe and wonder. Emerging research reveals that awe is a distinct emotional state that benefits physical and mental well-being. Physicians suffering from burnout get to the point where they're no longer amazed by the world around them, Sexton says.

Awe can be cultivated even by simple acts, like walking in nature. "When you're walking the dog, notice the clouds. When you're planning a vacation, watch a sunset or visit something that's going to make you stare at it in wonder for a while—that has remarkably restorative effects," Sexton says.

One dose of awe isn't the cure for burnout, but it's one of many easy well-being strategies that CAWS offers. "There's no magic wand that works for everyone—you can't just tell everyone to go to bed 30 minutes earlier and, voilà, the workforce is healed," Sexton says. "Having options, or a suite of well-being strategies for a person's well-being profile, is really important. There are huge, individual differences in what people are struggling with regarding their well-being."

CAWS well-being programs, tools, and research can be found at:

Research Advances ACL Injury Management

By Jordan McCollum

PHOTO CREDIT: LightFieldStudios/iStock.

ACL tears are among athletes' most common injuries, with approximately 400,000 ACL reconstructions performed annually in the U.S. "Research continues to try to determine how best to prevent ACL injury, optimize treatment and rehabilitation, and prevent reoccurrence once the patient has returned to sport," says orthopaedic surgeon Annunziato "Ned" Amendola, MD, Duke's division chief of sports medicine. "It's a significant area of concern."

Risk Factors for ACL Injury

Sports participation is a well-established risk factor for ACL injury, but anatomic factors, including the shape and orientation of bones in the leg, can also increase risk. Additionally, muscle imbalances, neuromuscular control, and biomechanics mean women face more than four times the risk of ACL injury as male athletes. "This is an important area of research," Amendola notes.

Surgical Advances To Prevent Reinjury in High-Risk Patients

Research has helped orthopaedists determine the best treatment course for each patient. "For patients at high risk of reinjury, the lateral extra-articular tenodesis (LET) procedure controls the knee's rotation, how the ACL is often injured," says orthopaedic surgeon Robert T. Tisherman, MD, who is a new provider to Duke Sports Medicine. Studies have validated LET, which adds additional stability to a reconstructed ACL by redirecting a strip of the iliotibial band to reinforce the side of the knee.

Duke is also one of the few centers in the region to perform the bridge-enhanced ACL repair (BEAR), which uses a biosponge implant to help an incomplete ACL tear heal. "With repairs, you're using the patient's own ACL, preserving its nerve endings and proprioceptive fibers," says Amendola. "Maintaining neuroproprioceptive input has been seen as beneficial to preventing reinjury."

Preventing Repeat Injury and Returning to Sport

Tisherman stresses that rehabilitation is also key to preventing reinjury. "Our data shows that six months postop is too soon to return to sport," says Tisherman. "We do intensive testing at nine months postop to detect any weaknesses and continue to address them in rehabilitation."

This therapy is an important part of Duke's multi-disciplinary ACL care. "We have a full team to evaluate athletes well and rehabilitate them optimally," Amendola says. These coordinated efforts enable Duke to offer comprehensive, customized care for each patient while advancing research to identify the best treatments.

Women's ACL Injury Research

Duke Orthopaedic Surgery has received a groundbreaking $3.9-million, five-year grant to investigate ACL injuries' underlying causes, with a particular focus on why younger women are disproportionately affected. The effort is spearheaded by orthopaedic researcher Louis DeFrate, PhD, and orthopaedic surgeon Jocelyn Wittstein, MD.

To refer a patient, visit:

Study showed 15% reduction in deaths from heart attack and stroke

Semaglutide Lowers Risk of Major Cardiovascular Events

By Jordan McCollum

PHOTO CREDIT: aprott/iStock.

Research continues to show health advantages for the glucagon-like peptide-1 receptor agonist (GLP-1 RA) semaglutide and similar agents. Originally developed to treat type 2 diabetes, GLP-1 RAs' weight loss benefits have attracted attention, but the drugs have also been shown to improve cardiovascular disease risk, high cholesterol, high blood pressure, heart failure, and chronic kidney disease.

