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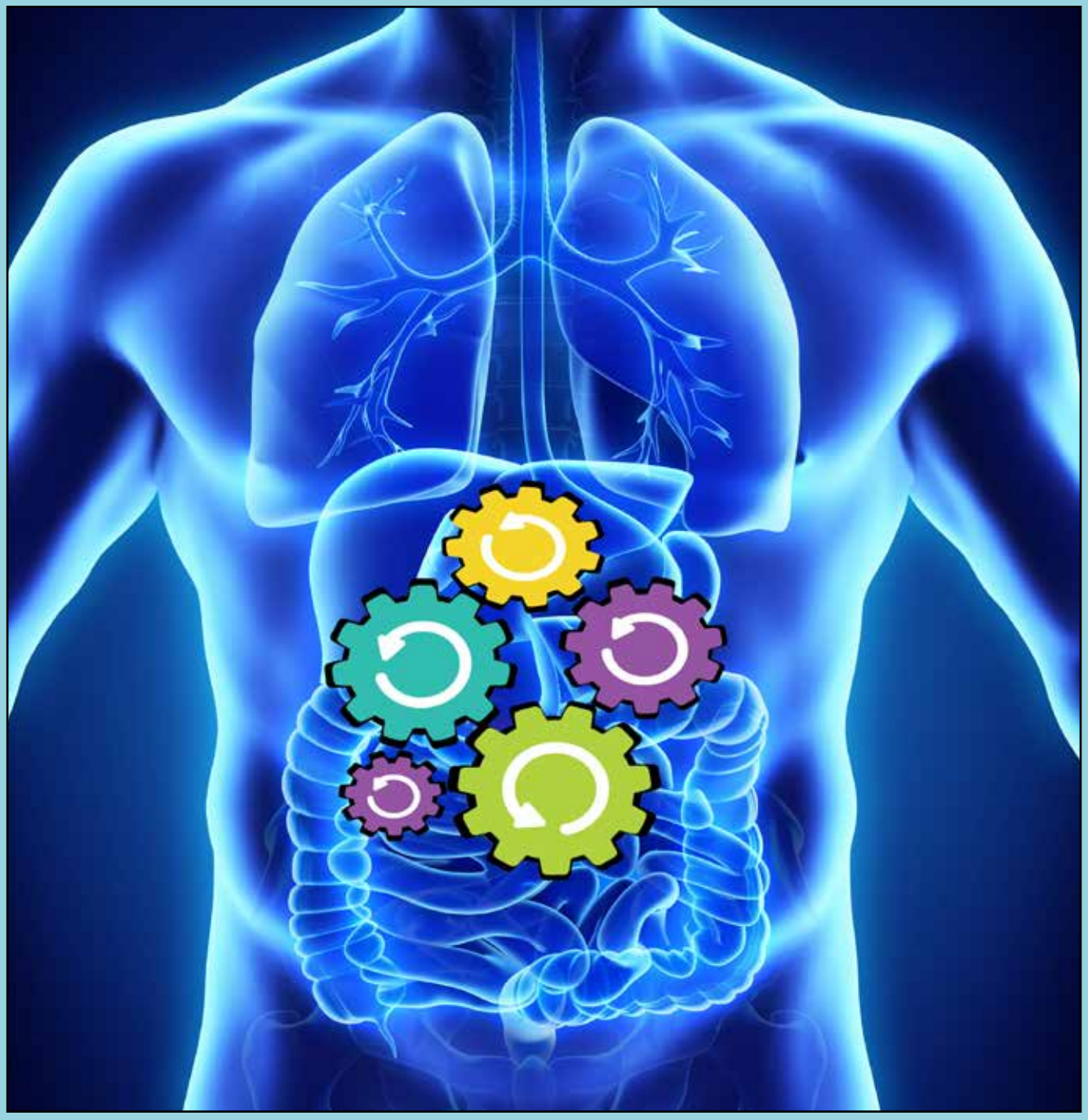
ALACHUA COUNTY MEDICAL SOCIETY

House Calls

FALL 2018



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CONTENTS

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UF Health Transplant Hepatology

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UF Health Dept. of Medicine

Dr. Joydeep Chakraborty is currently a fellow in the Department of Gastroenterology, Hepatology and Nutrition at the University of Florida College of Medicine. He received his medical degree from Kasturba Medical College, Mangalore, India and post-graduation in General Medicine from Kasturba Medical College, Manipal, India. He subsequently went on to complete his residency in Internal Medicine at UF. His clinical interests includes metabolic liver diseases and liver transplant and he aspires to pursue further fellowship in Transplant Hepatology.

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Dr. Chini earned his medical degree from the University of Florida, where he also completed his Internal Medicine residency and Gastroenterology fellowship training. He joined Digestive Disease Associates in 2012 after completion of his medical training. He is a member of the American College of Gastroenterology and Florida Gastroenterologic Society, and is board certified in Internal Medicine and Gastroenterology.

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Dr. Lambrou is currently in her third year of residency in internal medicine at the University of Florida. She graduated from the Florida State University College of Medicine. She plans on going into a gastroenterology and hepatology fellowship after she completes residency.

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Scott Medley, MD

Retired Family Physician

After graduating from the University of Kentucky College of Medicine, Dr. Scott Medley served in the U.S. Army, completing his Residency in Family Medicine and attaining the rank of Major. He entered Private Practice in Gainesville, establishing Gainesville Family Physicians. After 20 years in Private Practice, Dr. Medley became a Hospitalist and later acting as Chief Medical Officer at NFRMC. He served as President of the ACMS and of the Florida Academy of Family Physicians, and as Chair of the Gainesville Area Chamber of Commerce. He was given the Gainesville Sun Community Service Award in 1987 and was chosen Florida Family Physician of the Year in 1992. He currently is retired and volunteers at Haven Hospice, where he was named Volunteer of the Year for 2017. Dr. Medley has served as Executive Editor of *House Calls* for the past 20 years, and has authored over 85 editorials and articles for this publication.

Caroline Rains, MD

CannaMD

Dr. Rains, from Tampa, is a University of Florida graduate. She received her M.D. from the University of South Florida. She was a resident at the University of Kentucky and became Medical Director of the West Bluegrass District Health Department. She moved to Gainesville in 1984 as the Medical Director of the Alachua County Health Department. She retired from public health in 2015 and now contracts with CannaMD to provide medical marijuana treatment to qualified patients. She also volunteers at the Helping Hands Clinic. Dr. Rains has been a member of the Alachua County Medical Society since 1984 and was president in 2008.

Christopher Forsmark, MD

Chief, UF Health Endoscopy

Dr. Forsmark is Professor of Medicine and Chief of the Division of Gastroenterology, Hepatology and Nutrition at the University of Florida. He earned his M.D. from Johns Hopkins University followed by completion of his Internal Medicine Residency, Gastroenterology Fellowship, and Research Fellowship at the University of California – San Francisco. Dr. Forsmark is Board Certified in both Internal Medicine and Gastroenterology. Dr. Forsmark's clinical and research interests are in the areas of acute and chronic pancreatitis, pancreatic function and function testing, biliary and pancreatic malignancy and advanced therapeutic endoscopy. Dr. Forsmark serves as the UF PI as well as Co-Chair of the entire CPDPC consortium.

Jesse Lipnick, MD

SIMEDHealth Rehabilitation Medicine

Dr. Lipnick has practiced Physical Medicine and Rehabilitation with SIMEDHealth in Gainesville, Florida since 1995. He completed medical school at Washington University St. Louis, internship in Internal Medicine at Albert Einstein College of Medicine in NY, and residency in Physical Medicine and Rehabilitation at the Thomas Jefferson University Hospital in PA. Dr. Lipnick has served on the Board of Directors of SIMEDHealth. He is the past President of the Tri-County Health Alliance, and he serves as Member at Large to the ACMS Board. He currently serves as President Elect of the Florida Society of Interventional Pain Physicians.

House Calls is a quarterly publication of the Alachua County Medical Society, Inc., Gainesville, Florida.

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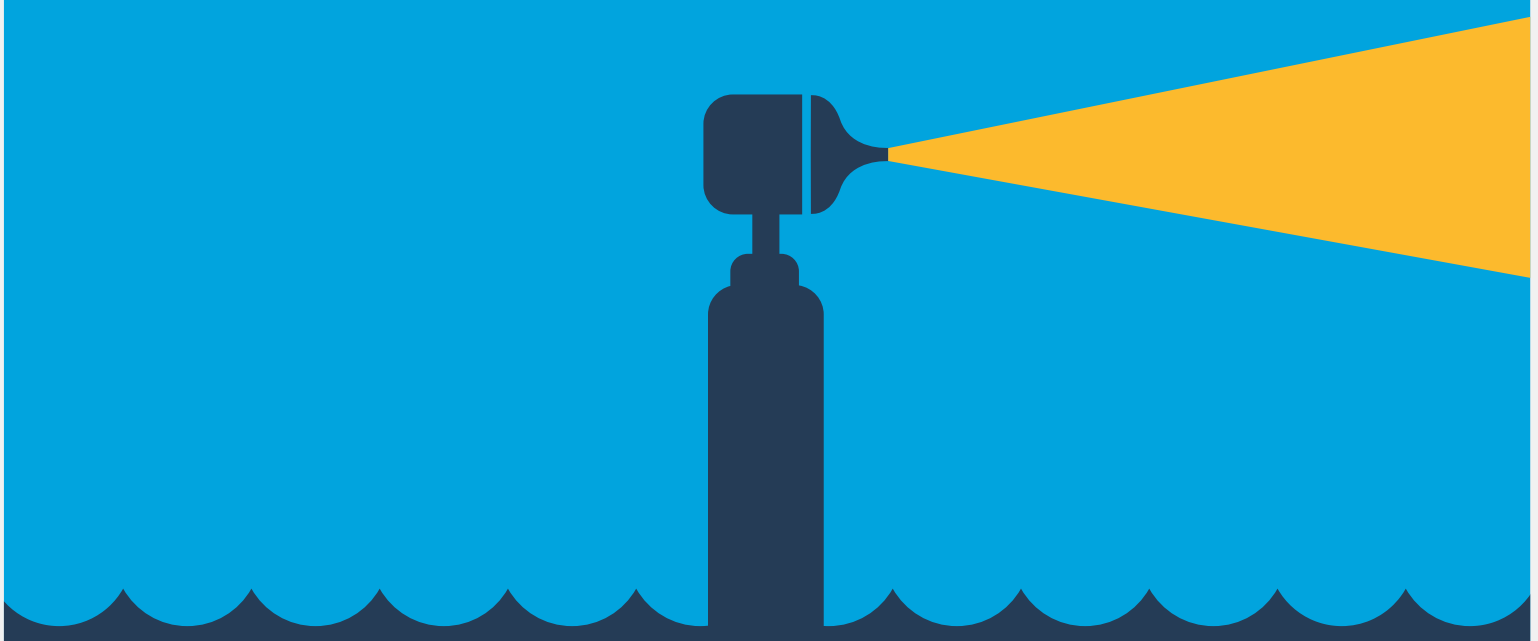

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From the Desk of the EVP

Leadership Transitions:
UF Health and North Florida Regional Medical Center

Jackie Owens, ACMS Executive Vice President

UF Health
UF Senior Vice President for Health Affairs and UF Health President

David S. Guzick, MD, PhD

Dr. David S. Guzick stepped down from his position as UF SVP for Health Affairs and UF Health President as of July 1, 2018. Having accomplished all of the goals he set out in July 2009 when he was appointed in this role, Dr. Guzick would like to spend time focusing on his family, health and perhaps writing a book on his experiences in the US health system.

