

GASTROENTEROLOGY

DIGEST

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Message from the Chief

By definition, “innovation” is the creation and implementation of new processes, products, services, and methods that result in improvements in outcomes, efficiency, effectiveness, or quality. We have the ability to improve patient quality of life, when we arm ourselves with the tools and know-how to better prevent, detect, and treat. Simply put, innovation means pushing beyond where we are to where we want to be. Our faculty at UPMC continue to dig deeper and, through their research and clinical work, uncover tools for better prevention, diagnosis, and treatment. Our goal is to give patients the opportunity for a better life. We have long been at the forefront of innovation and clinical excellence, but at this moment we concentrate on pushing ourselves even further, bringing not simply knowledge but new discovery to our bedside practice.

“Every article in this issue touches on innovative advancements, as we hear from senior faculty, young investigators, and our outstanding fellows in training.”

In this issue of Digest, **David Medich, MD** and **Andrew Watson, MD, MLitt**, explore the total telemedicine pathway available to colorectal surgery patients at UPMC. **Sultan Mahmood, MD**, also shares his expertise with third-space endoscopy, an innovative procedure to treat achalasia, esophageal diverticula, gastroparesis, and esophageal motility disorders. More than a year after the tragic train derailment in East Palestine, OH, our experts, including **Juliane I. Beier, PhD**, continue to study the immediate and long-term effects to residents in western PA and eastern OH. Finally, we will hear from **David Binion, MD**, on leveraging data analytics to advance our understanding of inflammatory bowel disease.

We make advances that matter to our patients, their loved ones, and the medical community. It is my pleasure to share our progress in this edition of Digest.

Sincerely,



Naudia L. Jonassaint, MD, MHS, MBA

Interim Chief, Division of Gastroenterology, Hepatology and Nutrition
Associate Professor of Medicine and Surgery
Associate Dean for Clinical Affairs
University of Pittsburgh School of Medicine



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UPMC LIFE CHANGING MEDICINE

Adopting Telemedicine for the Preoperative and Postoperative Care of Colorectal Surgery Patients

Over the last several years, the UPMC Division of Colon and Rectal Surgery has implemented a total telemedicine pathway as a novel and high-quality option for preoperative patients. David Medich, MD, and Andrew Watson, MD, MLitt, explain the benefits of telemedicine, a natural evolution for health care in today's world of comprehensive electronic health records (EHR) and widespread use of advanced consumer electronics.



David S. Medich, MD

*Chief, Division of Colon and Rectal Surgery
Associate Professor of Surgery*



Andrew R. Watson, MD, MLitt

*Professor of Surgery
Senior Medical Director, UPMC Health Plan
Senior Medical Advisor, UPMC Enterprises*

Telemedicine allows UPMC physicians to provide high-quality care in a virtual setting using video-communication through a smart phone, computer, or tablet. During a video visit, the physician discusses the patient's health issues and concerns and performs a telemedicine physical examination. Similar to an in-person consultation, the physician also reviews test results, the patient's medical history, and the findings of other specialists to develop a care plan tailored for each patient. The main difference is that the patient is at home or work and does not have to travel to access UPMC's world-class care.

The Colorectal Surgery Total Telemedicine Pathway

The total telemedicine pathway established by the UPMC Division of Colon and Rectal Surgery promotes the use of video visits for consultations, preoperative patient evaluations, and postoperative follow up. Using the portal provided by the MyUPMC app, a new patient engages with the surgeon via videoconferencing from a location of the patient's choosing, typically home or work. The surgeon can participate from any location with sufficient privacy and a secure internet connection, but typically works from a UPMC workstation with multiple monitors where they can interact with the patient and view the electronic health record (EHR) simultaneously. This operational model for physician workflow makes the total telemedicine pathway seamless for the colorectal surgeons and gastroenterologists at UPMC. Currently, multiple physicians use this infrastructure as part of their surgical toolkit in blended clinics — mixing telemedicine and face-to-face interactions each day.

