LIVER CARE:
Unflappable Commitment to Quality
Digestive Disease Institute at Virginia Mason

Virginia Mason’s Digestive Disease Institute optimizes patient care through innovations in research and education as well as a multidisciplinary approach to quality treatment of digestive and liver diseases.

Areas of Emphasis

Education & Training | Director Blaire Burman, MD, is standardizing fellow evaluations and initiating outside training in clinical and research mentorship for program directors.

Research | Focused on growing the next generation of medical research scientists, director Flavio Rocha, MD, is providing research experiences to undergraduate students at the University of Washington.

Quality Improvement | Joanna Law, MD, is working with director Otto Lin, MD, to quantify radiation exposure in real time, implementing measures to minimize such exposure in the therapeutic endoscopy suite.

Innovation | Enhancing patient-physician communication and improving health literacy through in-person, interactive lectures on digestive disease topics is the passion of director Asma Siddique, MD.

Centers of Excellence

The Digestive Disease Institute’s eight centers of excellence promote new knowledge and treatment through research, education, innovation and continuous quality improvement.

Bariatric Surgery Center of Excellence | A bariatric surgery ERAS pathway inclusive of interdisciplinary perioperative glycemic control is being developed by director Jeffrey Hunter, MD, Connie Miller, RN, and team.

Esophageal Center of Excellence | Donald Low, MD, is exploring sarcopenia in esophageal cancer patients, from methods of definition to grading processes to assessing the effects of nutritional supplementation.

Inflammatory Bowel Disease Center of Excellence | The potential of a largely unknown, simple process for archiving biopsies that allows live immune cells to be retrieved for IBD research is being investigated by James Lord, MD, PhD.

Liver Center of Excellence | Director Alexander Kuo, MD, and team are using abbreviated eovist MRI for HCC surveillance and implementing a clinical pathway to evaluate bariatric surgery candidates for liver disease.

Liver, Pancreas and Biliary Surgical Center of Excellence | Hepatic artery infusion pump therapy for refractory, metastatic colon cancer to the liver and multidisciplinary pancreas cancer care are at the forefront for Scott Helton, MD, director.

Nutrition Center of Excellence | Seamless care for weight loss patients via a system-wide, standardized assessment utilized in all specialties as well as primary care, is being led by director Jonathan Stoehr, MD, PhD.

Pancreatic Center of Excellence | Long term outcomes of disconnected pancreatic ducts treated endoscopically are the focus of Shayan Irani, MD, while Vincent Picozzi, MD, engages in Precision Promise for pancreas cancer.

Therapeutic Endoscopy Center of Excellence | Andrew Ross, MD, director, is leading the team in perfecting endoscopic anastomosis, including gastrojejunostomy, choledochoduodenostomy, hepaticogastrostomy and others.
Richard Kozarek, MD, founding Executive Director, reflects on current initiatives and his experience as a gastroenterologist, physician scientist, and leader.

How are hepatologists, endocrinologists, and bariatric surgeons working together at the crossroads of liver disease, obesity, and nutrition at the Digestive Disease Institute?

We are seeing a twofold epidemic in this country: NAFLD and obesity. Our best minds are working across disciplines to manage and develop new treatments for these conditions. This collaboration extends to managing hepatotoxicity as a consequence of diet, to treating hemochromatosis and Wilson’s Disease as disorders of iron and copper metabolism, and to developing best practices and effective options for treatment of obesity.

How has the Institute’s multidisciplinary structure supported its work building evidence-based care pathways?

In addition to patient care and standard conferences, providers from multiple disciplines meet regularly in work groups to review the literature as well as our own experience, with the subsequent creation of algorithms with supporting references. As such, we have evidence-based, multidisciplinary pathways for pancreatic cancer, benign pancreatic disorders, complications of bariatric surgery, and hepatoma treatment, to name only a few.

You have contributed directly to that base of evidence. What common treatment could you not have imagined in your early career?

I remember Joe Geenen presenting the first five cases of endoscopic sphincterotomy in the US. I believe one patient bled and one was locally perforated, but he was successful in bile duct stone retrieval in all. I thought, “That man is crazy!” Little did I know that I would be doing the same thing six months later!

What motivates you to keep working as hard as you do?

I owe a responsibility to my patients to care for them to the best of my ability. I owe a responsibility to my colleagues, to include young physicians. And I have a need to be smarter than I am, to posit a question that may require a clinical trial to answer, and to collaborate with interdisciplinary colleagues around the world.

What advice would you give to digestive disease providers just entering the field?

Pursue lifelong learning and keep an open mind: what we do routinely today may be rendered obsolete tomorrow. As with peptic ulcer surgery after the discovery of H. pylori, basic science can suddenly delete a disease entity. What if a vaccination is developed for colorectal polyps? If there was a quick and lifetime cure of inflammatory bowel disease?

