Nemours Cardiac Center Florida
Integrated Practice Unit
Setting New Stage for Pediatric Cardiac Care
Dr. Nitzmari Melendez-Vazquez is a board-certified neurologist treating young patients with an array of neurological issues including headaches, movement disorders, peripheral neuropathy, seizures and more. Her research includes the study of rare immune diseases and infections affecting the central nervous system. Dr. Melendez-Vazquez is fluent in English and Spanish.

Specialties
- Demyelinating Diseases
- Epilepsy Syndromes in Children
- Headaches
- Movement Disorders
- Peripheral Neuropathy
- Seizures

Diana Balsalobre is a board-certified neurologist with more than 20 years of experience and advanced, subspecialty training in clinical neurophysiology. She specializes in treating adult patients diagnosed with neurological disorders including headaches, dementia, Multiple Sclerosis, and Parkinson's Disease. Dr. Balsalobre is fluent in English and Spanish.

Specialties
- Epilepsy
- Multiple Sclerosis
- Movement Disorders & Tremors
- Peripheral Neuropathy
- Parkinson's Disease
- Stroke/TIA
- Traumatic Brain Injuries
Families of children with congenital and acquired heart issues can now look to Nemours Children’s Hospital in Orlando for patient centered pediatric cardiac care. The Nemours Cardiac Center in Florida opened its doors at the children’s hospital in Lake Nona’s Medical City in the summer of 2016. Since then, the team has been building the program into an integrated practice unit unlike anything else in the nation. The cardiac center, offering integrated expertise in cardiology, cardiothoracic surgery, interventional cardiology and advanced cardiac imaging, is comprised of the best and brightest in their fields. The physicians, surgeons and staff recruited from all around the nation now make up a team of over 100 people, working together to provide exceptional care to pediatric cardiac patients in central Florida and beyond.
FROM THE PUBLISHER

I am pleased to bring you another issue of Florida MD. Sometimes a patient may have the opportunity to participate in a clinical trial. Sometimes a patient may need specialized treatment that is not available in Central Florida. And sometimes there is no money for that patient to get to those places. Fortunately there is Angel Flight Southeast to get those patients where they need to go. I asked them to tell us about their organization and how you, as physicians, can help. Please join me in supporting this truly wonderful organization.

Best regards,

Donald B. Rauhofer
Publisher

COMING UP NEXT MONTH: The cover story focuses on cosmetic surgeons Robert Rey, MD and Alex de Souza, MD and their cutting edge procedures. Editorial focus is on Women's Health and Advances in Cosmetic Surgery.

Angels on Earth Help Patients Get to Lifesaving Medical Treatment

Everyone knows angels have wings! But did you know in Florida and many parts of the nation they have engines and tails with dedicated volunteers who donate lifesaving services every day?

Leesburg, Fla.-based Angel Flight Southeast is a network of approximately 650 pilots who volunteer their time, personal airplanes and fuel to help passengers get to far-from-home medical care. A member of the national Air Charity Network, Angel Flight Southeast has been flying passengers since 1993.

Almost all of its passengers are chronic-needs patients who require multiple, sometimes 25-50 treatments. Passengers may be participating in clinical trials, may require post-transplant medical attention or are getting specialized treatment that is not available near home.

Each passenger is vetted to confirm medical and financial need and is often referred to Angel Flight Southeast by medical personnel and social workers.

Angel Flight Southeast “Care Traffic Controllers” arrange flights 24 hours a day, 365 days a year. In the event of a transplant procedure, the Care Traffic Controllers have precious minutes to reach out to its list of volunteer pilots who have agreed to be prepared on a moment’s notice to fly a patient to receive his or her potentially lifesaving organ.

The organization is completely funded through donations by individuals and organizations. A typical Angel Flight Southeast pilot donates $400 to $500 in services-per-trip. In fact, Angel Flight Southeast has earned the Independent Charities of America Seal of Approval as a good steward of the funds it generates from the public. Each $1 donated generates more than $10 worth of contributed services by Angel Flight Southeast.

The charity always seeks prospective passengers, volunteer pilots and donations. For additional information, please visit https://www.angelflightse.org or call 1-888-744.8263.
My primary care has always told me there are key times in life to have certain medical evaluations done, so that I can stay on track of leading a healthy and long life. Shouldn't that also be true for having a plan to review our financial wellness, and include those areas that may impact that important type of wellness?

As a busy practitioner immersed in the day-to-day challenges of helping your patients and managing your practice, you can easily lose sight of your broader goals and ambitions for the future. By taking some time to crystallize your financial goals and size up your current standing, you’ll have a much better chance of achieving those goals in the long run.

Here’s a short checklist of questions to ask yourself to help guide your thought process:

WHERE DO YOU WANT TO GO?

The first questions to ask are the biggest: Where do you see yourself—and your practice—in the future? Are there near term goals, such as expanding your practice or helping your spouse or child achieve their own ambitions? Farther along, how do you want to spend your retirement? This is a good time to speak with your family to set common goals so that your financial plans accommodate the expectations of everyone who will be affected.