Telemedicine Is a Safe and Effective Way to Establish the Surgeon's Relationship With the Patient

When preoperative care is provided using the total telemedicine pathway, we are introduced to the patient in the videoconference. Rapport and the patient's condition are established quickly. In most cases, the physician interacts with them in-person for the first time on the day of their procedure. The day of the scheduled surgical procedure is a continuation of the relationship first established on the screen, when the physician meets the patient face-to-face and interacts with family members or friends supporting the patient.

Importantly, telemedicine does not preclude in-person care when required or requested. Most of the time, the total telemedicine pathway allows the surgeon to accomplish everything needed to prepare for the day of surgery. Nonetheless, there will always be situations when an anesthesiologist or the colorectal surgeon need to see the patient in-person to provide appropriate care. In these instances, or if a patient requests it, a preoperative clinic visit is scheduled. Telemedicine is simply another tool for comprehensive, high-quality surgical care. The decision to employ the total telemedicine pathway is one of the surgical assessments that the UPMC colorectal surgeons make daily, with similar significance as decisions made routinely in the operating room.

Postoperative care is by far the easiest aspect of the total telemedicine pathway. Postoperative visits are typically short and involve inspection of incision healing, diet

discussions, and postoperative expectations. Patients report great satisfaction with avoiding driving trips and extensive waiting room times. For most colorectal surgery patients, postoperative telemedicine is an appreciated convenience, and few have medical issues necessitating in-person evaluation and care.^{1,2}

Telemedicine Benefits Patients

UPMC adopted the total telemedicine pathway because it is the patients' best interest.³ When patients travel to our clinic for a straightforward surgical issue, the time, expense, and stress of travel are not ideal. Time and money are spent on each visit, and, for some patients, this presents significant hardship, especially if they have to take time off work. Patients routinely face challenges when they do not drive and need to find other transportation.

Because of colorectal issues, some patients have a very difficult time when they do not have easy access to a bathroom. The side effects of travel in this patient population are not inconsequential. A car trip might take twice as long as anticipated for a patient with a colorectal disorder because of the need for bathroom stops, or a patient may accept soiling themselves as the only way to make the trip. When we can reach out to patients using telemedicine and see them in an easy and convenient location (e.g., at home or at work), receiving care is less burdensome and less stressful and saves both time and money. The vast majority of patients report that they are very satisfied after telemedicine visits.

The total telemedicine pathway is also appreciated by the UPMC medical team. The same preparation is required for telemedicine and in-person preoperative visits. With the evolution of the electronic health record (EHR), the surgeon can assess every detail of a patient's medical record (e.g., laboratory tests, colonoscopy results, CT scans) from a single, stationary location. When patients are seen via telemedicine, they are significantly less likely to cancel or

no-show to their appointments, especially in the winter. We also know from our personal experiences that the surgeon may gain additional insight into the patient's condition or lifestyle factors impacting the patient's health by viewing their home or local environment.

Why Now?

Although some remote interactions became normalized during COVID-19, the total telemedicine pathway for colorectal surgery was not the result of the pandemic's precautions. Its foundations were in place 10-15 years ago, since telemedicine is a natural evolution of health care in today's digital world.⁴

The establishment and maintenance of the EHR have been integral to the development of telemedicine. UPMC was an early adopter of the EHR and has been recognized as one of the most wired health care systems in the United States for 25 consecutive years. More than a dozen UPMC hospitals are at the highest levels of EHR adoption. Advancements in consumer electronics and the near-universal adoption of the smart phone have also been essential to the establishment of telemedicine. Americans have become accustomed to downloading applications for specific purposes, logging into these applications with unique identifiers, and communicating in real-time using video. For most, the nuts and bolts of a telemedicine visit are not new. Moreover, by possessing, or even just having access to, a cell phone, our patient population has given us a cost-effective way to deliver high-quality medical care.