What accomplishments are you most proud of at the Digestive Disease Institute?

I am most proud of assuring that the DDI leadership is truly multidisciplinary, including gastroenterologic, hepatologic, and surgical leadership, as well as leadership from oncology and endocrinology. Programmatically, I am proud of our academic output, resulting in multiple national and international presentations and 50-100 yearly publications. And I am most happy that we have used that collaboration to improve the care of our patients.
Pursuing a New Standard of Care for NAFLD

Virginia Mason’s Liver Center of Excellence merges multidisciplinary care with cutting-edge research to advance treatment of all forms of liver disease. A current focus area is improving treatment of nonalcoholic fatty liver disease (NAFLD) at a time when the obesity epidemic is spurring an unprecedented number of NAFLD cases.

“NAFLD will affect tens of millions of Americans and may be the biggest clinical challenge we face over the next 20 years,” says director Alexander Kuo, MD. “As a field, we need to look beyond treating risk factors like metabolic syndrome and insulin resistance, and find better ways to understand and address NAFLD’s damage to the liver.”

With this goal in mind, Kuo and his colleagues — including Blaire Burman, MD, and Asma Siddique, MD — are embracing alternative imaging strategies for NAFLD, participating in innovative clinical trials, and developing new treatment strategies and pathways.

“We’re just at the beginning of understanding NAFLD’s pathophysiology and applying it to the development of therapeutic interventions,” Dr. Kuo says. “The revolution in hepatitis C therapies has given us a roadmap to follow, and I’m optimistic that we’ll make fast progress.”

Adopting state-of-the-art imaging

Digestive Disease Institute hepatologists, radiologists and interventional radiologists are teaming up to adopt more precise, less invasive imaging technologies and protocols, including:

- An abbreviated MRI protocol for liver cancer screening:
  Between 20 and 30 percent of Virginia Mason patients who need regular screening for liver cancer have suboptimal ultrasound results due to obesity. To address this concern, an abbreviated MRI protocol utilizing gadoxetic acid is provided to patients, yielding outstanding images in just five to 10 minutes.
  “It’s a lot more convenient for patients than traditional MRI or multiphasic CT, and it’s far more cost-effective,” says Dr. Kuo, who helped develop the new protocol at the University of California, San Diego before he joined Virginia Mason in 2017.

- Contrast-enhanced ultrasound to evaluate liver lesions:
  In cases where MRI or multiphasic CT scan detect a liver lesion but malignancy is indefinite, encapsulated microbubbles are used as a contrast agent. Widely used in South Korea and Europe, the liver team has partnered with radiologist Beverly Hashimoto, MD, to deliver this non-invasive technique. The yield is very precise images of liver lesions as the microbubbles travel through the liver, following the pattern of uptake and dispersion.

- Noninvasive tools to evaluate cirrhosis:
  Transient fibroscan and magnetic resonance elastography are a key part of the team’s push to use noninvasive modalities to monitor cirrhosis.
  “Transient fibroscan generates a stiffness value that corresponds with the amount of scarring we would see from a needle biopsy,” Dr. Siddique says. “It helps us identify cirrhosis earlier and enroll patients in liver cancer surveillance in order to detect cancerous tissue at the earliest possible time.”
  In contrast, magnetic resonance elastography measures hepatic parenchyma and quantifies the amount of liver fat.

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Alexander Kuo, MD, Blaire Burman, MD, Gyongyi Szabo, MD, PhD and Asma Siddique, MD, prepare for grand rounds.
“It’s a great tool for assessing liver fat and fibrosis and for monitoring how fibrosis changes in response to therapy,” Dr. Siddique says, “It alerts us to modify treatment, and it can reassure and motivate patients as they see their fat fraction drop.”

Investigating bariatric surgery for NASH patients

Weight loss is one of the most effective NAFLD treatments and is often a prerequisite for liver transplant. But patients with nonalcoholic steatohepatitis (NASH) are often seen as poor candidates for bariatric surgery because they may have portal hypertension or other issues that increase the risk of surgical complications. To address these concerns, the Liver and Bariatric Surgery Center of Excellence teams together developed a pathway stratifying NASH patients into risk categories and thus standardized the circumstances under which surgery may be a viable option.

“Portal hypertension increases abdominal pressure and significantly increases risk of severe bleeding,” says Jeffrey Hunter, MD, Bariatric Surgery Center of Excellence Director. “But we think there may be a subset of patients for whom bariatric surgery is still viable.”