From 2002 to 2009, Dr. Guzick was dean of the School of Medicine and Dentistry at the University of Rochester in Rochester, New York. In addition to serving as dean, he was principal investigator for Rochester's National Institutes of Health Clinical and Translational Science Award. From 1995 to 2002, Dr. Guzick served as the Henry A. Thiede professor and chair of the department of obstetrics and gynecology at the University of Rochester. He earned his medical and doctoral degrees from New York University as part of the Medical Scientist Training Program of the National Institutes of Health. Following a residency in obstetrics and gynecology at the Johns Hopkins Hospital, he completed a fellowship in reproductive endocrinology at the University of Texas Southwestern Medical School.

During his tenure at UF, Dr. Guzick made significant accomplishments including the expansion of research funding from the National Institute of Health by 60%, and completion of the UF Health Heart & Vascular and Neuromedicine Hospitals. Overall, Dr. Guzick worked in academic medicine for 35 years since residency, never taking a sabbatical. We thank him for all of his contributions to UF Health and the ACMS and hope he'll finally get to write that book. And yes, we would like a signed copy.

David R. Nelson, MD

Dr. David R. Nelson has been appointed as the Interim Senior Vice President for Health Affairs & President of UF Health. Dr. Nelson was previously the director of the UF Clinical and Translational Science Institute since 2010. He received his undergraduate degree from Dartmouth College and his medical degree from State University of New York Upstate University in Syracuse, New York. His residency was completed in internal medicine at the University of Massachusetts and he obtained fellowship training in gastroenterology and hepatology at UF.

We welcome Dr. Nelson to his new position and look forward to working with UF Health under his tenure.

Dean - UF College of Medicine

Dr. Michael Good announced that he has accepted the positon of Senior Vice President for Health Sciences, CEO of University of Utah Health and Executive Dean of the Utah Health School of Medicine, effective this fall. Dr. Good completed his residency training in anesthesiology and a research fellowship at UF, joining the UF faculty in 1988.

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LEADERSHIP TRANSITIONS

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He has served as the Dean of the College of Medicine since 2008. Previous to that appointment, he held leadership positions as the COMs Senior Associate Dean for Clinical Affairs and Chief of Staff for UF Health Shands Hospital.

In his 34 years with UF Health, Dr. Good has seen substantial clinical growth at UF, significant improvements in quality of care and patient safety, and advances in research and education programs. He has always been a strong supporter of the ACMS and organized medicine. We thank Dr. Good for all of his guidance over the years and wish him the best in his new life in Salt Lake City.

Adrian Tyndall, MD, MOH, FACEP, FAAEM

Dr. Adrian Tyndall has been named the interim dean of the College of Medicine effective July 30th. Previously, Dr. Tyndall served as the Chair of Emergency Medicine at UF College of Medicine (since 2008), and Physician-in-Chief of emergency services for UF Health, becoming a UF faculty member in 2006. As Chair of UF Health Emergency Medicine, Dr. Tyndall was responsible for UF Health Shands E.R and Level 1 Trauma Center, the UF Health Shands Children's Hospital's Pediatric E.R., two freestanding emergency centers, and the EM Residency training program; overseeing 53 faculty members and fellows. He has served on the board of directors of UF Health Shands for four consecutive terms and has been a longstanding elected member of the UF Health Shands Medical Executive Committee. Prior to joining UF, Dr. Tyndall held faculty appointments at the Weill Medical College of Cornell University and at the State University of New York Health Sciences Center in Brooklyn.

Dr. Tyndall completed his undergraduate studies at the George Washington University with concentrations in chemistry, music and zoology. He graduated from the University of Maryland School of Medicine, and completed his residency in Emergency Medicine at the University of Maryland Medical Center and the R. Adam Cowley Shock Trauma Center. His Master's Degree is in Health Services Management and Health Policy from Columbia University in New York.

Welcome, Dr. Tyndall! We look forward to working with you.

North Florida Regional Medical Center:
Chief Executive Officer

Brian Cook accepted the appointment of President of HCA's Las Vegas-based Far West Division, effective May 1st. Mr. Cook fills the role previously held by HCA veteran Bryan Rogers who is retiring after nearly 20 years with HCA. In his new role, Mr. Cook will oversee operations for eight hospitals, nine surgery centers and numerous other outpatient locations in California and Nevada.

Brian Cook has been with HCA for fifteen years in various leadership roles, joining North Florida Regional Medical Center as CEO in 2014. He is a graduate of Florida State University and earned his MBA at Rollins College's Crummer Graduate School of Business.

Under Mr. Cook's tenure as CEO, NFRMC has expanded its facilities and services, including Florida Heart & Lung Institute, the NFRMC Neuroscience Center, a behavioral health unit and two free-standing ERs. We wish Brian well in his new position in Las Vegas and thank him for all of his support over the years.

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NFRMC recently named **Eric Lawson** as its new Chief Executive Officer. Mr. Lawson will oversee all hospital operations, planning and strategy development. Overall, Eric has nearly 30 years of experience in the HCA system and seven years at NFRMC. Previously, he served as the Division Chief Financial Officer for HCA TriStar Health in Brentwood, Tennessee, from 2012 to 2018, overseeing a division of 14 hospitals, 10 ambulatory surgery centers and 386 service providers. From 2005 to 2012, Mr. Lawson served as the CFO and Ethics and Compliance Officer at NFRMC. Mr. Lawson has a Bachelors in Business Administration from Tennessee Technological University.

Under his guidance, NFRMC will undergo a $110M hospital renovation and expansion project, with plans to add three floors to its south tower, expand its emergency rooms, modernize its north tower and build a new parking garage. The ER expansion is expected to be completed this month while the other projects should be completed within two years.

The ACMS welcomes Mr. Lawson back to Gainesville and is excited to work with you again.

NFRMC - Chief Medical Officer

Dr. Ann Weber has stepped down as Chief Medical Officer of NFRMC, serving as the CMO from 2012 to 2018. Dr. Weber was responsible for the operational oversight of 450 physicians in areas of physician relations, operational management, strategic discipline, quality care, collaborative team building and building clinical excellence. She has been with HCA for 14 years including the previous roles of Designated Institutional Official, Medical Director, Member of the Board of Trustees, Chief of Medical Staff and Chair of the Department of Medicine. Dr. Weber graduated from the University of Florida College of Medicine, with an Internship and Residency in Internal Medicine. She is Board Certified in Internal Medicine.

Under her leadership, NFRMC has implemented a Graduate Medical Education Program in family medicine and internal medicine, and plans to add additional programs in psychiatry, emergency medicine and OB-GYN. Dr. Weber will be continuing with NFRMC/HCA as the Assistant Program Director in the Internal Medicine Residency program.

We would like to thank Dr. Weber for her strong support of the ACMS over the years and wish her luck in her future endeavors.

Leonardo Lozada, MD, MBA

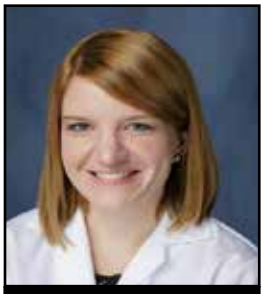
Dr. Len Lozada has accepted the positon of Chief Medical Officer at HCA - North Florida Regional Medical Center. Before joining NFRMC, Dr. Lozada was a consultant for the Physician Leadership Development Group, providing executive leadership coaching to Medical Directors, CMOs and hospital Presidents of Medical Staffs. Previously, he served as the Chief Physician Executive at St. Luke's Health System in Kansas City, Missouri. He has extensive experience in hospital building and expansion. He has served as the Senior VP for Medical Affairs at the Riverside Methodist Hospital and Chairman of Anesthesiology at Eastern Maine Medical Center. Dr. Lozada received his medical degree from Universidad Central de Venezuela and an MBA from Duke University specializing in Global Business. He completed his residency in anesthesiology at the Cleveland Clinic Foundation, a fellowship in Neurosurgical Anesthesia at the Cleveland Clinic and a fellowship in Neuroanesthesia at the Mayo Clinic. Dr. Lozada is a member of the America Society of Anesthesiologists, European Society of Anesthesiology, and the Society of Neurosurgical Anesthesia and Critical Care.

Welcome, Dr. Lozada! We're excited you are joining the NFRMC team.

RECENT ADVANCES IN THE TREATMENT OF HEPATITIS C

Roberto J. Firpi, MD, MS;
Tiffany Lambrou, MD; and Joydeep Chakraborty, MD
Department of Medicine at the University of Florida

Dr. Firpi



Dr. Lambrou

Dr. Chakraborty

Hepatitis C may be a short-term illness for some people, but for 70%–85% of patients who become infected with Hepatitis C Virus (HCV), it becomes a long-term, chronic infection. Per the most recent Centers for Disease Control and Prevention (CDC) estimate, 3.5 million people in the United States have chronic HCV. About 50% of HCV infected people are unaware of their infection. This type of chronic HCV is a serious disease that can result in chronic liver disease that is typically insidious in onset with varying disease courses. Of note, 10-20% of those with acute HCV infection go on to have cirrhosis over a 20 to 30-year period. For those with cirrhosis, there is a 1 to 5% annual risk of hepatocellular carcinoma and 3 to 6% annual risk of hepatic decompensation (with the risk of death in the following year at 15-20%). Thus, the importance of HCV screening and early referral to an HCV-treating provider cannot be overemphasized as most patients are unaware that they have the infection until consequences of chronic liver disease become apparent.

Unfortunately, there is no vaccine for HCV, and the best way to prevent HCV is by avoiding behaviors that can spread the disease. People at risk who are recommended for screening include current or former injection or intranasal drug users, recipients of blood transfusions or solid organ transplants prior to 1992, chronic hemodialysis patients, people with HIV, people with known exposures (for example, healthcare workers and those born to HCV positive mothers), history of incarceration, those who received an unregulated tattoo and all people born between 1945 and 1965 ("baby boomers").