The Total Telemedicine Pathway Is Equivalent to In-person Care

Although UPMC believes that we are improving the patient experience and are not compromising care by implementing telemedicine preoperatively and postoperatively in our specialty, we recognize the need to verify the feasibility and quality of this approach as a tool for colorectal surgery and medicine in general.

As telemedicine for preoperative visits was adopted, UPMC surgery successfully utilized telemedicine to evaluate 93 patients from 96 referrals. Three patients with planned telemedicine preoperative visits were converted to in-person preoperative care (~5%) — two due to medical issues and one due to an insurance issue. Dr. Watson has conducted more than 950 telemedicine visits, with only three instances of in-person visit requests. Implementing a total telemedicine pathway for preoperative and postoperative care for patients undergoing colorectal surgery is clearly feasible, safe, and effective.

To verify that care is not compromised using the total telemedicine pathway, key performance indicators (KPIs) were examined as a quality metric. These KPIs (re-admissions, length of stay, length of surgery, cancelled cases, and morbidity and mortality) are routinely monitored by UPMC and the total telemedicine pathway team. No difference in safety, as indicated by KPIs, has been observed using the total telemedicine pathway as compared with in-person clinic visits. There was also no significant difference in KPIs when comparing the first 70 patients cared for with a previous iteration of the total telemedicine pathway with the 70 patients treated immediately prior to its adoption. Thus, UPMC has documented that the quality of care is the same for patients evaluated with telemedicine and patients seen in-person.⁵ Finally, patients rarely need to be rescheduled due to last minute issues discovered on the day of surgery.

Telemedicine is an important advance in health care. It is more convenient for the patient, saving them both time and money. Exceptional health care can be delivered to most patients using telemedicine, with in-person appointments prioritized as needed. The availability of UPMC's technology platforms, technological support, and its well-established and maintained EHR further elevate our application of telemedicine.

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A Comprehensive Third-space Endoscopy Program at UPMC Passavant

In Summer 2023, UPMC launched a new, comprehensive third-space endoscopy program within the Division of Gastroenterology, Hepatology and Nutrition and headquartered at UPMC Passavant. Sultan Mahmood, MD, is an expert in third-space endoscopy and is looking forward to expanding the application of cutting-edge interventional endoscopy at UPMC.



Sultan Mahmood, MD

From the esophagus through to the colon, the gastrointestinal (GI) tract is composed of organs with an endoluminal mucosal epithelium, a submucosal layer, muscular layers (the muscularis propria), and an outer serosa or adventitia. Third-space endoscopy takes advantage of the ability to separate the superficial mucosal layer and the deep muscular layers within the gastrointestinal tract and then use that space to perform interventions. We create this space through an incision in the mucosal epithelium, which is easy to close with standard endoscopic devices and is quick to heal after the procedure, thereby restoring luminal integrity. This access is minimally invasive and utilizes natural orifices, such as the mouth or the rectum, rather than skin incisions.

Third-space endoscopy gives us the ability to cut the muscular layers in the GI tract without surgery and to treat a number of conditions including achalasia, esophageal

diverticula, gastroparesis, and esophageal motility disorders that previously required surgery. Our team is applying third-space endoscopy to perform per oral esophageal myotomy (POEM) to treat achalasia via myotomy of the lower esophageal sphincter (E-POEM), Zenker's diverticulum via cricopharyngeal myotomy (Z-POEM), and gastroparesis via myotomy of the pyloric sphincter (G-POEM) (Table 1).¹

We are also using third-space endoscopy to remove large lesions, polyps, and early cancers of the GI tract through endoscopic submucosal dissection (ESD). ESD enables us to remove cancers that are still in superficial layers of the GI tract in their entirety and in one piece.² When we can completely remove a lesion using ESD, we save the organ and will likely have cured the patient. Traditionally, superficial lesions have been removed with endoscopic mucosal resection (EMR),