Per this pathway design, patients with NASH are referred for bariatric surgery if they do not have portal hypertension or cirrhosis. When patients do have portal hypertension, hepatic venous pressure gradient (HVPG) is measured and patients are divided into three categories:

- Patients in the “mild” category (HVPG<10) are eligible for gastric sleeve with intraoperative liver biopsy.
- Patients in the moderate category (HVPG 6-10) are considered for bariatric surgery with use of a transjugular intrahepatic portosystemic shunt to reduce abdominal pressure and risk of severe bleeding.
- Patients with severe portal hypertension (HVPG>10) are ineligible for bariatric surgery.

Future outcomes studies will determine how these groups respond to therapy.

“People who are not good bariatric surgical candidates are also the ones who would benefit the most from surgery,” Dr. Siddique says. “We’re hoping this pathway will help stop the vicious cycle.”

Investigating promising new drugs

While there are no approved medications for treating NAFLD, a growing number of therapies are in the pipeline. The Liver Center of Excellence is participating in three key clinical trials and expects to join more as they develop.

“I anticipate that we’ll eventually need a combination of drugs that focus on multiple pathways. We’re excited to be part of clinical trials that move us in that direction,” Dr. Siddique says.

For more information, please see clinical trials currently open at the Digestive Disease Institute on page 14.

Evaluating palliative care for end-stage disease

Blaire Burman, MD, is launching a study to investigate whether early access to palliative care could help patients with end-stage liver disease.

“Hepatologists tend to be optimistic and focused on helping patients get better,” Dr. Burman says. “But the median survival for patients with cirrhosis is approximately one year, so we also need to be open to the possibility that liver disease can be terminal — and that palliative care could significantly improve quality of life.”

Previous studies show that only 10 to 15 percent of patients with end-stage liver disease receive palliative care. That care usually isn’t provided until within 10 days of death — too late to make a significant difference in quality of life.

The first phase of Dr. Burman’s study will pinpoint how often providers refer end-stage liver disease patients for palliative care and how often advanced directives of care are established for them. The second phase will offer early palliative care to patients with end-stage disease, and evaluate how it affects the number of hospitalizations and emergency department visits, the cost of care, and the rate of dying at home versus dying in the hospital.

“Palliative care can yield significant improvements for patients with cancer, but it hasn’t been thoroughly studied for patients with liver disease,” Dr. Burman says. “I’m hoping this study will be a significant step toward improving quality of life, without compromising longevity.”

For more information about the Liver Center of Excellence, see VirginiaMason.org/Liver-Center or call 206-223-2319.
Bariatric Surgery Candidates with NAFLD Multidisciplinary Care Pathway

Bariatric Surgery Pre-Operative Evaluation
CMR & CBC Labs

Elevated Aminotransferases, Fatty Liver on Abdominal Imaging and/or History of Liver Disease

Hepatology Consult
Assess liver stiffness with MR Elastography, Aspartate Aminotransferase to Platelet Ratio Index (APRI), Fibrosis-4 (FIB-4) and NAFLD Fibrosis Score

MR Elastography
Steatosis grading and fibrosis staging to r/o cirrhosis

No Cirrhosis
Choice of intervention up to surgeon and patient

Gastric Sleeve or Gastric Bypass if GERD

Cirrhosis
EGD to screen for varices

Well Compensated Cirrhosis
Normal platelets, no varices, no ascites, Child-Pugh-Turcotte class A (CPTA)

Refer to Interventional Radiology for transjugular liver biopsy with portal pressure measurements

Hepatic Venous Pressure Gradient (HVPG) >10
No Bariatric Surgery

Hepatic Venous Pressure Gradient (HVPG) 6–10
Consider Clinical Trial

Hepatic Venous Pressure Gradient (HVPG) <6
Gastric Sleeve Preferred with intraoperative biopsy of liver (16 fr needle)

Decompensated Cirrhosis

No Bariatric Surgery
Raising the Bar on Weight-Loss Treatment

When Jonathan Stoehr, MD, PhD, joined Virginia Mason in 2012, the obesity epidemic was growing — and patients and providers were frustrated. Patients had spent years trying fad diets or commercial weight loss programs, with little success. When they came to Virginia Mason to receive treatment for type 2 diabetes, fatty liver disease or sleep apnea, they experienced outstanding care — but it didn’t help with the root cause of their health problems. Surgeons, gastroenterologists and endocrinologists were eager to address the issue, but appointment types did not accommodate the work, nor were they trained to facilitate patients starting a weight loss journey.

“As I talked to providers in different departments, everyone agreed that many patients would be better served by weight loss than by medication or surgery,” says Dr. Stoehr, who directs the Digestive Disease Institute’s Nutrition Center of Excellence. “We needed to restructure care so it was easier to access evidence-based weight loss solutions.”

Dr. Stoehr and his colleagues addressed this problem by creating the Weight Loss Center — an integrated clinic that puts Virginia Mason at the forefront of finding better, more cost-effective ways to help patients lose weight, overcome weight-related co-morbidities, and improve their health.