Also meet with any business partners to set priorities and timing, again with the idea of clarifying and coordinating ways to reach everyone’s goals. These professional discussions should conclude with written goals for succession, exit strategies, a schedule for each physician’s retirement, plans for frequent reevaluation and the names of successors.

WHERE ARE YOU NOW?

The next step is a thorough financial checkup with your financial advisor to establish a starting point. How much have you set aside for retirement? How are your investments distributed in terms of risk, horizon and diversification?

Any evaluation of your practice’s health should include benchmarking against a relevant comparison group. Metrics include gross billings per provider, market penetration and billing results, among others. Any significant variances from the norm suggest further analysis.

HOW WILL YOU GET THERE?

The third and last step involves creating a road map that gets you from where you currently stand to where you want to be. A qualified financial advisor can create a financial plan combining savings, investments and projected earnings to reach your goals and revise them later if they turn out to be unrealistic. A good financial plan is granular enough to break long-term goals into short-term ones, such as setting monthly savings and expenditure goals, and flexible enough to address unexpected contingencies.

It’s important to remember that no plan is set in stone. Meet regularly with your financial advisor to make adjustments for new goals, recent or upcoming events and the current economic environment.

If you need help with making a decision that is financially impactful to your practice…. just ask me for assistance!

References:
Available upon request

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Jeff Holt is a Senior Healthcare Business Banker and V.P. with PNC Bank’s Healthcare Business Banking and is a Certified Medical Practice Executive. He can be reached at (352) 385-3800 or Jeffrey.Holt@pnc.com.
Families of children with congenital and acquired heart issues can now look to Nemours Children’s Hospital in Orlando for patient centered pediatric cardiac care. The Nemours Cardiac Center in Florida opened its doors at the children’s hospital in Lake Nona’s Medical City in the summer of 2016. Since then, the team has been building the program into an integrated practice unit unlike anything else in the nation. The cardiac center, offering integrated expertise in cardiology, cardiothoracic surgery, interventional cardiology and advanced cardiac imaging, is comprised of the best and brightest in their fields. The physicians, surgeons and staff recruited from all around the nation now make up a team of over 100 people, working together to provide exceptional care to pediatric cardiac patients in central Florida and beyond.

BUILDING THE PROGRAM FROM THE GROUND UP

The Nemours Cardiac Center began as a vision by Nemours administrators to build on their existing hospital system and develop a department in their new Orlando facility to address a need in the state for a fully integrated cardiac system devoted entirely to pediatrics.

“We have an amazing opportunity to create a program like no other because we were able to develop it from inception,” explains Dawn Tucker, who had been a cardiac ICU nurse practitioner and administrator prior to becoming the administrative director of the Nemours Cardiac Program in Florida. “Our patients and families are at the center of everything we do, and we developed our healthcare team based on their needs,” says Tucker.

That recruitment began with pediatric cardiothoracic surgeon Dr. Peter Wearden, who was named the director and chair of the Nemours Cardiac Center. Dr. Wearden came to Nemours from Children’s Hospital of Pittsburgh of UPMC (University of Pittsburgh Medical Center).

“What drew me here was the commitment to care for children, with no distractions of an adult health system,” explains Dr. Wearden. “Here, cardiologists and surgeons work together in a cooperative environment to determine what’s right for the patient.”

THE INTEGRATED PRACTICE UNIT

The Nemours Cardiac Center built the integrated practice unit by recruiting the top cardiac experts in their fields from around central Florida and the nation. For
Dr. Wearden and Dawn Tucker that included building a team that incorporated the operating room staff as well as pre and post-operative environments that could work seamlessly together. Dr. Wearden encouraged many colleagues whom he had worked with in Pittsburgh to make the move to Nemours, including pediatric cardiac intensive care physician Dr. Constantinos Chrysostomos and pediatric anesthesiologist Dr. Steven Lichtenstein. Additional cardiologists, nurses and staff, all with extensive experience in pediatric cardiac care, were also added to the group.

“The majority of the team has now worked together for a decade and the uniformity of this team helped us achieve some of the best outcomes and survival rates in the country,” says Dr. Chrysostomos, chief of cardiac critical care. “When children are sick, every second counts and if I know what my colleagues are thinking and vice versa it saves a lot of time questioning and testing. Because of that, we anticipate problems faster and resolve them quicker.”

“When I put my surgical mask and headlight on and walk into that OR, I know I’m with a team I trust,” says Dr. Wearden. “Trust was an extremely important factor as we were building a new program. We may be new to Orlando and central Florida but our team is not new to this.”

**CARDIAC COMPREHENSIVE CARE UNIT**

The Nemours Cardiac Center team includes surgeons, cardiologists, interventional cardiologists, electrophysiologists, nurses, scrub teams and anesthesiologists fully concentrating on cardiac care. The CCCU (Cardiac Comprehensive Care Unit) provides seamless care from the time the patient first visits with members of the team, through surgery and post-operative care.