Table 1. Applications of Third-space Endoscopy

Third-space Procedure	Pathology Treated	Description
E-POEM	Achalasia	Myotomy of the lower esophageal sphincter
Z-POEM	Zenker's Diverticulum	Endoscopic division of the septum using a submucosal tunnel and cricopharyngeal myotomy
G-POEM	Gastroparesis	Myotomy of the pyloric sphincter
D-POEM	Esophageal diverticula (non-Zenker's)	Diverticulotomy through a submucosal tunnel; often accompanied by E-POEM
ESD	Superficial/early-stage esophageal, gastric and colorectal cancer	En bloc resection
STER	Subepithelial tumors of the esophagus and stomach	En bloc resection

E-POEM, esophageal per oral endoscopic myotomy; Z-POEM, per oral endoscopic myotomy to treat Zenker's diverticulum; G-POEM, gastric per oral endoscopic myotomy; D-POEM, per oral endoscopic myotomy with diverticulotomy/septotomy; ESD, endoscopic submucosal resection; STER, submucosal tunneling endoscopic resection.

which can only remove lesions <1.5-2 cm in diameter from the esophagus and <2-3 cm in diameter from the colon in a single piece. With ESD, we can remove much larger lesions. Recently at UPMC Passavant, we removed a 12-cm rectal tumor as a single piece. (Figure 1)

Keys to successful ESD include the ability to remove the lesion in one piece and pathologist confirmation that malignant lesions were completely removed after examining resection margins that include vertical margins. Appropriate patient selection is based on lesion location and gross morphology by an experienced gastrointestinal endoscopist. Prior to ESD, the size, location, and features of the target lesion are evaluated to determine if it is amenable to resection using this procedure.

Third-space endoscopy offers a unique approach to GI disorders and malignancies because it is minimally invasive and requires no incisions through the skin. Morbidity and mortality are extremely low. Patients recover much faster after third-space endoscopy than after open surgery and can often be discharged home on the same day as the procedure or the next day. In some studies, hospital stay after E-POEM to treat achalasia was shorter than after laparoscopic Heller's myotomy (LHM), the traditional minimally invasive

approach for treating achalasia.³ Other studies have suggested fewer complications after E-POEM as compared with LHM.⁴ Symptom relief after E-POEM and Z-POEM has proven durable in studies with multiyear follow up.⁵⁻⁷ When an en bloc resection was accomplished in patients undergoing ESD for superficial colorectal cancer, local recurrence occurred in only 0.6% of patients during a median follow up of six years, and five-year disease-specific survival was 100%.² Additionally, obtaining a complete specimen allows the pathologist to evaluate multiple tumor characteristics, including the presence or absence of lymphatic or vascular invasion (LVI), an important prognostic indicator in patients with colorectal cancer.

Multidisciplinary collaboration is a significant part of the third-space endoscopy program at UPMC Passavant, since continuity of care before and after the procedure is essential for successful outcomes. As an interventional endoscopist, I rely on the unique expertise of surgeons, gastric motility specialists, specialty nurses, advanced practice providers, and dietitians. This ensures that every patient who comes in for a procedure receives an appropriate surgical consult, an appropriate dietary consult, appropriate nursing care, and appropriate follow-up after their third-space endoscopy procedure.

Significant delays in the diagnosis and treatment of achalasia are typical due to the nature of the disease. Patients often have symptoms for four to five years before seeking diagnosis and treatment. Most of the patients who are coming in for third-space POEM procedures have had issues with eating for a long time and are malnourished. The dietitians on our team can evaluate if nutritional improvement is needed before they undergo the planned procedure. Fortunately, because third-space endoscopy is a minimally invasive procedure, we can often consider POEM in patients who are not surgical candidates due to frailty and other comorbidities. A stepwise approach to oral intake is needed during their recovery.

The ESD program at UPMC Passavant, in collaboration with the colorectal surgery team, is completely new and did not exist previously within the UPMC system. POEM is not new to UPMC — the Department of Cardiothoracic Surgery has been offering cutting-edge POEM procedures on a case-by-case basis for several years. Our new program at UPMC Passavant expands on this expertise significantly and is a robust, comprehensive program offering POEM for all disorders of the gastrointestinal tract that can be treated with myotomy. Our POEM program was developed in

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L-R: Suzanne Regney, RN, Lisa Jacobs, RN, Tiffany Rothermel, RN, Kate Frioni, RN, Jess Hogue, Sultan Mahmood, MD, April Morales.