Integrated care

As Dr. Stoehr and his colleagues launched the Weight Loss Center, they were excited — and relieved — to establish standards for weight loss treatment using evidence-based medicine, as were their colleagues in disciplines as diverse as primary care and orthopedic surgery.

“No one was territorial or afraid we’d put them out of business,” Dr. Stoehr says. “Instead, they put patients at the top of the pyramid — and recognized that weight loss would help patients have better outcomes when they needed things like knee replacements or apnea treatment.”

Today, the Weight Loss Center team includes bariatric surgeons, gastroenterologists, endocrinologists, internists, registered dietitians, a licensed social worker, physician’s assistants and a nurse practitioner, working together to provide a wide variety of weight-loss solutions. Specialists treating patients with weight-related co-morbidities refer them to the center as a first or complementary step in treating their health problems.

Tailored weight-loss solutions

Patient input played a key role in creating the center. Through experience-based design, weight-loss patients described how they’d been battling weight problems for years. They wanted providers to understand that they desire to be fit, not thin, and that they direct a considerable amount of time, thought and effort toward their weight. These themes spurred the team to create Virginia Mason’s unique, “Get Started” intake appointment, using standard tools to engage with and understand each patient’s detailed medical history and pinpoint the course of treatment likely to be most effective.

To start, patients complete an extensive health history questionnaire, which includes the Epworth Sleepiness Scale for sleep apnea and the PROMIS-10 tool to evaluate health-related quality of life. The “Get Started” appointment helps providers gain a deeper understanding of the patient’s goals, which serves as the foundation for prescribing weight loss medication and/or
scheduling appointments with Virginia Mason dietitians, physical therapists, endocrinologists, gastroenterologists, bariatric surgeons, or mental health providers.

From there, an individualized, medically-supervised weight loss plan is devised, and can include:

- **Nutritional counseling with registered dietitians** for as-needed lifestyle management
- **FDA-approved weight-loss medications**
- **A 12-week, medically-supervised meal replacement program**, followed by weekly group sessions for a duration of 40 weeks
- **Get Healthy Series** – a seven-week medically-supervised group appointment for weight loss, including a private Facebook page for patients
- **FDA-approved gastric balloon**
- **External, non-surgical stomach pump** using a large-bore PEG tube
- **Bariatric surgery** – for patients who have a BMI over 40, or who are obese and have a weight-related low morbidities

“Patients are excited when they find out that there are effective solutions, and that we can customize their care — it’s a huge relief for them, and it’s incredibly gratifying for us to be able to give them hope,” Dr. Stoehr says.

**Cost-effective care**

Virginia Mason’s approach does more than give patients the best chance at a good outcome — it provides a cost-effective model at a time when more payers are considering outcome-based medicine.

“If we invest in addressing the root causes of weight-related morbidities, patients will improve, and we’ll recoup those dollars down the road when we need to order fewer vials of insulin, fewer knee replacements and fewer CPAP machines,” Dr. Stoehr says.

With no end to the obesity epidemic in sight, the Weight Loss Center is adding providers, broadening its services and expanding to more locations in order to help more of the approximately 40,000 new patients who come to Virginia Mason each year with weight-related health issues.

“Evidence-based weight-loss programs are a key part of improving outcomes for millions of Americans,” Dr. Stoehr says. “We’re proud to be at the vanguard and to act as a model for other centers to follow.”

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**Virginia Mason’s Nutrition Center of Excellence delivers nutritional care across the spectrum of digestive diseases — from pancreas cancer to inflammatory bowel disease to obesity — with a special emphasis on weight loss.**

*For more information about the Nutrition Center of Excellence, see VirginiaMason.org/Nutrition-Center or call 206-223-6729.*
Developing Nurse-Assisted Sedation to Transform Care

When an industry partner discontinued its computer-assisted propofol sedation system (CAPS) in 2016, the Digestive Disease Institute team knew it couldn’t go back to midazolam and fentanyl.

“Patients love propofol because it makes colonoscopies nearly painless and the recovery is so much shorter,” says Deborah Tombs, RN, “and we loved CAPS because it empowered nurses and increased throughput.”

So Tombs, along with Otto Lin, MD, and their anesthesia colleagues, rolled up their sleeves and created an alternative: Nurse-Administered Propofol Continuous Infusion Sedation (NAPCIS). With this innovative system, registered nurses and physicians administer propofol without the presence of an anesthesiologist. Used in more than 10,000 cases, it has proven to be outstanding in both safety and efficacy.

“NAPCIS is so effective and affordable that it could change the paradigm for GI propofol sedation, especially if more payers create incentives to lower costs,” Dr. Lin says. “It’s a great example of how Virginia Mason is constantly developing ways to improve care.”