“In a typical cardiac program, a patient will be moved from unit to unit from the moment they arrive for pre-op to the moment they finally go home. Those are all transitions that pose a potential risk for our patient’s safety,” explains Tucker. “Our solution is to minimize patient transitions of care by having the patient stay in the CCCU from admission to discharge. It’s all about patient continuity, patient safety and minimizing transitions.”

One of the critical components of the cardiac center is anesthesiology, led by Dr. Steven Lichtenstein, chief of cardiac anesthesiology. Dr. Lichtenstein brings 30 years of pediatric experience to the OR, many with members of the existing Nemours team and he works exclusively with the cardiac team.

“We are all on the same team,” says Dr. Lichtenstein. “Each person contributes to the greater good of the patient. By having worked together in the past and developed a pattern of practice, we allow people to concentrate on their area of expertise.”

**THE INTEGRATED PRACTICE UNIT**

The team works closely to develop a consensus plan of what is best for each patient, conferencing on each case.

“We have open and robust discussions about patients, so that we find the best path of care,” says Dr. Wearden. “Everyone on the care team, who the patients and families meet, has been a part of that conference. This avoids a lot of frustration and confusion.”

“This approach ensures that we interchange ideas, knowledge and skills,” says Dr. Gul Dadlani, chief of pediatric cardiology.
A FAMILY APPROACH

The cardiac team remains focused on patient centricity and access.

“We strive for true access to healthcare,” says Tucker. “Many organizations view access as opening their doors, making a patient appointment and requiring families to drive to see their provider.” Tucker explains that for Nemours, it’s about bringing the pediatric cardiology expertise to patients who don’t have access to this care where they live. Nemours is now operating specialty care clinics across Florida so families can have the care they need in their own communities.

“A family from Pensacola can come to Nemours Children’s Hospital for complex surgical needs and return right back to their community to receive ongoing care,” says Tucker.

According to Dr. Chrysostomosis, the team is dedicated to making sure this integrated network of cardiac specialists, coupled with Nemours’ unique approach to patient centered care, is available to as many families as possible.

“We treat our patients as our own children. We understand these are very stressful and difficult times which is why we develop strong relationships with the families,” says Chrysostomos. “When a parent comes to us, they are entrusting us with the most important thing in their lives, their child.”

THE NEMOURS CLINICAL LOGISTICS CENTER

“Patients can be monitored every day of the year and physicians can also keep track of their patients from their mobile device at any time thanks to an app that we specifically developed for the CLC,” says Dr. Chrysostomos. “If something is not right with the vital signs or clinical measurements, the CLC team can video conference into any patient room, with the family’s permission, and intervene. There is no other center like this.”

PHOTO: PROVIDED BY NEMOURS CARDIAC CENTER FLORIDA

The Nemours Clinical Logistics Center (CLC) is a centralized monitoring facility located in Nemours Children’s Hospital in Orlando that takes technology to a new level. Data from all monitored patients is consolidated and displayed. It is monitored 24/7 by a clinical staff that helps identify trends before they reach alarming levels.
Supporting a New Era in Medicine

Financial Peace of Mind for Medical Marijuana-Related Businesses

If you operate a medical marijuana-related business (MRB) in Florida, you may face challenges finding a solution for your banking needs. First GREEN Bank provides you with safe, secure, convenient banking that is in full compliance with regulatory guidelines.

“Medical marijuana can be an effective treatment for a myriad of conditions. As members of my family have benefited from the curative effects of medical marijuana, I am passionate about playing a critical role in shaping federal and state legislation that protects MRBs.”

– Ken LaRoe, Esq., LEED AP Founder & Chairman

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Offices Throughout Florida
Outpatient Joint Replacement Surgery Helps Patients Return Home Hours After Surgery

By Corey Gehrold

Thanks to advances in technology and pain management, outpatient joint replacement surgery can save patients an overnight trip to the hospital and even bring rehabilitation right into the living room.

Bradd G. Burkhart, M.D., a board-certified orthopaedic surgeon specializing in sports medicine, knee and shoulder surgery at Orlando Orthopaedic Center, explains the benefits outpatient surgery provides to patients: “The reasons to do outpatient surgery are numerous but the biggest one is that you get to go home at the end of the day.”

Benefits of outpatient joint replacement surgery include:

• Patients return home within hours of surgery, compared to an overnight stay in the hospital with a traditional inpatient procedure
• Ease of access when checking-in and checking-out at an outpatient surgery center
• Smaller risk of infection from an outpatient surgery center versus a hospital
• The ability to recover and rehabilitate the joint at home quickly following the procedure without traveling to a rehabilitation clinic several times per week

Joint replacement surgery is always regarded as a last resort, employed only when nonsurgical methods such as medication, injections, and physical therapy have proven unsuccessful at alleviating chronic pain and restoring proper function. Outpatient joint replacement surgery is a minimally invasive process by which the worn and injured parts of a joint (partial) or the entire joint itself (total) are removed and replaced with new synthetic components.

As there are many benefits to outpatient surgery, Dr. Burkhart states: “We like to try and do as many surgeries as we can outpatient. Sometimes the nature of the surgery requires that you have to do it in an inpatient setting, but when you can do it outpatient we try and do that.”