Adopting Telemedicine for the Preoperative and Postoperative Care of Colorectal Surgery Patients (continued)

Twenty years ago, the total telemedicine pathway would have been unthinkable. Today, the evolution of consumer electronics and the EHR have made telemedicine easy, affordable, and an essential component of patient care. Care plans without the benefits of telemedicine would be a disservice to our patients. We are striving to develop evidence-based best practices for telemedicine in surgery and medicine and seek to pioneer new care delivery pathways.

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A Comprehensive Third-space Endoscopy Program at UPMC Passavant (continued)

consultation with Ryan Levy, MD, Department of Cardiothoracic Surgery. We anticipate that third-space endoscopy will be preferable to surgery in many patients.

To advance the field of interventional endoscopy and thereby improve care, we are tracking the outcomes of all patients who undergo third-space endoscopy at UPMC. After receiving consent from patients for participation in our database, we will track symptoms, comorbidities, and outcomes over time to improve our ability to predict clinical outcomes. We are also seeking to advance third-space endoscopy by pioneering and testing new techniques.

Third-space endoscopy is technically challenging due to the small space that the endoscopist can clear to work among the separated layers of the GI tract. Procedures require a high degree of dexterity, and there is a learning curve to acquire clinical knowledge and skills.⁸ After focusing on clinical program development during the first year, GI fellows will get the opportunity to learn third space endoscopy procedures and enhance their clinical skills starting in summer 2024.

Third-space endoscopy procedures are groundbreaking and available only at specialized centers. We are proud to have the expertise and support for this specialized care at UPMC centers. It is an exciting time to be an interventional endoscopist at UPMC!

Note: *Dr. Mahmood recently gave a presentation titled "Recent Advances in Third-space Endoscopy" that can be viewed through UPMC Physicians Resources (<https://www.upmcphysicianresources.com/cme-courses/recent-advances-in-third-space-endoscopy>) until December 11, 2024, for further information on third-space endoscopy and the opportunity to complete an additional learning activity for AMA CME credits.*

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What Is This?



Sagar Joshi, MD
Gastroenterology & Hepatology
Fellow, Year III

A 40-year-old female patient with a history of Crohn's disease, Ehlers-Danlos Syndrome, poor nutritional intake requiring total parenteral nutrition, and chronic pain presented to establish care. She has a complex surgical history including a subtotal colectomy for Crohn's colitis. She underwent a small bowel resection for a small bowel volvulus; the procedure was complicated by an ischemic stricture requiring resection and an end jejunostomy. In addition, she underwent a duodenal derotation for superior mesenteric artery syndrome. Her primary symptoms included abdominal pain, nausea, vomiting, poor oral intake, and constipation. She brought a copy of her computed tomography (CT) scan of her abdomen and pelvis.



What is the diagnosis? Compare your answer to Dr. Joshi's.

Patient's Outcome (turn over to read)

Her CT scan shows visceroptosis, a prolapsing or sinking of abdominal organs below their natural positions. She has significant dilation and elongation of her stomach (gastroptosis) which extends from the left upper quadrant to her pelvis abutting her bladder (Figure 1). Visceroptosis was first described in the late 1800s and is a rare phenomenon with largely unknown etiology. Relaxation of ligaments that hold the viscera in place may play a role, and this has been previously reported in patients with Ehlers-Danlos Syndrome. Although patients with visceroptosis may be asymptomatic, most patients have nonspecific symptoms including abdominal pain, dyspepsia, reflux, nausea, vomiting, constipation, and diarrhea. Patient symptoms result from severe organ sinking leading to compression of other internal organs or kinking of smaller structures including blood vessels and nerves. Treatment of this condition usually involves symptom-guided therapy with the use of antiemetics, prokinetics, laxatives, etc. Surgical intervention may transiently improve symptoms but then may worsen the patient's overall health status.