Empowering nurses

To develop NAPCIS, the gastroenterology and anesthesia teams partnered to create a protocol for propofol dosage in low-risk procedures such as colonoscopy, EGD, colon EMR, balloon assisted retrograde enteroscopy and EGD-EMR. After finalizing the protocol to the satisfaction of all stakeholders, the algorithm was programmed into an infusion pump. Once the pump calculates drug dosage based on the patient’s weight, a registered nurse oversees the infusion and monitors the patient’s oxygen saturation and vital signs during the procedure. The process is supervised by a physician trained in advanced cardiovascular life support.

“It’s the nurses’ responsibility to monitor patients, and to cut back or stop the infusion if there’s a problem,” says Tombs, Director of Gastroenterology Nursing. “Nurses are happier and even more engaged because they’re working at the top of their skill set.”

More effective sedation

After a pilot project showed NAPCIS could be successful, the system was implemented for all low-risk colonoscopy patients. Initial data demonstrates that NAPCIS is safe and effective — with much faster recoveries than midazolam and fentanyl.
Patients sedated via NAPCIS had no significant adverse events, and procedures done using the system showed a 98.6 percent success rate — identical to procedures that used CAPS (98.7 percent success rate) or midazolam and fentanyl (98.8 percent success rate).

The biggest differentiator? The average recovery time after NAPCIS sedation was just 23.2 minutes, compared to 39.1 minutes with midazolam and fentanyl.

“A lot of patients are awake by the time they get to the recovery room, which significantly shortens time to discharge,” Dr. Lin says.

This change not only enhances the patient’s experience, but also enables the team to increase the number of daily procedures and reduce recovery room staffing each day.

“From a patient experience perspective as well as financially, NAPCIS is a huge win,” Dr. Lin says. “It’s far more affordable for patients because there’s no anesthesiologist bill.”

**Expanding to other hospitals**

Approximately 41 states allow nurse-administered sedation. NAPCIS may be a particularly good fit for self-contained health care systems like HMOs and the Veterans Health Administration, and could become more attractive to traditional health systems as more payers embrace bundled payments. The Digestive Disease Institute is currently working with CHI Franciscan Health to help it implement NAPCIS for its patients, with the hopes of improving care as well as the financial landscape for all.

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**Otto Lin, MD, leads the Digestive Disease Institute’s commitment to quality by improving care and patient outcomes across the spectrum of digestive diseases.**

For more information about Quality Improvement at the Digestive Disease Institute, see VirginiaMason.org/DDI-Quality-Improvement
Visiting Scholars Shed New Light on Digestive Disease – From Seattle to Korea to Switzerland

The Digestive Disease Institute’s Visiting Scholar Program attracts international experts interested in conducting research in collaboration with the Institute’s renowned faculty. “Many visiting scholars are top physicians and researchers in their home countries,” says Blaire Burman, MD, Director of Education and Training. “It’s an amazing opportunity — for them and us — to expand our perspectives and discover new insights that influence care around the world.”

Three current scholars are co-investigating topics ranging from the health economics of fecal transplants to walled-off pancreatic necrosis to paraesophageal hernias. In just over a year, they’ve prepared nearly a dozen manuscripts, including several published in key journals.

“The Visiting Scholars Program makes it extremely easy for physicians like me to step in and start doing research. It will be a big help for my career.”
— KYEONG OK KIM, MD

Learning from a legend

To Jong Jin Hyun, MD, PhD, the Visiting Scholar Program is a once-in-a-lifetime opportunity to learn from gastroenterology experts including Richard Kozarek, MD. “He’s a legend in the field,” says Dr. Hyun, who is an associate professor of gastroenterology at the Korea University College of Medicine in Seoul.

After just five months at Virginia Mason, Dr. Hyun has submitted five manuscripts and conference presentations — including one accepted in Gastroenterology — with more in process. His work includes:

• Leading a retrospective study of the incidence of biliary stricture in patients undergoing extracorporeal shock wave lithotripsy (ESWL) for severe, chronic pancreatitis. Dr. Hyun and his colleagues found that, of patients who underwent ESWL for pancreatic stone removal at Virginia Mason, 35 percent had biliary stricture present at the time of procedure, and a third of those patients had significant biliary stricture.

Unraveling IBD

As an assistant professor of gastroenterology and hepatology at Yeungnam University College of Medicine in South Korea, Kyeong Ok Kim, MD, has an intense interest in inflammatory bowel disease (IBD) and associated colorectal cancer — but IBD is hard to study in her home country because it isn’t very prevalent there. The Visiting Scholar Program enables her to access a large cohort of IBD patients in partnership with IBD Center of Excellence Director Michael Chiorean, MD.