OUTPATIENT KNEE REPLACEMENT SURGERY

Knee replacements are one of the most successful procedures in all of medicine with more than 600,000 knee replacements performed annually in the United States. According to the American Academy of Orthopaedic Surgeons (AAOS), over 90% of patients who undergo knee replacement surgery show a remarkable decrease in knee pain and a considerable improvement in their capacity to engage in normal daily activities.

According to Dr. Burkhart, outpatient knee replacement surgery is the same surgery that one would have done in a big hospital. The same medical implants are used by the same surgeons and highly-trained staff, all without the hospital hassle.

“You come into the outpatient center, you go to sleep for your surgery and then during the procedure we use special medication that can keep your knee numb for up to three days,” says Dr. Burkhart.

This added benefit allows for faster recovery times and patients also can avoid lengthy stays at unfamiliar rehab centers. “You can actually start walking in the recovery area and then when you go home, we try to do outpatient physical therapy, as opposed to staying in a rehabilitation center for two or three weeks,” says Dr. Burkhart.

“With outpatient joint replacement surgery, patients return home within hours of surgery, compared to an overnight stay in the hospital with a traditional inpatient procedure.”
The surgeons at the Advanced Center for Colorectal Surgery at Florida Hospital Tampa are leading experts in the treatment of colorectal diseases, such as colon, rectal, and anal cancer, diverticulitis, inflammatory bowel disease, fecal incontinence and much more. We offer minimally invasive laparoscopic and robotic procedures including ileal pouch-anal anastomosis, sphincter preserving, and ostomy-free surgeries that can greatly improve the quality of life for patients.

Cancer treatment is a top priority for our surgeons, who make themselves available immediately to see patients diagnosed with cancer. Using a multidisciplinary approach, our physicians collaborate with gastroenterologists, oncologists, radiation oncologists and other specialists at Florida Hospital Tampa to provide a comprehensive treatment plan that meets each patient’s individual needs.

Our experts will diagnose and treat your condition, and help you return to leading a normal lifestyle.

For more information on The Advanced Center for Colorectal Surgery or to schedule an appointment, please call (813) 615-7366 or visit FLColonSurgery.com.
Proven Strategies to Get Patients to Use Your Patient Portal

By Jennifer Thompson

You need patients to use your patient portal, right? So, how can you get them on board to meet meaningful use requirements without creating a lot of work for you and your staff?

To help patients use your patient portal, here’s a few tips and strategies we’ve used with clients to get patients engaged and signed up.

UNDERSTAND BEHAVIOR AND DEMOGRAPHICS

Instead of just creating a blanket statement and telling patients to use your patient portal, consider who your patients are and why they would want to use it in the first place. In other words, you’ll want to make a case that appeals to them specifically.

For patients with chronic conditions, promote the fact the portal offers:

• Lab results
• Vitals tracking
• Care plans
• Communication with a coach or provider

For healthy patients, promote the fact the portal offers:

• Appointment scheduling
• Wellness resources (health tips, HRA assessments, etc.)
• Diet/exercise management
• Communication with a coach or provider

Diving into the demographics of your office can help create a plan that works for all of your patients. Plus, odds are you’ll find some valuable information about age, income, location, etc. that can be used for other areas of marketing your practice. Win-win.

CREATE A MARKETING PLAN

How do you tell patients to use your patient portal? Is it just a sheet of paper you hand them before they leave? Is it a reminder email? You’ll want to tell them in as many ways as you can; so, although these are good ways to spread the word about your patient portal, they’re not enough. In addition to the methods mentioned above, consider:

• Creating an eye-catching graphic you can use on your social media channels
• Using the same graphic to create a flyer / poster you can put around your office and in exam rooms so patients see it everywhere
• Use giveaways and promotional products with reminders if you have the budget
• Put a table in your lobby with material for patients to take home (this may sound silly, but they will be drawn to whatever is on the table - this is valuable real estate!)

PUT IT ON YOUR WEBSITE

This is kind of a no-brainer, but you’ll want to add a link or button for patients to use your patient portal on your website. Make sure the link button is easily visible and accessible on all pages of your website. We suggest keeping it out of your main navigation menu (because that’s probably crowded enough) and adding it to the header (top) section of your website. This way it’s easy to find, identify and click.

INCLUDE ENROLLMENT AS PART OF REGISTRATION

Again, this is kind of a no-brainer, right? When patients are filling out their intake paperwork, make sure you collect email addresses and have a form or flyer ready to hand out. We also suggest having a front desk “champion” that understands the patient portal like the back of her hand.

This way, whenever a patient is having trouble signing up or has a question, there is a designated resource person for them to go to. This may also help ensure continued use of the portal if she checks in on patients occasionally to make sure they’re using the portal as they should.

ENCOURAGE PROVIDERS TO PROMOTE THE PORTAL

Your patients are a captive audience that listen to your doctors, right? In a perfect world they listen anyway - but we digress. By having providers promote the portal, the idea is that adoption rates will go up because they’re being told by their doctor.