Overview of Current Therapy

Per AASLD/IDSA HCV Guidance updated in May 2018, treatment is recommended for all patients with chronic HCV infection except for those with otherwise short life expectancies due to co-morbidities. Goal of treatment is to prevent complications of cirrhosis by achieving Sustained Virologic Response (SVR). SVR is defined as continued absence of detectable HCV RNA for at least 12 weeks after the completion of treatment. Patients are considered having current HCV infection when both the HCV antibody and HCV RNA are positive. Further, patients need to have an HCV genotype tested to determine therapy. As per a recent study presented at AASLD 2017, the total recognized HCV Genotypes has increased to 8 and subtypes to 84 (from the previously known 7 Genotypes and 67 sub genotypes). Genotype 1 is the most common (70% of cases) genotype in the United States. Other genotypes have endemicity in certain regions of the world - for example, genotype 3 in India and Pakistan and genotype 4 in Egypt and the Middle East. We will be focusing our discussion on the more commonly found Genotypes 1 to 6.

Additionally, it is of paramount importance that prior to initiation of treatment, each patient should be evaluated for staging of liver fibrosis. The gold standard for this diagnosis is liver biopsy, but non-invasive means of testing include elastography, serum biomarkers of fibrosis including APRI and FIB-4 scores, and CT/MRI/Ultrasound imaging which can show cirrhotic morphology and evidence of portal hypertension. Other evaluations should also be addressed, including the assessment of liver function tests, presence of HIV co-infection and the determination of the need for hepatitis A and hepatitis B vaccination (vaccinate if no serology is positive for active infection; treat if HBV is positive and meets AASLD criteria for treatment).

HCV treatment has changed substantially since the introduction of highly effective direct-acting antiviral (DAA) drugs in 2011 and replacement of Interferon-based therapy by DAA regimens in 2014. Currently

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available first line therapies can achieve SVR in around >95% of HCV infected persons and patients can be cured of HCV infection, regardless of HCV genotype, with 8-12 weeks of oral therapy (except in specific decompensated cirrhosis patient population where 24 week therapy is warranted).

Common first-line direct-acting antiviral (DAA) treatment regimens in patients without cirrhosis and those with compensated cirrhosis:

- **Elbasvir-Grazoprevir (Zepatier®)** is a single tablet once-daily combination pill that provides a safe and effective option for the treatment-naïve and treatment-experienced patients with genotype 1 or 4 infection. The course of therapy is 12 weeks. Elbasvir is an inhibitor of nonstructural protein 5A (NS5A) and Grazoprevir is a protease-inhibitor that reversibly binds to the HCV NS3/4A protease. Patients with genotype 1a will need resistance testing prior to initiation of therapy because those with resistance-associated substitutions (RASs) at amino acid positions 28, 30, 31, or 93 will require the addition of ribavirin and extension of therapy from 12 to 16 weeks. Due to presence of protease inhibitor, it should not be used in decompensated cirrhosis. This regimen is a particularly attractive option for patients with HCV and severe renal impairment (stage IV and V CKD). The most common side effects include fatigue, headache and nausea. We should be aware of drug interactions with glucocorticoids, PDE-inhibitors, statins and rifampin.

- **Glecaprevir-Pibrentasvir (Mavyre®)** is a three-tablet once-daily with food combination pill that provides treatment for HCV genotypes 1 through 6 with a potential 8-week course of treatment for non-cirrhotic patients with renal disease or HIV coinfection and a 12-week course in compensated cirrhosis. Glecaprevir is a NS3/4A protease inhibitor and Pibrentasvir is a next-generation NS5A inhibitor with pan-genotypic activity due to potent antiviral activity against common HCV NS5A single-position variants that confer resistance to first-generation NS5A inhibitors. This regimen is not an option for patients with decompensated cirrhosis, given the presence of the protease inhibitor. Of note, this drug is the least expensive of all the direct acting antivirals. No resistance testing is required. The most common side effects include fatigue and headache. Drug interactions with statins and rifampin should be noted.

- **Ledipasvir-Sofosbuvir (Harvoni®)** is a single tablet once-daily combination pill which is an effective treatment for genotypes 1, 4, 5 and 6. Ledipasvir is a potent inhibitor of HCV NS5A and Sofosbuvir is a nucleotide analog inhibitor of HCV NS5B polymerase. Duration of therapy is usually 12 weeks. Patients who are treatment-naïve, non-black, HIV uninfected, HCV RNA <6 million IU/ml and without cirrhosis may be eligible for an 8-week duration. This medication has been found to be safe to use in patients with decompensated cirrhosis (as no protease inhibitor is being used) but not recommended for Stage IV/V CKD. No resistance testing is required. The most common side effects are headache and fatigue. Drug interactions may occur with acid-reducing agents, statins and rifampin.

- **Sofosbuvir-Velpatasvir (Epclusa®)** is a single tablet once-daily combination pill that is effective for treating HCV genotypes 1 through 6. See above for Sofosbuvir mechanism of action. Velpatasvir is a novel NS5A inhibitor that has potent anti-HCV activity across all genotypes. The course of therapy is 12 weeks. This medication has been found to be safe to use in patients with decompensated cirrhosis but is not safe for use in those with CKD stages IV and V. Resistance testing is required for those with genotype 3 (to look for Y93H substitutions). The most common side effects are headache and fatigue. The use of this drug is not recommended with acid-reducing agents and rifampin.

Other Populations:

Of note, there is potential for lower efficacy of some regimens with shorter duration (8 wks.) in blacks and Hispanics. In those with HIV/HCV co-infection, avoid drug interaction between DAAs and anti-retroviral therapy while formulating therapy in conjunction with an HIV practitioner. These patients with co-infection have greater chances of liver-related morbidity and mortality compared to HCV mono-infected individuals. For those who are post-liver transplant, the most efficacious combinations include Ledipasvir/Sofosbuvir + ribavirin, Daclatasvir + Sofosbuvir + ribavirin, Glecaprevir-Pibrentasvir (off-label, no ribavirin) and Sofosbuvir-Velpatasvir (off-label, no ribavirin). For those with CKD stage IV and V, recommendations for initial therapy include

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TREATMENT OF HEPATITIS C

Glecaprevir-Pibrentasvir for 8 weeks if no cirrhosis, and for 12 weeks if compensated cirrhosis for genotypes 1-6, and Elbasvir-Grazoprevir for 12 weeks if genotype 1 or 4.

Monitoring:

- During treatment: clinic visits to monitor for treatment adherence, side effects, possible drug interactions and labs (BMP, hepatic function panel and HCV RNA after 4 weeks of treatment)

- Post-treatment: HCV RNA after 12 weeks of therapy completion (HCV antibody tests will remain positive for most)

  If patient achieves SVR, no further follow up of HCV RNA level is indicated unless patient has ongoing risk factors or ALT significantly increases as re-infection is still possible.

  If patient does not achieve SVR, consider alternative treatment regimen (refer to AASLD/IDSA HCV Guidance for management of treatment-experienced patients)

- Surveillance for hepatocellular carcinoma (HCC) post SVR: In patients with F0-F2 fibrosis, no surveillance is required. In those with F3-F4 fibrosis, Ultrasound of the liver every 6 months should be continued.

Conclusion:

The majority of chronic HCV infections are now curable with the advent of DAA-based therapy. The efficacy and safety of these regimens has been demonstrated in various HCV Genotypes as well as in special populations who were previously considered to be difficult to treat. This finding underscores the importance of rigorous HCV screening in susceptible individuals and early diagnosis and treatment of chronic HCV infection. This strategy would translate into decreasing overall morbidity and mortality associated with chronic liver disease secondary to HCV.

For more information about new therapies and HCV regimens, please see http://www.hcvguidelines.org

Updates in Colorectal Cancer Screening

Payan Chini, MD
Digestive Disease Associates, A Division of SIMEDHelth

Background

Over 140,000 Americans are expected to be diagnosed with colorectal cancer (CRC) in 2018. It is the 2nd leading cause of cancer death in the United States. Approximately 1 in 3 adults who develop CRC die of this disease. Both the incidence and mortality from CRC in the United States has been declining, with death rates declining by 2.7% each year between 2004 and 2013, with CRC screening playing a large role in this decline.

CRC screening is the process of detecting early stage CRC and pre-cancerous lesions in asymptomatic individuals with no prior history of CRC or pre-cancerous lesions. Screening differs from surveillance in that surveillance refers to interval colonoscopy for an individual with a prior history of CRC or a pre-cancerous lesion. Screening also differs from diagnostic examinations, as those are performed for investigation of symptoms or positive screening tests other than colonoscopy.

The U.S. Multi-Society Task Force (MSTF), which encompasses the 3 major GI societies (American College of Gastroenterology, American Gastroenterological Association, and American Society for Gastrointestinal Endoscopy) published CRC screening guidelines in 2017. They recommend CRC screening begin at age 50 years old for average risk individuals, which is consistent with the 2016 U.S. Preventive Service Task Force (USPSTF) guidelines. MSTF guidelines do suggest that CRC screening begin earlier, at age 45 in African-Americans due to higher CRC incidence and earlier age of onset seen in this population. Discontinuation of screening should be considered at age 75 if that individual has had negative prior screening (particularly colonoscopy) or <10 years life expectancy. CRC screening has potential benefit for patients up to age 85 if they have not had prior screening, depending on co-morbidities.

MSTF gives the following recommendations to those that would be considered high risk: Individuals with a family history of CRC or documented advanced pre-cancerous lesion (adenoma) in a first-degree relative age <60 years or 2 first-degree relatives with these findings at any age are recommended to undergo screening by colonoscopy every 5 years, beginning 10 years before the age at diagnosis of the youngest affected relative or age 40, whichever is earlier. Persons with a single first-degree relative diagnosed at ≥60 years with CRC or an advanced adenoma can be offered average risk screening options beginning at age 40 years.

The American Cancer Society (ACS) recently updated its guidelines in 2018 and recommend that CRC screening begin at age 45 for all average-risk individuals. Despite the decline in CRC incidence and mortality overall, individuals younger than 50 years old have actually had an increase in incidence and mortality, and this was the basis for these new recommendations to begin screening earlier. The ACS designated this as a 'qualified recommendation' because there is less direct evidence related to CRC screening in individuals age 45-49 since most studies have historically included patients over age 50. They made these recommendations based on microsimulation modeling studies that suggest the benefit in beginning screening earlier.

CRC screening tests

The 2017 MSTF guidelines ranked CRC screening options in a 3-tier system based on performance features, costs, and practical considerations (Table 1). MSTF recommends offering colonoscopy first with fecal immunohistochemical testing (FIT) offered to patients who decline colonoscopy, followed by second-tier tests for patients who decline FIT. Second-tier options include CT colonography, FIT-Fecal DNA (Cologuard®), or flexible sigmoidoscopy. Third-tier tests include capsule colonoscopy. The

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COLORECTAL CANCER SCREENING

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focus of the remainder of the discussion will be on first and second-tier CRC screening options, since capsule colonoscopy does not have FDA approval at this time for CRC screening of average-risk individuals.