Dr. Kim has submitted three first-author abstracts to Digestive Disease Week and hopes to turn them all into published manuscripts this year:

• Comparing the efficacy of chromoendoscopy (CE) to white light endoscopy (WLE) in detecting colorectal neoplasia in IBD patients, showing that CE has detected overall neoplasia in 40 percent of colonoscopies versus 23 percent for WLE.
• Evaluating outcomes for patients who present with lower gastrointestinal bleeding.
• Examining the cost and scheduling difficulty of different types of fecal transplants for recurrent Clostridium difficile infection.
“The Visiting Scholars Program makes it extremely easy for physicians like me to step in and start doing research. It will be a big help for my career,” Dr. Kim says.

Evaluating outcomes for paraesophageal hernia surgery

Andrea Wirsching, MD, came to Virginia Mason to gain new insights on esophageal care after she finished her general surgery residency — as well as basic science research on liver regeneration — in Switzerland.

Her first project compared outcomes among patients who receive emergent surgery for acute paraesophageal hernias vs. patients who undergo elective surgery. She found that a semi-elective approach that includes gastric decompression, followed by repair within a month of a patient’s first admission, is safe — and that patients have similar rates of postoperative dysphagia, heartburn, early satiety, chest pain and cough. These findings were published in the *Journal of Gastrointestinal Surgery*.

“We showed that a more conservative approach allows for an opportunity to relieve acute obstruction, without increasing morbidity or mortality,” Dr. Wirsching says.

She also led an outcomes study showing that surgery to repair giant paraesophageal hernias had similar outcomes in patients with pathologic motility and patients with normal motility.

“This study suggests that pathologic motility shouldn’t preclude surgical repair of giant paraesophageal hernias unless there is a major motility disorder such as achalasia or scleroderma,” Dr. Wirsching says.

The Digestive Disease Institute’s commitment to learning and teaching sparks new insights and innovations that improve care. A wide range of education programs support physician learning and help us share new knowledge with audiences around the world.

For more information about Education and Training at the Digestive Disease Institute, see VirginiaMason.org/Digestive-Disease-Training-and-Education.
Srekeer Vennelaganti, Prashanth Vennalaganti, Pratiksha Singh, April Higbee, Kevin Kennedy, Irving Waxman, Gary Falk, Andrew Ross, Rajesh Krishnamoorthi, Ahmed Saeed, Anjana Sathyamurthy, Tarun Rai, Abhishek Choudhary, Alessandro Repici, Nei Gupta, Prateek Sharma

Chromogranin A and Predicting Recurrence in Pancreatic Neuroendocrine Tumors: A Novel Pre-Operative Risk Scoring System

Monday, June 4

Complications of Endoscopic Mucosal Resection in Barrett’s Esophagus are Directly Related to the Number of Resected Specimens: Results from a Large Multi-Center Consortium

Differences in Lower Gastrointestinal Bleeding Management and Outcomes over a 10 Year Span
*Kyeong Ok Kim, Otto Lin, Richard Kozarek

Nurse Administered Propofol Continuous Infusion Sedation (NAPCIS): A New Paradigm for GI Procedural Sedation
*Otto Lin, Danielle La Selva, Deborah Tombs, Richard Kozarek, Andrew Ross

Patient and Endoscopist Satisfaction with Nurse Administered Propofol Continuous Infusion Sedation: A Comparative Study Against Midazolam/Fentanyl and Computer Assisted Propofol Sedation
*Otto Lin, Danielle La Selva, Deborah Tombs, Richard Kozarek, Andrew Ross

Incidence and Significance of Biliary Stricture in Chronic Pancreatitis Patients Undergoing ESWL for Obstructing Pancreatic Duct Stones
*Jong Jin Hyun, Shayan Irani, Andrew Ross, Michael Larsen, S. Ian Gan, Michael Gluck, Richard Kozarek

Safety and Efficacy of Using Lumen Aposing Metal Stents in the Management of Post-Operative Fluid Collection (POFC): A Large International, Multi-Center Retrospective Study

Tuesday, June 5

Oops, the Lumen-Apposing Metal Stent (LAMS) Misdeployed!
Stay Calm. Now Let’s Rescue It
*Shayan Irani

When Cholecystostomy Tube & Transpapillary Stents for Recurrent Cholecystitis Fail Due to Large Gallstones: Rescue with Laser Lithotripsy via Cholecystoduodenal Fistula
*Jennifer Higa, Shayan Irani

Long Term Follow-Up of Patients with a Disconnected Pancreatic Duct Following Treatment of Walled-Off Necrosis
*Nadav Sahar, Richard Kozarek, Michael Gluck, Michael Larsen, Andrew Ross, Shayan Irani