To help, provide training and incentives for providers to connect with patients using the portal. Make sure providers acknowledge when patients use the portal, or continue to use it.

Consider creating a canned phrase your providers can use to encourage continued use when they see a patient has used the portal. Something as simple as “Thank you for using our portal; we can really see your health matters to you.”

Jennifer Thompson is co-founder and chief strategist for DrMarketingTips.com, a website designed to help medical marketing professionals market their practice easier, faster and better.
Medical Marijuana: A Promising Aid for Cancer
By Cindy LaRoe, MD

Marijuana is a dried version of the cannabis sativa plant that can be smoked, vaporized or ingested for physiological effects. While the U.S. Drug Enforcement Administration considers marijuana an illicit drug under federal law due to its ability to provide a “high,” it has been used for medical benefits for thousands of years. Specifically, the cannabinoids present within marijuana have been forensically proven to treat a variety of ailments. Only one compound in the plant, tetrahydrocannabinol (THC), has any psychoactive effects. On the other hand, some of the active components in marijuana, including THC, have been proven to reduce pain, nausea, inflammation, anxiety and seizures.

Medical marijuana is openly supported by The American Cancer Society, which states the plant helps combat the pain and nausea associated with chemotherapy, a common cancer treatment. The society emphasizes the need for scientific research on cannabinoids for cancer patients. According to The National Cancer Institute, several clinical trials have already shown that medical marijuana helps manage the side effects of cancer, but the federal law against cannabis prevents extensive research.

Cancer affects millions of Americans and is a leading cause of death worldwide, prompting the question: Why don’t these individuals, who are suffering and fighting the toughest fight, have access to a basic herbal remedy?

The U.S. Food and Drug Administration has approved two synthetic cannabinoid drugs, dronabinol and nabilone, for treating chemotherapy side effects. Yet, the organic marijuana plant is still considered a Schedule 1 drug, alongside more potent drugs such as heroin, LSD and methamphetamine. This frustrating fact fails to acknowledge the growing evidence that often the benefits of cannabis outweigh any negative side effects. Additionally, marijuana is rarely addictive and overdose and death from marijuana is impossible, unlike several legal drugs in the market such as OxyContin and morphine. Fatalities from these highly addictive drugs have quadrupled since 1999. In fact, from 1999 to 2015, more than 183,000 people died from overdosing on opioids.

One study conducted in Spain, confirmed that one of the most aggressive agents for fighting tumor growth is the combined treatment of THC and CBD, which are the main active ingredients of marijuana. Research proves that these components help combat tumor growth by interfering with cellular communication in tumors and instigating cell death. Other recent trials have concluded that THC slows cancer migration and helps relieve the painful effects of several cancers, including breast, lung, prostate, colon, cervical and more.

Not surprisingly, a 2014 poll conducted by Medscape and WebMD found that more than three-quarters of U.S. physicians believe cannabis provides real therapeutic benefits. Using my background as a physician specializing in internal medicine, I don’t understand how a natural plant with medical benefits is illegal. In 2011, as a result of a cycling accident, I suffered a traumatic brain injury that temporarily prevented me from being able to drive, travel, read, and left me with crippling seizures. I can confidently say that through this life-changing process, medical marijuana cured my seizures and was the only treatment that relieved my suffering.

Following my accident, I became passionate about sharing my positive experience with cannabis treatment and invested my time in researching more about how it can help people suffering through traumatic experiences like mine. After seeing firsthand the efficacy of cannabis in the treatment of seizures, my husband, Ken LaRoe, joined in my mission to help others have access to this amazing treatment. Ken now offers banking depository solutions to cannabis professionals through First GREEN Bank, a bank he founded in 2009 with a mission to promote responsible business practices. While environmental issues consumed the bank’s initial focus, the company has since expanded into other areas to improve the lives of people. One of these initiatives is the decision to become the first bank in the state of Florida to bank the medical marijuana industry. Often, marijuana curators do not have access to the soundness of the American banking system, creating a public safety issue that we hope to help solve.

Even in states with legalized medical marijuana, such as Florida, dispensaries are frowned upon and locally regulated within each city. Many city officials fear federal pushback, since technically the industry is still illegal at the federal level. Therefore, marijuana businesses are heavily regulated, banning when and where dispensaries can open, and who can receive treatment.

Nonetheless, there is a positive history and promising future for medical marijuana. Together we can raise awareness around this issue by getting involved with local government. Ask lawmakers to support a comprehensive medical marijuana bill. Every notion of support brings us one step closer to helping those in need.

Cindy graduated from the University of Florida with honors and the University of South Florida College of Medicine. She completed her residency at the University of Florida Health Shands Hospital.

In 2011, Cindy crashed in a local circuit cycling race. She sustained multiple broken bones and a traumatic brain injury.