Colonoscopy is considered the gold standard in CRC screening because of its ability to view the entire colon and both detect and remove pre-cancerous lesions during the same procedure. It is recommended once every 10 years for average-risk individuals. It is the only suitable test for high-risk patients. There are multiple observational studies that demonstrate the effectiveness of colonoscopy in reducing CRC incidence and mortality. Patients who value the highest level of sensitivity in detection of pre-cancerous lesions and are willing to undergo invasive screening should consider undergoing colonoscopy. Disadvantages of colonoscopy include the need for thorough bowel cleansing, and risks of perforation, post-procedure bleeding and aspiration pneumonitis. A meta-analysis of population-based studies found risks of perforation and bleeding of 0.5 per 1000 and 2.6 per 1000, respectively.

FIT is the other first-tier option available for patients who decline colonoscopy. Advantages include its non-invasive nature, improved sensitivity when compared to the old guaiac-based stool tests, and relatively low cost compared to the other options (approximately 20 dollars). Disadvantages of FIT include the need for frequent testing, which often leads to non-adherence to the suggested annual screening protocol. Another disadvantages is the relatively low sensitivity in detecting pre-cancerous lesions when compared to colonoscopy.

FIT-Fecal DNA (Cologuard®) was FDA-approved in 2014 as a CRC screening option and is currently considered a second-tier option in the MSTF guidelines. It combines FIT with markers for altered DNA that tumors and pre-cancerous lesions may shed in stool. It is recommended every 3 years if the test is negative. Colonoscopy is recommended for further evaluation of a positive test result. In a randomized controlled trial comparing FIT-Fecal DNA to FIT published in NEJM in 2014, FIT-Fecal DNA demonstrated improved sensitivity (92.3%) when compared to FIT (73.8%) in detecting CRC. In the same study, it also had decreased specificity (86.6%) compared to FIT (96.4%), leading to increased false-positive test results. Both FIT-Fecal DNA and FIT had low sensitivity in picking up advanced pre-cancerous lesions (42.4 and 23.8%, respectively). The other main disadvantage of FIT-Fecal DNA when compared to FIT is its high cost ($500-$600).

CT colonography is a second-tier option for CRC screening. It has largely replaced double-contrast barium enema as the test of choice for colorectal imaging, as it is more effective than barium enema and better tolerated. Advantages of CT colonography include a lower risk of complications

Multi-Society Task Force Ranking of Current Colorectal Cancer Screening Tests

Tier 1	Tier 2	Tier 3
Colonoscopy every 10 years	CT Colonography every 5 years	Capsule colonoscopy every 5 years
Annual fecal immuno-chemical test	FIT-fecal DNA every 3 years	
	Flexible sigmoidoscopy every 10 years (or every 5 years)	

Table 1

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compared with colonoscopy and comparable sensitivity for CRC screening and pre-cancerous lesions > 1cm in size. Disadvantages of CT colonography include the use of bowel cleansing required and the purely diagnostic nature of this test. Therefore, patients may potentially need to undergo bowel cleansing on 2 separate occasions in a short time interval if they are to need a follow-up colonoscopy for a positive test result. Other disadvantages of CT colonography are the reduced sensitivity for polyps < 1cm in size compared to colonoscopy, radiation exposure, and detection of incidental extracolonic findings which may precipitate unnecessary additional work-up. Medicare and most insurance carriers do not cover the cost of CT colonography as a screening test, making it a less practical CRC screening option at the current time.

Flexible sigmoidoscopy is the final second-tier option available for CRC screening. Randomized controlled trials involving flexible sigmoidoscopy demonstrate reductions in CRC incidence and mortality, and this data has been extrapolated to colonoscopy being of the same benefit. Disadvantages of flexible sigmoidoscopy include a lower benefit in detection of right-sided colon cancer. Also, the absence of sedation leads to low satisfaction experience for patients, such that they are less willing to repeat the examination compared with colonoscopy. Further, the concept of examining only part of the colon has been unpopular in the United States, so that screening by flexible sigmoidoscopy has almost disappeared.

Summary

CRC screening has contributed to the decline in CRC incidence and mortality. Historically, the standard recommendation to begin screening has been at age 50, and MSTF and USPSTF guidelines continue to make this recommendation for average-risk individuals. MSTF guidelines do suggest screening begin earlier, at age 45, in African-Americans. ACS guidelines recently took this a step further to recommend screening at age 45 for all average-risk individuals. Despite these new age recommendations, most insurance carriers currently provide CRC screening benefits beginning at age 50. Therefore, clinicians and patients should be aware that CRC screening prior to age 50 may be subject to insurance copays and deductibles.

From a practical standpoint, the 3 main options to choose from for average risk CRC screening are colonoscopy, FIT, and FIT-Fecal DNA (Cologuard®). Colonoscopy is the gold standard in CRC screening due to its high level of sensitivity in detecting CRC and pre-cancerous lesions. In addition, it is a preventive test as pre-cancerous lesions can be removed at time of colonoscopy. Stool-based testing with FIT or FIT-Fecal DNA is a reasonable alternative for those reluctant or unwilling to undergo invasive evaluation. Any positive result from stool testing should be followed up with colonoscopy. It is important for the clinician and patient to understand that insurance carriers often will not cover more than one screening benefit in a year. Therefore, an initial screening colonoscopy is covered under screening benefits, but colonoscopy performed for evaluation of positive stool test results will no longer be considered screening and may be subject to insurance copays and deductibles. CRC screening rates in the United States are approximately 60% for eligible adults, so there is certainly room for improvement. Regardless of which CRC screening option is chosen, it is important that clinicians discuss the various options with their patients to hopefully continue the downward trend in the incidence and mortality from this disease.

Spanish-speaking Primary Care Providers Needed!

Two of our local safety net clinics need help from Spanish-speaking primary care providers for their monthly Monday night Spanish Clinics. We'll take help whenever you can come!

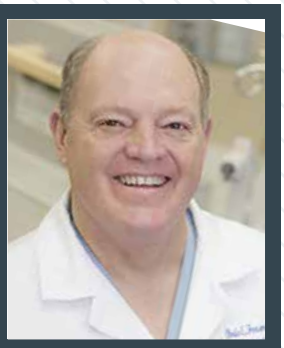
ACORN Medical Clinic has held their FREE monthly Spanish Clinic for over 11 years. Dr. John Shahan is the main provider for this clinic. He recognizes how a language barrier and residency status may prevent some community members from receiving medical care and wants to help patients overcome these challenges. He believes these patients are permanent members of our community and need our medical support and attention. The Spanish speaking patients are referred by Pastor Jonathan Colon. ACORN Clinic provides the space/supplies (in rural northern Alachua County), a nurse, and recruits volunteer translators and medical assistants.

Contact Candice King for more info:
352-485-1133, ext 20.
cking@acornclinic.org

ACORN CLINIC

UPDATE ON ENDOSCOPY

Christopher E. Forsmark, MD
Professor of Medicine and Chief,
Division of Gastroenterology, Hepatology and Nutrition
University of Florida



What is new in endoscopy? Just about everything. When I finished training I was using fiberoptic scopes with limited flexibility, poor visualization, and very few therapeutic options. Now, a whole new world of diagnostic and therapeutic options have been developed. I would like to describe a few of these advancements.

For most patients and most clinicians, screening colonoscopy is the most familiar endoscopic procedure. Most colon cancers can be prevented by removing their precursor, the adenomatous polyp. Colonoscopy, along with other screening efforts, has been effective in significantly lowering the mortality from colorectal cancer in the US. Many options also exist for patients unwilling or unable to undergo colonoscopy, and any screening is better than none. Limitations in colonoscopy effectiveness include the fact that only about two-thirds of eligible adults above the age of 50 are currently screened, the cost and complications of the procedure, the unpleasantness of the prep, and the fact that colonoscopy does not prevent all colon cancer. Recent evidence points to an increase in colon and rectal cancers in patients younger than 50 years, a group that does not undergo routine screening. Colon cancers which occur despite adherence to screening are called interval cancers or post-colonoscopy cancers, and are mainly due to poor prep, inadequate technique, or difficult to visualize polyps (usually flat polyps in the right colon) [1]. The difficulty in visualizing and removing premalignant polyps has become a very important quality concern for endoscopists. Several strategies have been developed to increase polyp detection rates. These include the use of a split prep (drinking half the prep around 12 hours prior, and half the prep a few hours before), which has been proven to improve overall prep quality and adenoma detection rate. Additional efforts include quality metrics for endoscopists (withdrawal or observation time and polyp or adenoma detection rate, which are routinely tracked).

One reason for the incomplete prevention of colon cancer using current colonoscopy techniques is missing subtle polyps during colonoscopy. These polyps tend to be flat, with subtle variations in mucosal pattern compared to normal mucosa, and occur in the right colon where the prep is usually worst. With the development and evolution of video chip scopes, the image quality of endoscopy has dramatically improved. Current scopes, using high-definition white light images, magnified images, chromoendoscopy (using a dye spray during colonoscopy) and images using only a portion of the visual spectrum (narrow band imaging) now allow a detailed examination of the mucosa of the GI tract. This improved imaging allows us not only to find subtle polyps, but also to differentiate premalignant polyps from those likely to harbor a focus of malignancy. Some new scope designs utilize multiple cameras, providing an ability to look behind folds and turns. Self-propelling endoscopes with 360 view are being developed.