"Cardiovascular disease is still the No. 1 cause of global morbidity and mortality," says Duke cardiologist Nishant P. Shah, MD. "We need to think of these drugs not as diabetes agents but as cardiovascular medications. When you frame your mindset that way, you're more likely to reach for these drugs beyond diabetes for the patients that need them most."

Cardiovascular Benefits of Semaglutide

After multiple studies showed cardiovascular benefits among patients with diabetes taking semaglutide, broader trials examined the effects for other patients. Among nondiabetic patients with

a BMI of 27 kg/m^2 or higher and established cardiovascular disease, the SELECT study found a 15% reduction in deaths from heart attack and stroke and a 23% reduction in deaths from other causes on semaglutide, compared with a placebo group.

Duke cardiologist Christopher B. Granger, MD, served on the study's data safety monitoring board. "We saw a clear difference even very early on," Granger says. "The curve showing cardiovascular benefit in the experimental arm separated almost immediately, before there was any weight loss. The benefits did not seem to be related to the baseline degree of overweight or obesity."

GLP-1 RAs can also be prescribed with other cardiovascular drugs like statins. "These drugs can and should be used together," says Shah. "We have many evidence-based therapies available to improve patients' cardiovascular risk, and we should leverage every appropriate option."

Prescribing GLP-1 RAs

Despite the accumulating evidence of the drugs' benefits, insurance approval continues to pose the biggest barrier in clinical practice, Shah explains. Without insurance, GLP-1 RAs can cost more than $1,000 per dose. "Diabetes is one of the most consistent ways to get a prescription approved," Shah says.

"For weight loss alone in patients without diabetes, that's where we see some complexities in access," he continues. "If you have a patient who wants the drug for weight loss, risk-stratify them from a cardiovascular standpoint. What other factors do they have that make them high risk enough to receive the drug?"

Shah notes that in the early days of prescribing GLP-1 RAs for weight loss, physicians and staff may have to work more with insurance companies to get approval, including conducting peer-to-peer reviews. Patients can also review their insurance policies for anti-obesity medication coverage and advocate for themselves alongside providers.

When prescribing, Shah urges physicians to start at the lowest dose and titrate upward every four to six weeks to get the dose-dependent cardiovascular and weight loss benefits. "If you start at high doses, you'll likely have side effects, including nausea, vomiting, abdominal bloating, and discomfort. When you start at the lowest possible dose, 0.25 mg, your body has the opportunity to adjust."

GLP-1 RAs are contraindicated for patients with certain endocrine conditions, thyroid cancer, or drug-induced pancreatitis. Patients on GLP-1 RAs can lose lean muscle mass, so they must maintain a good exercise routine.

Obesity as a Chronic Disease

"Some people tend to hold on to weight, despite eating well and exercising, suggesting that obesity is a chronic disease," says Shah. "It's a disease with detrimental health effects, and treating it will have a great public health benefit."

"The obesity epidemic is growing and needs to be addressed urgently," says Neha J. Pagidipati, MD, MPH, Duke cardiologist and director of the Duke Cardiometabolic Prevention Clinic. At the clinic, Pagidipati, Shah, and colleagues see patients with high cardiovascular risk and other comorbidities, including obesity.

"We use a customized approach for each patient, but for everyone, we emphasize lifestyle," says Pagidipati. "Patients with elevated cardiovascular risk now have additional options. Semaglutide is another exciting tool we can utilize to help patients live healthier and longer lives."

> **"Patients with elevated cardiovascular risk now have additional options. Semaglutide is another exciting tool we can utilize to help patients live healthier and longer lives."**
>
> ***Neha J. Pagidipati, MD, MPH***

Shah and Pagidipati are among the PETAL study research team working to understand the barriers to implementing effective weight loss interventions and how to better measure obesity outcomes. The study will also calculate GLP-1 RAs' public health benefit on a population level.

"We're looking at understanding how many people would be eligible and what the estimated benefit would be if they all took these drugs—the aggregate total in health care benefit for improved cholesterol, weight, and cardiovascular risk," says Shah.

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