Cindy has always been artistic and initially considered seeking a degree in art. Since her injury, painting has been her therapy, which she practices daily. Contact Cindy at greenlaroe@gmail.com.
Recent Supreme Court Rulings Affecting Health Care Providers  By Julie Tyk, Wilson Elser

Physicians in Florida are required to report to the Department of Health any adverse incident that occurs on or after January 1, 2000, in any office maintained by a physician pursuant to section 458.351, Florida Statutes. These reports are discoverable under a patient’s constitutional right under Article X, Section 25 of the Florida Constitution (Amendment 7). Also, adverse incident reports placed in a Patient Safety Organization (PSO) under the federal Patient Safety and Quality Improvement Act of 2005 (PSQIA) are most likely discoverable following a recent Florida Supreme Court decision.

The Florida Supreme Court held in Charles v. Southern Baptist Hospital of Florida, Inc., No. SC15-2180 (Fla. Jan. 31, 2017), that adverse incident reports produced in conformity with state law could not be classified as confidential and privileged patient safety work product under the PSQIA. The Supreme Court reasoned that adverse incident reports do not constitute patient safety work product because Florida Statutes and Florida Administrative Rules require that providers create and maintain adverse incident reports. Additionally, the Court noted that patients have a constitutional right to access records relating to adverse medical incident reports. The Court also held that the PSQIA did not expressly or impliedly preempt a patient’s constitutional right under Amendment 7.

As background, the plaintiffs in Charles sent an Amendment 7 request to Baptist Hospital. The plaintiffs’ discovery request asked for reports prepared pursuant to several sections of the Florida Statutes. The request specifically stated:

This request is limited to adverse incident documents (as described above) that are created by you, or maintained by you, or provided by you to any state or federal agency, pursuant to any obligation or requirement in any state or federal law, rule, or regulation. As limited, this request includes, but is not limited to, documents created by you, or maintained by you pursuant to Fla. Stat. § 395.0197, 766.010, and 395.0193. This request, as limited, specifically includes, but is not limited to, your annual adverse incident summary report and any and all Code 15 Reports.

In response, Baptist Hospital produced Annual Reports, Code 15 Reports and two incident reports relating to the decedent. However, the hospital objected to the production of any other document claiming privilege under the PSQIA. Plaintiffs filed a motion to compel production of all Amendment 7 documents. The trial court held that the information required to be gathered under Florida law, whether reported or not, is precluded from being protected patient safety work product under the PSQIA. The hospital appealed to the First District Court of Appeals, which held that the documents were entitled to federal protection and that Amendment 7 was preempted by the PSQIA.

This request is limited to adverse incident documents (as described above) that are created by you, or maintained by you, or provided by you to any state or federal agency, pursuant to any obligation or requirement in any state or federal law, rule, or regulation. As limited, this request includes, but is not limited to, your annual adverse incident summary report and any and all Code 15 Reports.

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Following the Supreme Court’s holding in Charles, it is clear that adverse incident reports do not become patient safety work product simply because they are placed in a PSO under the PSQIA. Therefore, a patient can obtain copies of adverse incident reports stored in PSOs.
The Florida Supreme Court held in *Hernandez v. Crespo*, No. SC15-67 (Fla. Dec. 22, 2016) that an arbitration agreement violated public policy under the Medical Malpractice Act and was therefore unenforceable.

Mrs. Crespo was 39 weeks pregnant and having contractions when she was turned away from her doctor's appointment because she was a few minutes late. Three days later she delivered a still-born son. The plaintiffs furnished the defendant health care providers with a notice of intent. The providers denied the claim. The plaintiffs filed a Complaint against the providers. The providers filed a motion to stay proceedings and compel binding arbitration. The arbitration agreement (agreement) was signed by Mrs. Crespo but not Mr. Crespo. Plaintiffs later requested binding arbitration pursuant to section 766.207, Florida Statutes, which was rejected as the providers were enforcing the signed agreement.

The Supreme Court found that the agreement signed by Mrs. Crespo was void and violated public policy because it included statutory terms that only favored the providers. The Court specifically noted that the agreement diverged from the requirements of the Medical Malpractice Act in that it:

- Did not concede the providers' liability
- Did not guarantee independent arbitrators
- Did not include that one arbitrator had to be an administrative law judge
- Did not provide for payment of interest on damages
- Did not require joint and several liability of the defendants
- Shared costs equally between the parties instead of the providers assuming most of the costs
- Dispensed with the right to appeal.

**PRACTICE POINTS**

The takeaway from *Hernandez* for providers is that arbitration agreements must follow the statutory arbitration scheme under Florida’s Medical Malpractice Act. If an arbitration agreement is one-sided or conflicts with the statutory arbitration scheme, the court will likely find the agreement void, against public policy and unenforceable. Providers should review their existing arbitration agreements following this holding by the Florida Supreme Court. In light of the holding in *Charles*, providers must ensure that mandatory reporting obligations are kept separately from PSQIA activities.

If you have specific questions about how *Charles* or *Hernandez* impacts your practice, its participation in a Patient Safety Organization, section 458.351, Florida Statutes requirements or other aspects of PSO development, strategy, implementations and policies, please contact Wilson Elser’s Medical Malpractice team in Orlando, Florida.