A careful examination of the size, shape, and mucosal pattern of individual polyps allows an accurate prediction of the potential of the polyp to harbor carcinoma. This information is used to guide the choice of therapy; e.g. a choice between referral to a surgeon or an attempt at endoscopic removal. Similar technology is used for upper endoscopy. A common example would be for Barrett's esophagus, where this detailed examination could help identify targeted biopsies for small areas of carcinoma within a long segment of metaplastic epithelium. (It makes me horrified to think about how much we might have missed with older technology). In addition to the dramatic improvement in image detail in standard endoscopy, a number of new options allow examination of mucosa during endoscopy to the same level as a pathologist. Optical coherence tomography (OCT) allows examination of the GI mucosa down to a resolution of 10-20 microns, nearly

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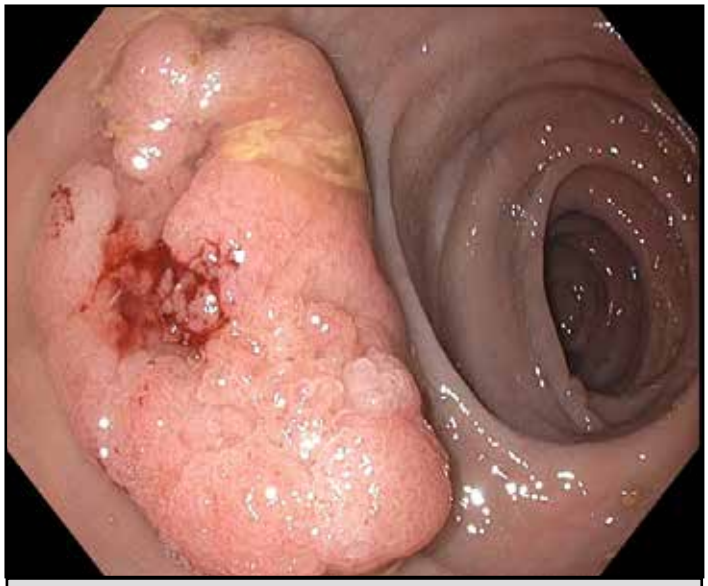

Figure 1a. A large colon polyp is seen, with some features suggesting it may harbor high-grade dysplasia or early cancer. Figures courtesy of P. Dragonov, MD and D. Yang, MD.

equivalent to histology. This device was initially a small probe, which was difficult to use to examine large areas of mucosa. A new device provides a much wider field of view, using second generation OCT technology termed volumetric laser endomicroscopy (VLE). This device is used primarily in the esophagus, but has applications in other endoscopic procedures. As an example, this allows an endoscopist to identify and target a small area of high grade dysplasia, or intra-mucosal cancer, in a patient with extensive Barrett's esophagus, "finding the needle in the haystack, so to speak". The probe identifies suspicious areas, and a laser marking system produces superficial cautery marks at those sites for subsequent targeted biopsies.

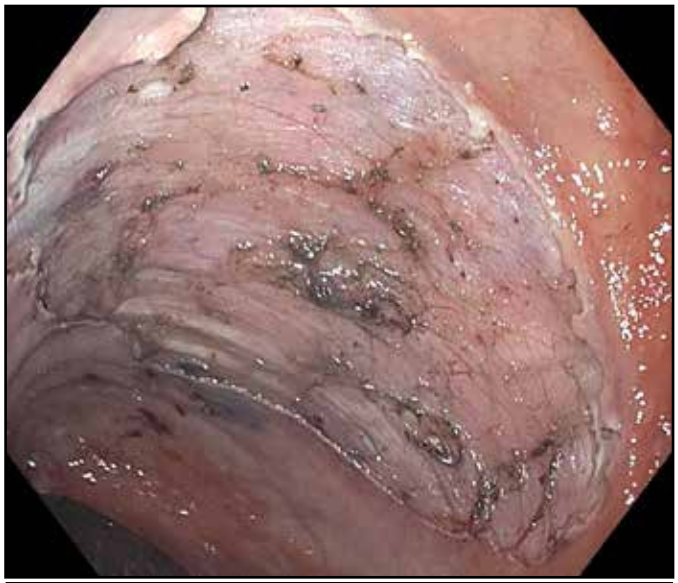

Figure 1b. The lesion is removed en bloc using ESD

Better imaging is huge, but is just one advance in endoscopic practice. A number of new therapeutic options also now exist. Most clinicians are aware of endoscopic retrograde cholangiopancreatography (ERCP), used for pancreatic and biliary diseases. Not everyone may be familiar with endoscopic ultrasonography (EUS). This device, a high-resolution ultrasound probe on an endoscope, allows detailed examination of the wall layers of the GI tract, as well as organs outside the lumen (e.g. pancreas, gallbladder, bile duct, liver, anal sphincters, and others). EUS is commonly utilized for diagnosis and staging of esophageal, gastric, pancreatic, and rectal cancers. EUS is routinely used for assessment of lesions in the GI tract which sit below the mucosa (e.g. gastrointestinal stomal tumors). EUS not only allows identification and staging of these conditions, but also targeted biopsy under ultrasound guidance. Finally, EUS has evolved to a therapeutic platform, allowing access to the gallbladder, bile duct, liver, and pancreas, through needles and devices passed through the wall of the gut and into the organ being targeted. For example, areas of walled-off pancreatic necrosis and pancreatic pseudocysts are now most commonly treated with EUS-guided transmural evacuation and drainage utilizing ultrasound-guided needle and wire access, followed by stent placement across the wall of the stomach. In the case of walled-off necrosis, the stent also allows passage of an endoscope into the area of necrosis, allowing endoscopic debridement of necrotic tissues.

A very wide variety of new therapies complement the diagnostic value of endoscopy. Many examples exist. Bleeding ulcers can be treated with injection, clips of various sorts, and hemostatic sprays. Bleeding varices can be treated with banding, or with injection of glue into the varix. A variety of stents to relieve obstruction are available for the esophagus, colon, duodenum, and bile duct. Several new devices exist to close fistulas or perforations in the GI tract. An endoscopic device can now provide full thickness suturing in the GI tract. These devices have ushered

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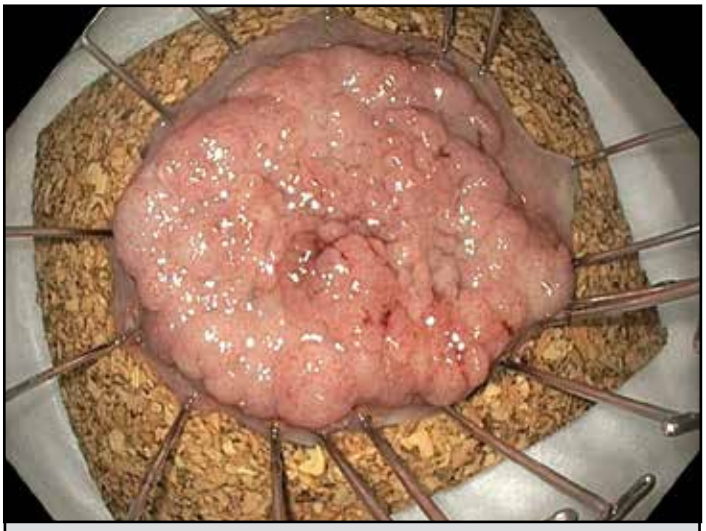

Figure 1c. The specimen after removal.

in a new era of interventional endoscopy. As surgeons strive to become less and less invasive, endoscopists are now becoming more and more invasive and therapeutic.

At the cutting edge of endoscopy now are therapeutic interventions that often take the place of surgery. Many of these approaches are collectively termed third-space endoscopy [(2)]. First-space is the lumen of the organ, second-space is the peritoneal cavity, and third-space is the intramural or submucosal space, within the wall of the gut. Access to this space allows resection of large areas of mucosa and submucosa (for malignant and pre-malignant conditions), removal of lesions within the muscular wall of the gut (e.g. a leiomyoma, or a gastrointestinal stromal tumor), or myotomy of the muscle layer. One example is endoscopic submucosal dissection (ESD), in which large mucosal lesions can be removed en bloc from the GI tract, using surgical dissection through the submucosa (Figure 1a-c). ESD is being utilized to manage large colon polyps, large areas of dysplastic Barrett's esophagus, and even early stage esophageal and gastric cancers. Another example is peroral endoscopic myotomy (POEM), which involves creation of a submucosal tunnel in the esophagus allowing access to the muscle of the lower esophageal sphincter, which can then be cut to treat achalasia (Figure 2). These techniques are now possible, with multiple devices available to carefully dissect lesions and to close the tunnel at the completion of the procedure. There is even a technique now to remove tumors within the muscular wall of the gut called submucosal tunneling and resection (STER). Other interventions rely on the new closure and suturing devices that make third space endoscopy possible. An example would be endoscopic gastric plication (similar to gastric sleeve operations for obesity). These are just some examples of a wide range of evolving interventional therapeutic procedures.

In the future, gastroenterologists and endoscopists are likely to be doing far less screening colonoscopy, as alternative testing identifies those individuals unlikely to harbor a polyp or cancer, and only those with a higher likelihood of colonic polyps would be referred for colonoscopy. As a training program, we need to prepare our trainees to deliver care to complex GI and liver diseases (e.g. inflammatory bowel diseases, motility disorders, functional disorders, fatty liver disease, pancreatitis, GI cancers) and to provide the most up-to-date diagnostic and therapeutic endoscopic interventions. Interventional endoscopy is one part of that training, but the most advanced procedures will require a very high level of technical skill. To accommodate that, most GI training programs, including UF, now offer a year (or more) of additional training after fellowship to learn these technically demanding interventions. Perhaps in the future, combined training programs of minimally invasive surgery and maximally invasive endoscopy will develop.

References available upon request

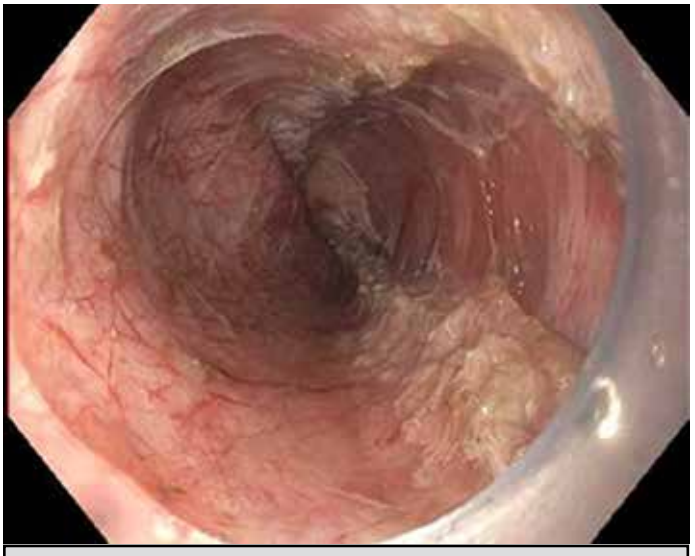

Figure 2. A scope is in the submucosal space of the esophagus, between the mucosa and the muscle. The muscle of the lower esophageal sphincter (on the right) has been cut, for the treatment of achalasia.

Opioid Prescribing - The Swinging Pendulum

Jesse Lipnick, MD
SIMEDHealth Rehabilitation Medicine

[Editor's note: House Calls has recently published several articles about the opioid crisis and the new opioid prescribing laws. This subject is of such great importance and the new laws are so far-reaching, that we felt even more review and clarification by Dr. Jesse Lipnick, an eminent pain management specialist, was in order.]

The CDC has flooded our media with estimates of death rates from opioid overdose in the USA. These rates have skyrocketed from approximately 3 to 14 overdoses per 100,000 population in the past two decades, or roughly an increase by a factor of 6. While death from prescription opioids has declined since 2011, death from illicit synthetic opioids: Fentanyl from China and Heroin from Mexico, has skyrocketed. As prescription drugs have become more difficult for users to obtain, cheaper and more powerful alternatives have become readily available. Death from prescriptions is declining, but new laws focus on this source of drugs because of the popular perception that prescription drugs represent a common beginning for the victim who eventually dies from an illicit drug.