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Low-level Exposure to Vinyl Chloride: Modeling the Impact on the Liver

In February 2023, a train derailed in East Palestine, Ohio, resulting in a hazardous chemical spill, massive fire, and evacuation of nearby residents. Many residents in western Pennsylvania and eastern Ohio began to consider the potential dangers of spilled toxins. Juliane Beier, PhD, Division of Gastroenterology, Hepatology and Nutrition, has been interested the hazards posed by vinyl chloride (VC) for years and has developed animal models to examine the potentially deleterious effects of VC at levels currently considered safe.



Juliane I. Beier, PhD
Assistant Professor of Medicine
Division of Gastroenterology,
Hepatology and Nutrition

Over 15 billion pounds of vinyl chloride (VC) are produced in the United States each year to enable the manufacturing of polyvinyl chloride (PVC) and other plastics. PVC is used in the construction industry as well as drinking water pipes, wire and cable insulation, plastic bottles, and medical devices. Increasingly, VC, an organic volatile compound, is being recognized as an occupational and environmental toxicant. Acute exposure to VC irritates the eyes and respiratory tract and impacts the central nervous system, causing dizziness, drowsiness, headache, loss of coordination, visual disturbances, and coma or death at very high concentrations. In the 1970s, exposure to high doses of VC was linked directly to a very rare liver cancer that developed in workers at a B.F. Goodrich plant in Kentucky. Chronic exposure to VC can also cause permanent liver damage and neurological symptoms.¹ Although we have known for decades that chronic exposure to high concentrations of VC

causes cancer, we do not know the impact of chronic exposure to lower concentrations of VC, and whether exposures deemed “safe” by United States Occupational Safety and Health Administration (OSHA) are, in fact, benign. My laboratory is studying the impact of low-level exposure to VC on liver health, especially its impact in the presence of underlying liver disease and other risks.

To model the potential health impacts of low levels of VC at concentrations deemed safe by OSHA (<1 ppm), such as one might see in a working environment, we exposed mice to 0.85 ± 0.1 ppm VC for six hours a day, five days a week. To model underlying liver disease that may be exacerbated by VC exposure, we fed mice a hypercaloric diet, similar to a Western diet, that causes obesity and then asked if the early stages of the accompanying liver disease were affected by low-level VC exposure.² This may be a very pertinent model as ~40% of Americans are obese, and the

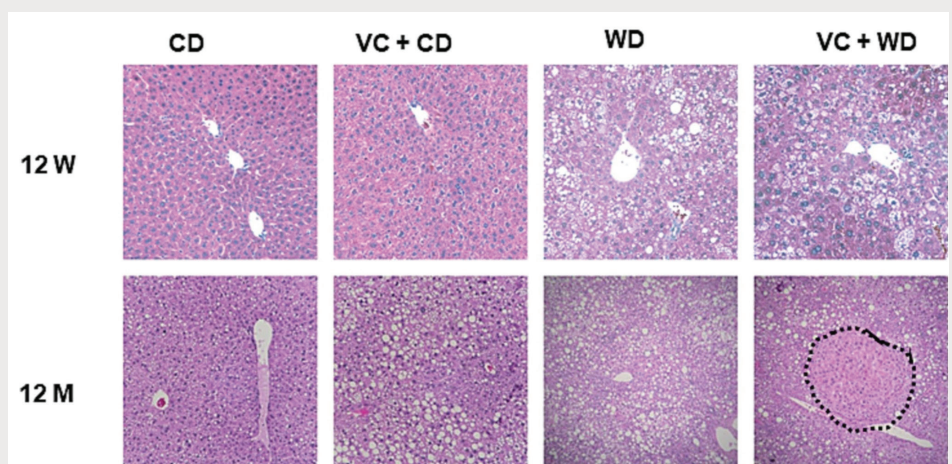


Figure 1. Vinyl chloride enhances pathological changes to the liver initiated by a high-fat/high-carbohydrate, “Western” diet. A hepatocellular carcinoma is outlined in the bottom right panel. 12W, 12 weeks; 12M, 12 months; CD, control diet; VC, vinyl chloride; WD, Western diet. Reprinted from reference 4, Copyright (2023), with permission from Elsevier.

proportion of Americans with obesity is trending upward.