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Surgical Treatment for Ulcerative Colitis: Ileal Pouch Anal Anastomosis (J Pouch)

By Allen P. Chudzinski, MD, FACS, FASCRS

Medical treatment for ulcerative colitis (UC) has improved dramatically over the last 10 years with major advances in biologic therapies. The development of these new therapies has allowed us to keep ulcerative colitis inflammation at bay and has significantly changed management of ulcerative colitis. However, UC patients may still develop a variety of medical conditions that necessitate surgical intervention including: high-grade dysplasia, adenocarcinoma, failure of medical therapy, and anemia due to hematochezia. Cure for ulcerative colitis is possible with surgical total proctocolectomy.

Historically, after surgical intervention, UC patients were left with a permanent end ileostomy until the advent of a variety of ileal pouches, the most common in the United States being the J pouch with anal anastomosis. Patients underwent a large open surgery followed by a 7-day or longer hospital stay. As medical therapies improve, so do surgical procedures with improved technology. It is now standard of care to undertake a total proctocolectomy with ileal pouch anal anastomosis using minimally invasive surgery. A laparoscopic or robotic technique is utilized. The entire dissection and mobilization of the colon and rectum is undertaken intraperitoneally, utilizing multiple 8 mm port sites and a final Pfannenstiel incision at the waist line for extracorporealization (removal site from the abdomen) of the large specimen. After the J pouch is formed and anastomosed to the anal canal, a temporary diverting ileostomy is fashioned in the right lower quadrant at a previous port site. It should be noted that given the correct patient body habitus, the extracorporealization site can be at the intended ileostomy site further limiting size of incisions. Our patients have significantly reduced pain, decreased length of hospital stay, and quicker return to normal activity, as result of the utilization of these methods. After the pouch has had time to heal (6 weeks), which is verified by pouchoscopy and radiographic studies, the diverting ileostomy is taken down in a minor second surgical procedure.

Patients with a J pouch are expected to have 6-8 controlled bowel movements a day. Historically pouches were not offered to patients over 50 years of age out of concern of incontinence. Currently J pouches are successfully undertaken with excellent function in patients as old as 70 years of age. The most important predetermining factor is excellent anal sphincter function.
Patients are warned about possible risks associated with having a J-pouch, the greatest of which is pouchitis. This is an inflammation of the pouch causing tenesmus and frequent bowel movements and is believed to be caused by an overgrowth of bacteria and is typically treated with a short course of antibiotics. Additionally, small bowel obstruction is a risk with this surgery, with the most common site being at the site of the prior ileostomy. Furthermore, pre-menopausal women are instructed that there can be a 50% chance of decreased fertility after the procedure. This is likely due to adhesions and scar tissues intertwining the fallopian tubes and ovaries. Finally, pelvic nerves controlling sexual and bladder function are abundant within the pelvis. Though these nerves are very low, there is possible risk of injury. Visualization of these nerves are significantly improved with laparoscopic and robotic techniques.

At the Advanced Center for Colorectal Surgery at Florida Hospital Tampa, we routinely perform minimally invasive total proctocolectomy with ileal pouch anal anastomosis with temporary diverting loop ileostomy, either using total laparoscopic or total robotic surgical technique. Using these methods, our patients have excellent outcomes, shorter hospitalization, and quicker return-to-life functions including school work and normal activity.

For more information about surgical treatment of ulcerative colitis, or to refer a patient, please contact the Advanced Center for Colorectal Surgery at Florida Hospital Tampa at (813) 615-7366, or visit FLColonSurgery.com.

Allen P. Chudzinski, MD, is Director Advanced Center for Colon and Rectal Surgery and Director Advanced Colon and Rectal Surgery Fellowship at Florida Hospital Tampa.

The surgeons at the Advanced Center for Colorectal Surgery at Florida Hospital Tampa are leading experts in the treatment of colorectal diseases, such as colon, rectal, and anal cancer, diverticulitis, inflammatory bowel disease, fecal incontinence and much more. They offer minimally invasive laparoscopic and robotic procedures including ileal pouch-anal anastomosis, sphincter preserving, and ostomy-free surgeries that can greatly improve the quality of life for patients.

Cancer treatment is a top priority; the surgeons make themselves available immediately to see patients diagnosed with cancer. Using a multidisciplinary approach, their physicians collaborate with gastroenterologists, oncologists, radiation oncologists and other specialists at Florida Hospital Tampa to provide a comprehensive treatment plan that meets each patient’s individual needs.
New Head and Neck Cancer Type, New 2017 Staging

By Bruce Haughey, MD

Though its numbers have risen rapidly over the last 30 years, cancers of the head and neck have barely caught the public’s attention. A few celebrity cases, including that of actor Michael Douglas, certainly drew press coverage, but the fact that this disease of the tonsils and base of tongue has risen in incidence by 225% between 1988 and 2004 has hardly been headline news. Oropharynx cancer, predominantly in men, will soon have a higher incidence rate than cervical cancer in women (1).