Florida Statutes 458 and 459 were signed into law in 2009. These laws establish the Prescription Drug Monitoring Program (PDMP) (or E-Forcse), a statewide database of controlled substance dispensing by pharmacies. Until now, the pharmacist dispensing medication entered this information into the database. The information includes the drug dispensed, the amount of medicine and the writing physician. The pharmacist had to enter the prescription into the database within two weeks of dispensing and any physician writing a new prescription for a controlled substance did not need to look at the data before writing it. According to this law, a pain clinic can be owned privately or publicly, and a medical practice qualifies as a pain clinic if it advertises in any medium for the treatment of pain; if the majority of its patients suffer from chronic non-malignant pain; or if in any month, the majority of its patients receive prescriptions for opioids, benzodiazepines, barbiturates or Carisoprodol.

Florida Statute 456 was enacted in 2011 and it governs physician care of chronic non-malignant pain, which it defines as pain lasting more than 90 days. This law required all prescribers of controlled substances in Florida to register with DOH by January 2012. It also lists the requirements for physicians writing prescriptions for treating chronic non-malignant pain: We must document a history and physical exam in the chart before we provide any treatment. We must document the indication for prescribing a controlled substance. We must assess the patient for risk of "aberrant drug related behavior" and we must record a written treatment plan containing a diagnostic evaluation, level of pain and functional goals for the patient. We must include informed consent and an opioid agreement in the chart. For a patient receiving DEA schedule II prescriptions, regular patient visits may not exceed a 3 month interval. We must refer these patients to an addiction specialist or to a psychiatrist if we feel that the patient has high-risk for abuse or misuse of pain medicine, and the prescription format, including the pad and the writing of the prescription, must adhere to DOH guidelines. The pad itself must be electronic - or counterfeit-proof and we must write out the date and quantity of medication in numeric and script format. If we refer a patient to an addiction specialist or a psychiatrist, we must acknowledge the specialist's recommendations in the chart. The law obligates the treating physician

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OPIOID PRESCRIBING

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to incorporate the consultant's recommendation for continuing, modifying or discontinuing controlled substance therapy. This short review covers treatment of chronic non-malignant pain before Governor Scott signed House Bill 21 into law, taking effect in July 2018.

To summarize the newest requirements, F.S. 456.0301 (previously "House Bill 21") requires each physician prescribing a controlled substance to check the PDMP first. The law limits the amount of medication that a physician may prescribe for treating acute pain. It mandates physician education in opioid pharmacology and it requires the treating doctor to prescribe an emergency opioid antagonist for trauma victims with an Injury Severity Score greater than 8. The DOH must now grant certificates of exemption to exempt pain clinics and finally, the law mandates the Board Of Medicine to establish standards of practice for treating acute pain.

Every physician prescribing a controlled substance in Florida (DEA schedule 2 – 4) for a patient older than 15 years, must consult the PDMP first. The PDMP, or E-Forcse (Electronic Florida Online Reporting of Controlled Substances Evaluation Program) records the dispensing of all controlled substances, and each physician with a DEA license must register online to use it (https://flmd.us.dig). It is now legal to delegate the query to a registered designee, such as a nurse, office manager or clinic assistant. If the PDMP is not available and the doctor prescribes controlled substances for treating acute pain, the doctor must document the reason for not checking it and the doctor may not prescribe more than a 3 day supply of medication. Failure to check the PDMP before prescribing controlled substances now carries criminal penalties. The first failure merits a non-disciplinary citation from the DOH. The second failure merits the charge of a first degree misdemeanor and the third failure results in direct punishment from the BOM. Specific punishment for failure to check the PDMP has yet to be defined by the Board of Medicine.

Florida law defines acute pain as " The normal, predicted, physiological and time-limited response to an adverse chemical, thermal or mechanical stimulus associated with surgery, trauma or acute illness." The law limits prescribing to a 3 day supply of medication, unless the prescribing doctor believes that the condition merits additional pain medication, in which case the doctor may prescribe up to 7 days of medication. In this case, the doctor must record " Medically necessary – acute pain exemption" on the prescription. In addition, the chart must reflect the reason for a greater number of pills and the lack of an alternative treatment that justifies a 7 day prescription. The idea here is that over-prescription of medications for treating acute pain results in a surplus of pills in the community and serves as a source for misuse or diversion.

Exemptions to the 3/7 day limit include the treatment of cancer or another terminal condition. The law defines Terminal Condition as a progressive disease with significant functional impairment, that is not reversible without life-sustaining procedures, and the patient has less than a year of expected life. The next exemption to the 3/7 day limit comprises the treatment of acute pain with an Injury Severity Score of 9 or greater.

For those of us who do not treat acute injury victims, the Injury Severity Scale is an internationally recognized scoring system which assesses injury severity for multi-trauma victims. Its results correlate with mortality and morbidity and with other measures of injury severity. To calculate the ISS score, the doctor assigns an injury score to each of 6 body areas. Scores range from 1 to 6 and get higher with increasing injury severity. The doctor then squares the 3 largest scores and adds them together to determine the ISS score. The sum ranges from 1 to 75 and if any region has a score of 6 (currently untreatable) then the composite score automatically reaches the maximum value of 75. If the doctor prescribes a " schedule II controlled substance" for acute pain and the ISS is greater than 8, the doctor must also prescribe an " emergency opioid antagonist." The law does not specify which antagonist the doctor must prescribe, but the only one which can be administered parenterally is Naloxone, as it can be administered IM, IV or intranasally. This particular requirement is awaiting BOM interpretation. There is an Autoinjector for Naloxone, which has FDA approval. Dimensions are similar to a credit card and it has the width of a cell phone. It has a retractable needle and it gives audible and visual cues to guide

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the use thru the process of injecting the Naloxone. It is important to train anyone who might be around the patient – that is – the mother or father or care-giver or first responder – as the patient himself will not be able to administer the Naloxone if he needs it to prevent overdose.

If the doctor writing the prescription is treating subacute or chronic pain, and not treating acute pain, she should write " Non-acute pain" on the prescription, and the dosing limitations of HB 21 no longer apply. Florida law currently defines acute pain as 7 days or less and chronic pain as 90 days or more, but there is no provision for pain that lasts from 7 to 90 days, or what we usually identify as subacute pain. I attended the Florida Board of Medicine meeting, June 21, 2018, and asked the board for definition of this point, and the board responded that if there is a reasonable expectation for the pain to last longer than 7 days, the physician may write " Non-acute pain" on the prescription so that the 3/7 day limits will not apply to that medication.

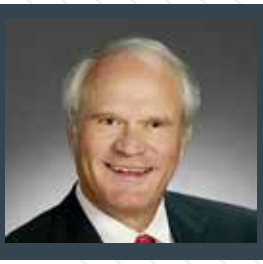
HB 21 requires each of us to complete 2 hours of opioid education before January 31, 2019. This requirement applies to all physicians with a DEA license. It does not apply to nurse practitioners or physician assistants, as they both already have a 3 hour requirement for opioid education. The BOM must approve the course and there are a number currently available. The course must be offered by a statewide association of physicians and the organization must be a CME provider. This education will be offered by the ACMS at a dinner meeting and it is available on-line at FMA.org and at CEBroker.com. Each of us must take these two hours of required opioid education every two years with each cycle of license renewal.

In the past, we physicians decided if we were exempt from the requirement to register with the DOH. Florida Statute 458.3265 specified that doctors were exempt if they came from the following backgrounds: Board eligible/certified as a pain management specialist, anesthesiologist, physical medicine and rehabilitation, rheumatologist, neurologist; affiliated with a board certified medical school, or a clinic exempt from federal taxation under 26 USC s 501 c (3), a surgery specialty practice, or a clinic held by a corporation with total assets exceeding $ 50 million. Currently, we must apply for a certificate of exemption from the Agency for Health Care Administration. The DOH will respond to applications for exemptions within 30 days of receiving the application and the FMA will notify physicians when the application form is available. This requirement goes into effect January 1, 2019.

The final requirement of HB 21 is that the BOM will establish guidelines for prescribing controlled substances for the treatment of acute pain. Presently, one doctor might prescribe 3 pain pills for treating post-surgical pain, and a second doctor might prescribe twice the medication, or maybe half the medication to the same patient. There is no standard for prescribing for acute pain, and so, none of these physicians is right or wrong in prescribing, even though the prescriptions differ greatly. The goal of the current legislation is to create standards for prescribing for the treatment of acute pain, including post-surgical pain. The BOM will take different practice settings into account as it establishes standards of practice and failure to follow these rules will be grounds for disciplinary action.

In conclusion, the pendulum is swinging back. We are no longer under scrutiny for the under-treatment of pain. Now, we are targets for over-treating pain with opioid medications and for opioid overdose. No one knows where the pendulum will stop and where will be our appropriate standard for compassionate and safe treatment of patients in pain. Vigilante pharmacies and insurance carriers apply their own standards for treating pain and for dispensing medications as the DEA has targeted them for inappropriate dispensing. In addition, we physicians are now acting as investigators and as enforcers of the law, as we asses a patient's risk of abuse and treat patients as though they might be misleading us to obtain a controlled substance. I hope we do not forget our role as healers and scientists as we take on the responsibility of an investigator for abuse of medications. May we continue to provide care to the sick and not forget that we came to our profession to learn the wonders of medicine and to alleviate suffering in our patients.

Fun in the Gut



By Scott Medley, MD

*[**Editor's Note**: We are reprinting this piece from the Summer 2014 issue of House Calls for this Gastroenterology Issue. When I originally wrote this article , little did I know that Fecal Microbiota Transplantation would become the treatment of choice for resistant recurrent "C. Diff" and that my close relative would remarkably benefit from this treatment!]*

I thought that this excellent "Infectious Diseases" issue of House Calls deserved a little levity. And though I know that intestinal infections are "no laughing matter", a little frivolity might be acceptable to our wonderful tolerant readers. So here goes:

If three organisms and their toxins were living happily in one's intestinal tract, their conversations might go something like this:

Camilia ("Camy ") campylobacter jejuni: "My, my, it sure is dark and damp inside this intestinal tract!"

"Chloe" Clostridium difficile: "Yeah, but I kind of like it here—I can wreak havoc with my cytotoxins on this guy's GI tract"

"Georgie" Giardia Lamblia: "Actually, I kind of like it in here, too. Except for causing this guy fever, I can do almost as much damage as you ladies can."

Chloe – "Well, we all know how we got here. This dummy went to a foreign country and drank contaminated water, consuming large quantities of good ole' Georgie Giardia here. Then, when he developed serious diarrhea, he took some old outdated antibiotics he found in his medicine cabinet, allowing yours truly, Chloe c. diff to proliferate"

Camy: "Surely this is fun, causing all this cramping and diarrhea and all, but I must say that I'm feeling a bit sad".