A Randomized Trial Comparing Fully Covered and Uncovered Biliary Self Expanding Metal Stents for Pre-Operative Drainage During Neoadjuvant Therapy in Patients with Pancreatic Cancer
*Dong Wan Seo, Kulwinder Dua, Stuart Sherman, Richard Kozarek, Adam Slivka, Andre Roy, Guido Costamagna, Jacques Deviere, Hiroyuki Isayama

High Dimensional Immune Phenotyping and Transcriptional Analysis Reveal Robust Recovery of Viable Human Immune and Epithelial Cells from Frozen Gastrointestinal Tissue
*Liza Konnikova, Gilles Boschetti, Adeeab Rahman, James Lord, Camilla Richmond, Vesselin Tomov, William Gordon, James Canavan, Sarah Wall, Michael Field, Fanny Zhou, Meenakshi Bewtra, Jeffrey Goldsmith, David Breault, Miriam Merad, Scott Snapper

Can Prophylactic APC Reduce Delayed Post-Papillectomy Bleeding? A Prospective Randomized Multicenter Trial
*Jae Kook Yang, Tae Hoon Lee, Jong Jin Hyun, Jun-Ho Choi, Jin-Seok Park, Seok Jeong, Chang Il Kwon, Yun Nah Lee, Hyun Jong Choi, Jong Ho Moon, Sang-Heum Park, Sun-Joo Kim

Reducing Cost and Scheduling Complexity of Fecal Microbiota Transplantation by Using Universal Donor Over Patient-Directed Donors in Patients with Recurrent Clostridium Difficile Infections
*Kyeong Ok Kim, Margot Schwartz, Michael Gluck

Dysplasia Free Survival in Patients with Barrett’s Esophagus After Successful Endoscopic Therapy: Results from a Large Multicenter Consortium

* Presenters

Virginia Mason’s Digestive Disease Institute optimizes patient care through innovations in research and education as well as a multidisciplinary approach to quality treatment of digestive and liver diseases. Faculty will present in multiple areas at Digestive Disease Week 2018 in Washington, DC.
Research at the Digestive Disease Institute

Digestive Disease Institute research currently focuses on identifying promising advances in the treatment of liver, inflammatory bowel, pancreas, stomach, bile duct and esophageal disease. Our research portfolio includes translational, medical device and pharmaceutical trials as well as observational research.

Right: The IBD research team is one component of DDI’s robust clinical trials team. Team members include (clockwise from top left) Angie Neal, Katie Gelinas, Kate Beck, Sarah Ackermann and Adrian Parker.

Currently Enrolling Clinical Research Studies

To refer patients or to see a complete list of the Digestive Disease Institute’s currently enrolling clinical trials, call the research hotline at 206-341-1021 or visit VirginiaMason.org/DDI-Research.

Cancer: Hepatobiliary

A Phase 1b, Randomized, Open-Label Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) in Combination With Cisplatin Plus Gemcitabine and PEGPH20 in Combination With Atezolizumab and Cisplatin Plus Gemcitabine Compared With Cisplatin Plus Gemcitabine in Hyaluronan-High (HA-high) Subjects With Previously Untreated, Unresectable, Locally Advanced, or Metastatic Intrahepatic and Extrahepatic Cholangiocarcinoma and Gallbladder Adenocarcinoma

Goal: To assess the safety and tolerability of (1) PEGPH20 in combination with cisplatin (CIS) and gemcitabine (GEM) (PEGCISGEM), and (2) PEGPH20 in combination with CIS, GEM, and atezolizumab (PEGCISGEMATEZO).

Inflammatory Bowel Disease

M14-433: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects With Moderately to Severely Active Crohn’s Disease Who Have Inadequately Responded to or Are Intolerant to Conventional Therapies but Have Not Failed Biologic Therapy

Goal: To evaluate the efficacy and safety of upadacitinib compared to placebo as induction therapy in participants with moderately and severely active Crohn’s disease.

M14-431: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects With Moderately to Severely Active Crohn’s Disease Who Have Inadequately Responded to or Are Intolerant to Biologic Therapy

Goal: To evaluate the efficacy and safety of upadacitinib compared to placebo as induction therapy in participants with moderately and severely active Crohn’s disease.

Cancer: Pancreas

Gemcitabine and Nab-Paclitaxel in Pancreatic Adenocarcinoma with Positive Peritoneal Cytology as a Sole Metastatic Site, a Pilot Study

Goal: To assess the frequency of cytological conversion in patients with pancreatic adenocarcinoma and positive peritoneal cytology as a sole metastatic site following gemcitabine nab-paclitaxel.

Cancer: Rectal

Neoadjuvant Chemotherapy, Excision and Observation for Early Rectal Cancer: The Neo Trial

Goal: To determine the organ preservation rate in patients with early (cT1-3 No) rectal cancer treated with neoadjuvant FOLFIRI or CAPOX and TEMS or TAMIS.