**THE HPV LINK:** The disease is strongly associated with high (malignancy) risk sub-types of the human papilloma virus (HPV), and is diagnosed predominantly in the palate and lingual tonsils, or occasionally found in the naso- and hypopharynx, oral cavity and larynx. There exists a strong propensity for early metastatic neck disease, more so even than in “traditional” head and neck cancer which, by contrast, is classically associated with smoking and/or excessive alcohol consumption. Presentation of HPV-related cases frequently includes enlarging lateral neck mass(es), with little or no aerodigestive tract symptomatology.

Other differences between HPV-associated and traditional disease are age of presentation (mid-50s vs. mid-60s), socioeconomic profile, and improved prognosis, with HPV-related cases carrying a (treated) prognosis of 85-90% survival at five years, versus an approximate 50% survival rate at five years for traditional head and neck cancer.

**SETTING THE “STAGE”:** This improved prognosis has ushered in a change in how head and neck oncologic practitioners perceive head and neck cancer, recognizing that if these HPV-associated patients are going to live long and productive lives, protocols are necessary to de-intensify the potentially toxic effects of both existing and recently used treatment modalities. Toxicities have classically been considered acute and late, and it is the late toxicity that has come under scrutiny which in the oropharynx concerns disruption of swallowing and speech. In the first nine months of 2015, for example, I personally had to preform total laryngectomy to prevent life threatening aspiration and restore swallowing in three male patients, each of whom was cancer free more than five years from treatment.

Cohort follow up studies established that HPV-associated cases had a different set of pathology-related risk factors, (Sinha et al 2011,(2) Maxwell et al 2013(3)) albeit with retention of pT associated risk. This finding led the NCCN in its 2016 Guidelines(4) to correctly point out that the trials upon which post-operative adjuvant therapy recommendations had previously been based contained no information on representation of HPV-related cases. The implication from this statement is that the relevance of the previous recommendations to this inewi disease is unknown.

As de-intensification trials have developed, the critical necessity of revised patient stratification according to risk of recurrence or death has also been recognized. For example in surgically managed cases, most of which are now handled with either transoral laser or robot-assisted removal of the primary tumor, and cervical lymphadenectomy, neck metastatic disease as categorized and staged in the past, (nodal presence, size, laterality and numbers >1) does not appear to have a striking impact on prognosis. Intriguingly, this “exemption” from risk of nodal stage does not hold up in non-surgically managed cases where, although requiring new “thresholds” for advancing clinical stage of neck disease, a new staging system retains the old N-classification criteria.

Either way, the “call” for new staging systems appropriate to HPV oropharyngeal disease, to be incorporated into upcoming editions of the AJCC/UICC Cancer Staging Manual, was heard. Not only was new staging essential for clinical trial and general prognostic purposes, but was also in deference to the patient “mind set.” Already grappling with a malignant diagnosis, the majority of individuals were also coping with the burden of correctly assigned, but incorrectly prognostic, “Stage 4” disease.

**THE NEW AJCC/UICC STAGE:** Published in January 2017, the 8th Edition AJCC Cancer Staging Manual (5) has separate, completely new staging systems, one clinical and one pathological, for HPV-associated oropharynx squamous carcinoma.

The new clinical staging system, validated in non-surgically managed cases (OSullivan B et al, 2106,[6]), has 3 loco-regional stages, with new combinations of T- and N-classifications, albeit built from 7th Edition AJCC/UICC (7) nomenclature.

The new pathologic system also has three loco-regional stages, but because pathology-based studies had shown that the 7th Edition clinical and pathological N-classification was not prognostic, it contains a cross tabulation of pT-classification and high (>5) metastatic node number (Haughey BH et al, 2016, [8]).

Both systems have Stage IV, the unifying criterion being presence of distant metastatic disease. To be included in these systems of staging, both also require a histopathology diagnosis of HPV-associated disease, commonly via p16 immunohistochemistry (>70 % staining) or HPV in-situ hybridization.

These new HPV-associated features of the 8th Edition Manual (5) will be implemented in early 2018, by which time cancer registries and pathology Departments will have had the opportunity to adjust their recording and reporting paradigms.

In future, further validation of these new Stages will be forthcoming in cohort follow up reports, national database studies and prospective clinical trials. Refinements and adjustments are expected, but the new Staging for this mini-epidemic of HPV-related oropharynx cancer is a welcome development for the profession and patients alike.

Dr. Bruce Haughey is a board-certified, fellowship-trained otolaryngologist-head and neck surgeon with extensive experience treating cancers of the tonsils, tongue, jaws, vocal cords, facial skin, scalp, sinus, and thyroid, parathyroid and salivary glands. His research interests extend to new techniques for minimally invasive head and neck cancer resection, reconstructive surgery and parathyroid surgical outcomes.

Dr. Haughey earned his medical degree at the University of Auckland in New Zealand, completed his residency and fellowship training at the University of Iowa Hospitals and Clinics, where he earned the title of Chief Resident. He also completed advanced subspecialty training at the University of Iowa with a highly prestigious skull base and neuro-otology fellowship.

If you want to refer a patient for an in-office evaluation, contact Florida ENT Surgical Specialists at 407-303-4120.

References available upon request.
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