Georgie: "Why is that Camy? You look lovely all covered in mucus and stuff."

Camy: "Yes, but unlike both of you, they describe me as 'self-limited'. Now that really hurts".

Chloe: "Don't be silly, Camy, ' self-limited' is not a commentary on your initiative or ambition, it just means you may not persist as long as we do".

Georgie: "Yeah, and besides, at least you're a real bacteria, I'm just a protozoan, and even worse, I'm really just a cyst-a trophozoite."

Chloe: "There you go again, using those big words. What if I said your efforts were supererogations?"

Camy: "Yeah, and what if I said my existence in this intestine is phantasmagorical, or that your attitude was supercilious?"

Georgie: "Supercilious? Does that have anything to do with the cilia I saw in this guy's trachea on my way toward his esophagus?"

Camy: "No, dummy, and if you want a really big word, how about 'SUPERCALAFRAGILISTICEXPIALIDOCIOUS' --- I learned that one when our 'host' was stuffing his gullet with popcorn while watching a rerun of 'Mary Poppins' ".

Chloe: "But what I like most of all is when this guy tries to get rid of us using 'coffee enemas'-I think the hazelnut vanilla is my favorite".

Georgie: "Only one big problem you lovely ladies need to worry about. Since the Vancomycin didn't get rid of chloe, and our dumb host never thought of trying metronidazole for me, guess what's coming 'down the pike', I mean through the rectum, next?"

Camy and Chloe together: "Oh, Georgie, you know that we are both big fans of yours, and surely you're not referring to a stool transplant, better known as a 'fecal microbiota transplantation' where they infuse some fresh donor stool into our nice comfy colon home via an enema?"

Georgie: "That's right ladies, and even more scary is the fact that our host searched the Internet and found a DIY (DO IT YOURSELF) article on 'How to safely do a fecal transplant at home'. [no kidding! ESM] But, either way, get ready for the SH+T to hit the fans!"

And, fortunately for their "host", thanks to "fecal bacteriotherapy" (44 refences in Wikipedia), [again no kidding! ESM] these 3 troublesome friends did not "live happily ever after". THE END

Contribute to the Robb House Endowment Fund

ROBB HOUSE MEDICAL MUSEUM

This Victorian cottage built in 1878 became the home and medical office of doctors Sarah Lucretia and Robert Robb. Sarah Lucretia was the first woman physician in Alachua County. She practiced medicine from 1884 to 1917.

Dr. Mark Barrow has pledged to match all contributions of $1,000 or higher, up to a total of $10,000 in 2018 towards the Robb House Endowment Fund. Please donate today!

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Dr. Mark and Mary Barrow
Dr. Thomas and Dr. Betsy Beers
Dr. Billy and Glenna Brashear
Dr. Cynthia Bush
Dr. George and Constance Caranasos
Dr. Joseph and Virginia Cauthen
Dr. Jean Cibula
Dr. Forrest and Kathy Clore
Dr. Chris Cogle and Ms. Alisa Guthrie
Colonial Dames XVII Century-
Abraham Venable I Chapter
Dr. Laurie K. Davies
Dr. Lee Dockery
Dr. Carl and Alissa Dragstedt (Grins and Giggles)
Dr. Leonard and Libby Furlow
Dr. Ann Grooms
Dr. Cherylle Hayes and Gary Schneider
Dr. Robert and Shari Hromas
Dr. Evelyn and Dr. Ronald Jones
Dr. Marie A. Kima
Mrs. Barbara Kirby in Memory of Dr. Taylor H. Kirby
Dr. Thomas Lau
Dr. Norman and Roslyn Levy
Dr. Judith Lightsey
Dr. Larissa A. Lim
Dr. Michael and Judith Lukowski
Dr. Terry and Jean Marshall
Dr. Thomas Martinko
Mrs. Shirley and Mr. William Matthews
Dr. Scott and Faye Medley
Dr. Walter and Barbara Probert
Dr. Nicole Provost
Dr. Eric Rosenberg
Dr. Glen Rousseau
Dr. Gerold Schiebler
Dr. Rick and Pat Tarrant
Florence Van Arnam
Dr. Justine Vaughen Fry
Dr. BJ & Eve Wilder

ACMS

HAPPENINGS

L to R: Matthew Ryan, MD, PhD, ACMS Vice President; and Mark Panna, MD.

David Tyson, ACMS UF Student Representative with UF Medical Student Delegation.

FMA 2018 Annual Meeting

At Loews Sapphire Falls Resort

August 3-5, 2018

L to R: Joseph E. Thornton, MD; Carl Dragstedt, DO, ACMS Secretary/ Treasurer; Charles Riggs, MD; and Jackie Jackson, MD.

L to R: Vincent DeGennaro, MD; David Winchester, MD, ACMS Past President; and Douglas Murphy, MD.

Karen Harris, MD representing the American Congress of Obstetricians & Gynecologists

L to R: Madison Zsar; Hasan Jhaveri; Michael Dangl, Victoria Bird, MD; Elizabeth Kwenda; and David Tyson, ACMS UF Student Representative.

Cherylle Hayes, MD and Mr. Jay Hutto, CPA, James Moore CPAs.

L to R: Julie Kniseley, with James Moore, CPAs; Denise Green-Hudson, with HSAG; and Norman Levy, MD.

Ms. Ann Rayner and Ms. Noelle Hagan with Florida Skin Cancer & Dermatology Specialists.

L to R: Theresa McFarland with Alan Lessner, MD; Ms. Tonya Pearson with Robert Ashley, MD, PA; and Kristie Waldron with Robert Ashley, MD, PA.

Practice Management Network Luncheon

Napolatanos Restaurant
August 23, 2018

L to R: Jackie Owens, ACMS EVP; Stacey Hayes, Business Developpment Officer, Campus USA; Denise Green-Hudson, Speaker; Magaly Dooley, Campus USA Service Representative; and Mr. Jay Hutto, CPA, James Moore, CPAs.

HAPPENINGS

L to R: Ronald Lee, MD; Arthur Lee, MD and their families enjoying the view from the balcony.

L to R: Madeleine Mills, VP Market Manager, CB&T; John Roberts, VP Commercial Banking, CB&T; and Barbara Noble.

ACMS Tailgate Party

Community Bank & Trust - Roberts Stadium Club

September 8, 2018

Mrs. Ellen Gershow and James Gershow, MD (foreground) with Howard Noble, MD and Barbara Noble (background).

L to R: Hugh Dailey, President, Community Bank & Trust; John Roberts, VP Commercial Banking, Community Bank & Trust; and Mr. Jeff Sims.

Norman Levy, MD and Mrs. Roslyn Levy.

Siddharth Thakur and Jyoti Budania, MD.

Madeleine Mills, VP Market Manager, CB&T; and Carolyn Carter, MD

Quinten Dragstedt and Carl Dragstedt, DO, ACMS Secretary/Treasurer.

L to R: ????; Caroline Rains, MD; and Jeff Sims.

HAPPENINGS

ACMS

L to R: Evelyn Jones, MD; Jeffrey Phillips, MD, Keynote Speaker; and Ronald Jones, MD.

Gleen Rousseau, MD and daughter, Celeste Rousseau.

Arthur Mauceri, MD and Ann Marie Mauceri.

L to R: Matheen Khuddus, MD, ACMS President; Ann Weber, MD, NFRMC Past Chief Medical Officer; and Leonardo Lozada, MD, NFRMC Chief Medical Officer.

ACMS September Dinner Meeting
North Florida Regional Medical Center
September 11, 2018

L to R: Arlene Colon; Barbara Noble; Howard Noble, MD; Gerri Gessner; and Ira Gessner, MD.

Eric Lawson, North Florida Regional Medical Center Chief Executive Officer.

Youssef Wassef, MD; Kathryn Ednie, MD; and Joseph Thorton, MD.

ACMS September Dinner Meeting
North Florida Regional Medical Center
September 11, 2018

Mercedes Pernice, MD, Cherise Bartley and Caroline Rains, MD..

Mrs. Mary Barrow and Mark Barrow, MD

Ann Weber, MD, NFRMC Past Chief Medical Officer and Scott Medley, MD, *House Calls* Executive Editor.

L to R: Norman Levy, MD; Karen Harris, MD; and Andrew Evans, PhD.

ACMS Board Highlights

Alachua County Medical Society - Board of Directors Meeting Minutes, May 1, 2018

Pursuant to notice, the Board of Directors of the Alachua County Medical Society met on Tuesday, May 1, 2018 at The Cardiac and Vascular Institute.

Approval of Minutes: The minutes of the April 2, 2018 meeting were presented. Dr. Riggs moved approval, seconded by Mr. Tyson to approve the minutes. The minutes were approved by the Board.

Secretary's Report: Dr. Dragstedt presented the following names for membership: Thomas A. Burkart, MD and Christopher E. Forsmark, MD. Dr. Jones moved approval of the new members, seconded by Dr. Riggs.

Treasurer's Report: Ms. Owens presented the April 30, 2018 Balance Sheet and P & L statement for the ACMS and the ACMS Foundation. Overall, revenues increased 7.3% over the previous fiscal year with expenses down 13% for the 9 months recorded. ACMS Foundation Revenues were largely derived from We Care Grant Contributions with expenses resulting primarily from Grant Disbursements. Dr. Jones moved approval of the report, seconded by Mr. Tyson.

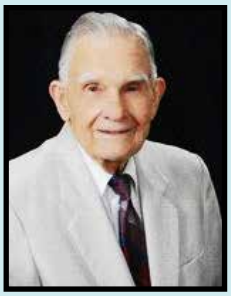
President's Report:
Dr. Khuddus discussed the nominations for the ACMS Board and for FMA Delegates with plans to meet the June 8th deadline for filing with the FMA. Also discussed was the status of the ACMS Resolution regarding a meningococcal vaccine to protect children and adults from the disease. Dr. Khuddus solicited additional judges from the Board for the ACMS Research Poster Symposium to be held on May 15th at NFRMC.

EVP Report: Ms. Owens reported on the status of the Research Poster Symposium and the Sey Park, MD Award of Excellence. The Annual Awards Dinner Meeting will be held on May 22nd at Mark's Prime.

A course on the recently required Opioid Prescribing CME will be offered to members in the Fall of 2018, along with courses on Domestic Violence and Prevention of Medical Errors.

There being no further business, the meeting was adjourned at 6:58p.m.

In Memoriam



It is with much sadness that we report that a beloved member of our medical family passed away….

Charles Pinkoson, MD

(1921 – 2018)

Dr. Pinkoson attended Tulane University's Medical School, earning his medical doctorate. After completing his residency at Tulane and a stint as a flight surgeon in the United States Air Force, Dr. Pinkoson married Rainer Nicholls in 1951, and moved to Gainesville to begin his practice.