Cancer: Colorectal

A Phase III Study of BBI-608 in combination with 5-Fluorouracil, Leucovorin, Irinotecan (FOLFIRI) in Adult Patients with Previously Treated Metastatic Colorectal Cancer (CRC)

Goal: To compare overall survival of patients with metastatic pretreated CRC treated with BBI-608 plus biweekly FOLFIRI versus biweekly FOLFIRI.

Inflammatory Bowel Disease

M14-434: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of ABT-494 in Adult Patients With Moderately to Severely Active Ulcerative Colitis

Goal: To evaluate the safety and efficacy of ABT-494 for further evaluation in sub-study 2.

Goal: To evaluate the efficacy and safety of ABT-494 compared to placebo in inducing clinical remission in participants who had a response following induction with ABT-494.

Pancreatitis

NI03-001: A Phase 1, Single Dose PK and Safety Study with NI-03 Followed by a Phase 2, Randomized, Double-Blind, Parallel-Group Dose-Ranging Study to Evaluate the Safety and Efficacy of NI-03 When Compared to Placebo in Subjects with Chronic Pancreatitis

Goal: To determine the safety and efficacy of NI-03 in subjects with chronic pancreatitis.

Therapeutic Endoscopy

3152-301-002: A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of LY3074828 in Subjects with Active Crohn’s Disease

Goal: To evaluate the safety and effectiveness of Mirikizumab in participants with active Crohn’s Disease.

16T-MC-AMAG: A Phase 2, Multicenter, Randomized, Parallel-Arm, Placebo-Controlled Study of LY3074828 in Subjects with Active Crohn’s Disease

Goal: To evaluate the safety and effectiveness of Mirikizumab in participants with active Crohn’s Disease.

SHP626-201: A Phase 2 Double-blind, Randomized, Placebo-controlled, Dose-finding Study to Evaluate the Safety, Tolerability and Efficacy of Volixibat Potassium, an Apical Sodium-Dependant Bile Acid Transporter Inhibitor (ASBTi) in Adults with Nonalcoholic Steatohepatitis (NASH)

Goal: To determine if the investigational treatment volixibat (SHP626) is safe, tolerable and effective in adults with NASH.
Selected Recent Publications

**PANCREATIC–BILIARY SYSTEM**


**PANCREAS CANCER**


**THERAPEUTIC ENDOSCOPY**


**GENERAL ENDOSCOPY**


**ESOPHAGEAL DISORDERS**


**BARIATRIC SURGERY**


**COLON**


**INFLAMMATORY BOWEL DISEASE**


**LIVER DISORDERS**


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CONDITIONS WE TREAT
• Acute Pancreatitis
• Acute Liver Failure
• Ascites
• Autoimmune Hepatitis
• Barrett’s Esophagus
• Benign Hepatic Tumors
• Bile Duct Strictures
• Bile Duct Disorders
• Biliary Duct Cancer
• Celiac Disease
• Chronic Pancreatitis
• Cirrhosis
• Colitis and Chronic Ulcerative Colitis
• Colorectal Cancer
• Colorectal Polyps
• Constipation
• Crohn’s Disease
• Cystic Fibrosis
• Esophageal and Gastric Varices
• Esophageal Strictures and Cancer
• Fatty Liver Disease
• Gallstones and Bile Duct Stones
• Gastroesophageal Reflux Disease (GERD)
• Gastroparesis (Delayed Gastric Emptying)
• Hemochromatosis
• Hepatitis B, Hepatitis C and Chronic Hepatitis
• Hepatorenal Syndrome
• Inflammatory Bowel Disease (IBD)
• Intraductal Papillary Mucosal Neoplasm (IPMNs)
• Irritable Bowel Syndrome
• Liver Cancer
• Neuroendocrine Tumors
• Nonalcoholic Steatohepatitis (NASH)
• Obesity
• Pancreatic Cancer
• Pancreatic Cysts
• Pancreatic Necrosis
• Primary Biliary Cholangitis
• Primary Sclerosing Cholangitis
• Small Intestinal Bacterial Overgrowth (SIBO)
• Swallowing and Motility Disorders
• Ulcerative Colitis
• Wilson’s Disease

WHY REFER YOUR PATIENTS?
• We treat complex patients who may be untreatable in your area
• Multidisciplinary care in GI, hepatology, surgery, oncology, endocrinology, interventional radiology and nutrition
• GI Cancer Care Coordination Team will provide your patient with personalized attention
• Clinical trials may offer new hope to patients with no other treatment options

You may refer a patient to the Digestive Disease Institute by calling (206) 223-2319, or visit VirginiaMason.org/DDI.

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