Ingestion of the hypercaloric diet for 12 weeks led to fatty liver, or hepatic steatosis, with little inflammation and without any other liver pathology. The combination of a fatty diet and VC exposure, five days a week for 12 weeks, led to inflammation, metabolic dysregulation, and liver damage characteristic of toxicant-associated steatohepatitis (TASH)^{2,3} This proved our hypothesis that exposure to low levels of VC enhances early disease states. Even more strikingly, when we let these mice sit for nine months with no additional VC exposure, 100% got liver tumors, most of which were verified as hepatocellular carcinoma (HCC) through immunostaining and assessment by a pathologist (Figure 1).⁴

To study the mechanisms underlying the development of HCC in our mouse model, we performed transcriptomics. This large-scale analysis revealed a gene signature associated with changes in metabolic processes after 12 weeks of VC exposure. When we examined the transcriptome 12 months after VC exposure, we again saw a gene signature associated with changes in metabolic processes but also saw ribosomal changes and changes in RNA processing. Moreover, when we compared the gene signature identified in the mice fed a Western diet and exposed to VC 12 months after VC exposure with human gene signatures in The Cancer Genome Atlas (TCGA), the signature in the mice correlated strongly with the known signatures for two HCC subtypes in humans.⁴ These two subtypes are associated with higher mortality than some other HCC subtypes even though the affected patients were younger, had less fibrosis, and had fewer known risk factors. This dichotomy in profiles in TCGA indicates unidentified risk factors. Thus, environmental chemicals, including but not limited to VC, are likely previously unidentified risk factors that impact whether a patient with fatty liver disease will develop cancer.

We are currently expanding our mouse models to assess the impact of VC at low levels in combination with other insults that lead to liver damage, such as alcohol-associated liver disease, to see

if other liver pathologies are exacerbated by VC and if other liver insults also increase the risk of developing liver cancer in synergy with VC.

Further research is clearly needed to determine if the current safety limits on VC exposure pose a risk to a subset of the individuals exposed. For example, will individuals suffering from obesity or alcohol-associated liver disease be particularly susceptible to HCC after chronic low-level VC exposure? Our animal models justify asking these questions. The previously unidentified interaction between VC and underlying steatotic liver diseases that we discovered raises concerns that the risk from low-level VC exposure may be underestimated.

We have focused on animal models, in part, because groups of individuals with defined low-level exposures to VC had not been identified. The citizens exposed to VC in East Palestine, Ohio, after the February 2023 train derailment and exposed in Paulsboro, N. J., after a 2012 derailment that resulted in a 23,000-gallon VC spill may provide study cohorts that have a low or known exposure. A biobank has been proposed to examine biomarkers that serve as indexes of liver damage as part of the follow-up to the East Palestine disaster. We are also attempting a geospatial analysis using PCORnet[®], an infrastructure resource launched in 2013 by the Patient-Centered Outcomes Research Institute (PCORI), to find individuals who lived or worked near Paulsboro in 2012. We may discover that these individuals are experiencing health effects with unidentified sources that might be attributable to VC exposure. Because 11 years have passed since the VC spill in Paulsboro, the timing would be particularly amenable to study the long-term impacts of VC exposure and to track patients and their health issues over the years. This should be a goal when following the individuals exposed in East Palestine, as well.