He began his career as an ENT and later focused his specialty on eyes as an ophthalmologist. Not only did he excel at his craft; his kind, compassionate, and caring demeanor created a special relationship with his patients. He was a member of the Alachua County Medical Society and the Florida Society of Ophthalmology.

He was devoted to the Alachua General Hospital where he served as Chief of Staff on more than one occasion. Dr. Pinkoson cared deeply for his community and generously contributed to many local charities, the library system, and Rotary, trying to make his community better for everyone. He is survived by his wife Rainer, his children Nona Upshaw, Lee Pinkoson, Beth Pinkoson, six grandchildren and seven great-grandchildren.

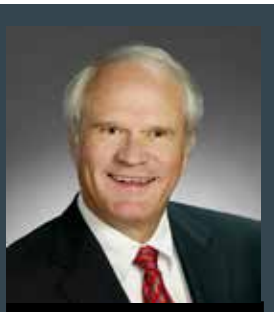
A Note from our **Editor**

MEDICAL MARIJUANA - A PRESCRIBER'S PERSPECTIVE

AN INTERVIEW BY SCOTT MEDLEY, MD, WITH CAROLINE RAINS, MD

SCOTT MEDLEY, MD
House Calls Executive Editor

Dr. Rains



Dr. Medley

I have known Dr. Caroline Rains for 34 years. I knew her first in her capacity as the Medical Director of the Alachua County Health Department, a position she held for a remarkable 24 years, from 1984 to 2008. During my years in Private Practice and as a Hospitalist, I had many occasions to consult with her on all manner of complicated questions regarding immunizations, contagiousness of various diseases, international travel issues for my patients, and a wide variety of other subjects. I always found her accessible, knowledgeable, professional and courteous. I have spoken with numerous physicians colleagues about her, and they share the same extremely positive sentiments. Caroline and I also have a personal connection, as her husband, Doug, was a high school classmate of my sister, Ginger, in my small hometown in Kentucky. Dr. Rains retired for awhile, but recently took on a new role, about which I had the opportunity to speak to with her.

Editor (Dr. Scott Medley): Your background is in traditional Medicine, and in being an exceptional Public Health physician. How did you develop an interest in "prescribing" marijuana products?

Dr. Rains: I think it all started several years ago when I was walking into our local library and was approached by a very nice gentleman who asked if I would sign a petition to get medical marijuana on the ballot. I signed, of course, because I believe in the process. But that got me thinking how I really feel about medical marijuana and Marijuana use in general.

Then, during a visit to friends in Colorado in 2015, my husband, Doug, and I were fascinated by the profusion of green crosses on wellness centers and marijuana shops which were on practically every street corner. One filling station even had a sign that read "Gas and Grass."

In November 2016, I was happy to see Amendment 2, allowing Medical Marijuana in Florida, pass by 70% of the vote.

Following that passage and its implementation in January 2017, I was driving down SW 34th Street and was amazed to see a sign with a green logo on it and the name "Knox Cannabis."

Little did I know that I would be offered employment as a "physician qualified to order medical marijuana" shortly thereafter. The job offer came from Compassionate Care Clinics of America, Gainesville. Apparently, the folks who set up that clinic (which was in the same building as, but not part of Knox) searched a list of retired physicians and came up with my name.

At that time, to qualify physicians were required to complete an 8-hour course entitled "Florida Physicians Low-THC Cannabis Course," which I did. What I learned from that course was fascinating. I had never heard of the endocannabinoid system! That convinced me to accept the position at Compassionate Care which I did in April 2017.

So I went to work in what my brother dubbed the "pot shop" and began the learning curve in a whole new field fraught with regulations, waiting periods for patients before obtaining their product (originally 90 days), and the task of figuring out what dosage and routes of administration to order for patients.

In June 2017, things got better because with the passage of Senate Bill 8-A we were given a longer list of conditions for which we could approve patients and less restrictions on the use of medical cannabis (THC), which was originally only for terminal patients. Prior to that, we could only order low-THC cannabis (CBD) which, as you said in one of your excellent articles on this subject, was known as the "hippie's disappointment." That is not to say that low-THC cannabis is not very beneficial - it is for many patients often in combination with medical cannabis. Low-THC cannabis does not have the psychoactive effects of medical cannabis so it is useful for patients who work and don't wish to be "foggy" during the day, but still need pain relief.

Editor: What are some of the most common problems that you treat?

Dr. Rains: As you know, the approved conditions are: cancer, epilepsy, glaucoma, HIV/AIDS, PTSD, ALS, Crohn's disease, Parkinson's disease, MS, medical conditions "of like kind or class" (other), terminal conditions and chronic non-malignant pain.

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In the course of a year at Compassionate Care Clinic, I saw patients with all of these conditions. Far and away most patients seek pain relief. Many of them want to stop opioids. PTSD is also a very common diagnosis-especially among veterans, but also among other patients who have suffered trauma in their lives. The next two most common diagnoses are cancer and Crohn's disease.

Regardless of the patient's qualifying condition, most suffer from insomnia. Of the feedback I get from patients, I most often hear "I have been able to sleep better than I have for many years."

If I could add approved conditions to the list they would include serious conditions "of like kind or class" as those on the list including osteoarthritis, rheumatoid arthritis, fibromyalgia, and anxiety/depression to name a few. I have seen patients with these conditions find relief of their symptoms with medical marijuana treatment.

Editor: What dosage and forms do you most commonly "prescribe?"

Dr. Rains: That is an interesting question. There is very little in the way of guidelines for dosage. When I first started out, I went to the staff at one of the dispensaries and asked for information on dosage and was told the usual (we've all heard it before) "you're the doctor, what you order is entirely up to you." My first clue was what I heard over and over at a medical marijuana meeting I attended early on: "Start low and go slow". I took this to heart but soon found I was starting too low. My patients let me know that!

Now I usually order 80mg. per day in four divided doses starting lower and working up to that. I start with lower doses in patients who are "marijuana naïve". Establishing the dose that works is trial and error for the patient, which some people find confusing. Unlike a prescription, people do not have to take their medicine exactly as ordered. Some patients require a higher dose and I can edit their order in the Registry when they let me know. The upper limit on dosage is high—up to 500 mg. per day, but I have not gone that high and I doubt that many patients would require such a high dose.

In addition, as you mentioned, there are different approved routes of administration available-except of course for smoking - which is still illegal in Florida. The two most frequently used routes are oral and inhalation. Oral includes sublingual drops, oral sprays and capsules (no "gummies" yet). The inhalation route employs a vaporizer and provides the quickest delivery. Many patients prefer that route.

When I place an order, I usually order four different items: medical cannabis by oral and inhalation and low-THC cannabis by oral and inhalation, each at the dose above. I then counsel the patient to choose the routes and products. Therefore, the patient has four products to choose from but does not purchase them all at once. I caution patients that they do not have to take the entire dose I order - instead they find the dose that works for them.

Needless to say, the first trip to the dispensary may be overwhelming for the patient. In addition to choosing low-THC cannabis or medical cannabis and which route to purchase, the patient is faced with selecting from among different strains which have different properties - e.g. indica-based strains make you sleepy, sativa-based strains help you focus and hybrids have different properties depending on the strain. To confuse the patient even more, street names are often used like "Sour Diesel," "Grand Daddy Purple," "Girl Scout Cookies" and "9 lb. Hammer." Needless to say, the last one helps you sleep!

Fortunately, the staff at the dispensaries - which are now called Medical Marijuana Treatment Centers (MMTCs) - are very helpful in guiding the patient through this process. Patients often ask me for recommendations, but I defer to the MMTCs. Regarding MMTCs, some have actual storefronts but all of them also deliver to the patients' homes. The latter perform an excellent job of counseling the patient over the phone and at the patient's home.

Editor: I know that some people respond well to "over the counter" cannabinoids - have you seen this in your practice?

Dr. Rains: I assume that you are referring to CBD oils, lotions, etc. Many patients have tried these with mixed results before coming to me. These products are made from hemp, which is illegal to grow in the U.S., so it comes from other countries. The quality may vary as does the concentration. These products are also quite expensive if you've ever gone shopping for them. That being said, many of these products are of very high quality and work very well.

Low-THC cannabis, on the other hand, is made from the flowers of a marijuana strain grown specifically to produce a CBD-dominant product and is tightly regulated. Therefore, I usually recommend that patients use low-THC cannabis instead of CBD oil.

Editor: Do you feel that some of your patients are just looking for a "high"? Can they even get "high" on the meds you prescribe?

Dr. Rains: A few may be looking for a "high" but they still have to meet the guidelines to qualify for treatment. Yes, they can get high on medical cannabis (THC) if they take large doses or if they are just using THC for the first time. However, the benefits of treatment outweigh the risks - which must be determined and documented at the initial

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visit. In my opinion, many of the patients are so sick and are suffering so much that being a little "high" might not be so bad. Instead of high, most patients say they feel relaxed and calm when using medical marijuana.

We are careful to counsel patients not to drive or operate heavy machinery while under the influence. That is part of the consent process also done at the initial visit and every 210 days thereafter when the patient is recertified for ongoing treatment. The state requires that a seven-page consent form be reviewed with the patient by the physician (not to be delegated) and that each section be initialed by the patient and finally signed by the patient and the physician.

Editor: Do you have a feeling about the use of recreational marijuana, such as in states like Colorado?

Dr. Rains: Yes, I am in favor of recreational marijuana. There has been prohibition for too long and I don't think it has done anything but waste law enforcement resources that could be used on more pressing problems such as opioid abuse and the need for treatment of opioid addicts.

I feel that there is still a place for medical marijuana in states that allow recreational marijuana, because I feel that treatment with medical marijuana under the supervision of a physician is necessary for dealing with serious medical conditions such as those listed in this interview.

Editor: Is there anything else you would like to add?

Dr. Rains: Just a cheap, shameless plug. I no longer work for Compassionate Care because they closed their Gainesville office. I now work for CannaMD, which will be opening an office here in Gainesville in August 2018. I will continue to see my former patients as well as new patients. I really appreciate all the referrals that have been made by ACMS members and many others over the past year and hope that will continue. Patients may call 1 (855) 420-9170 to schedule an appointment.

Editor: Thank you, Dr. Rains, for this fascinating perspective. I believe that our readers will learn a great deal from it.

Dr. Rains: Thank you!

[**Editor's note:** Marijuana is still designated by the FDA as a "Schedule 1" drug and therefore technically cannot be "prescribed", but rather must be "recommended" or "ordered" by a "qualified" physician. For simplicity, we still use the term "prescribed" in this piece.]

Alachua County Medical Society
235 SW 2nd Avenue • Gainesville, FL 32601-6256

CHANGE SERVICE REQUESTED