Dogma in the field of occupational medicine has long advised that exposure to <1 ppm of VC per workday (OSHA's permissible exposure limit) is safe, although there has never been high-level evidence that this is true. Through our

research and the work of a handful of others, awareness of the effects of chronic exposure to low levels of VC and the interactions of VC exposure with a variety of commonly observed liver pathologies is increasing. The health implications of co-exposure to a high-fat diet and low-levels of VC are likely underappreciated with our current knowledge base, and current safety restrictions may be insufficient to account for other factors that influence hepatotoxicity. Our work at UPMC may prove essential in redefining employee and community safety protocols.

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Leveraging Big-data Analytics to Understand Inflammatory Bowel Disease

Faced with the challenge of making precision medicine an effective reality for patients with inflammatory bowel disease (IBD), David Binion, MD, and his team leveraged the UPMC electronic medical record and big-data analytic techniques to create a metadata platform for scientific discovery. They are now performing cutting-edge research using this resource to understand the clinical features of IBD, better target treatment recommendations, and expand prognostic capabilities for patients with IBD.



David Binion, MD

Professor of Medicine, Clinical and Translational Science

Co-Director, IBD Center

Director, Nutrition Support Service

Medical Director, Intestinal Rehabilitation and Transplant Center

UPMC Presbyterian Hospital

Inflammatory bowel disease (IBD) is a chronic, lifelong inflammatory disorder of the gastrointestinal tract. Care for patients with IBD is multifaceted and may include preventative measures comprised predominantly of medical therapeutics (both for maintenance and to treat acute flares and accompanying pain), dietary modifications, and surgical treatments. While IBD is commonly divided into two disorders — Crohn's disease and ulcerative colitis — this classification is an oversimplification of a heterogeneous disease. IBD is a complex syndrome, and over 200 genetic polymorphisms associated with the development of IBD have been identified. To effectively treat IBD, we need to implement strategies informed by each patient's genetics, symptoms, and risk profile. When we understand the complexity of IBD, we can begin to realize the dream of precision medicine.

Establishing the UPMC IBD Natural History Registry and a Metadata Platform

UPMC's electronic medical record (EMR) presented a fantastic opportunity to better understand and characterize the heterogeneity of IBD. The UPMC EMR is one of the largest repositories of comprehensive medical data in the country and has been in use longer than many other EMRs. We set out to develop tools using UPMC's vast EMR and big-data analytic tools informed by our ability to track outcomes and patient trajectories over time. Our goal was, and remains, to gain an essential understanding of each of the many biologic endotypes of IBD in order to reverse engineer treatments that

will drastically improve the quality of life (QoL) for individuals with IBD.

We have accrued over 5,000 patients in the UPMC IBD Natural History Registry, a prospective, longitudinal registry (Clinicaltrials.gov NCT 04243525), by recruiting most patients who receive care at the UPMC Center for Inflammatory Bowel Disease for registry participation.¹ When patients consent to registry participation, we obtain not only current clinical data and clinical information, but also medical data from their EMR from 2009 to the present. Moreover, the database builds off each prior project and curates and transforms observational clinical information from the EMR continuously.

Potentially useful metrics are built into clinic encounters that are then documented in the EMR. Additionally, for patients treated at the UPMC Center for Inflammatory Bowel Disease, the EMR contains surveys completed in the clinic, including quantitative pain assessments, dietary surveys, QoL surveys, and surveys assessing anxiety, depression, and other psychosocial measures. Health care charges have also been included in the registry database and are used as a markers of disease severity. Using the EMR as the data source for registry studies reduces the burden of participation for both the patient and their physician and promotes patient retention.

Starting with the Epic and Cerner EMR systems, we learned how to pull patient data, how to extract information from that data, and how to store it securely. We developed a simple platform with

programming in Microsoft Excel. In collaboration with Claudia Ramos Rivers, MD, a research analytic scientist at the University of Pittsburgh School of Medicine, and with help from faculty affiliated with the University of Pittsburgh School of Computing and Information and School of Public Health, we tackled each challenge encountered to create a flexible metadata platform to handle data from the EMR responsibly and safely (Figure 1). The platform also uses natural language processing to extract health information that is not entered into the EMR in a standardized format. Examples include patient discharge summaries, surgical notes, pathology reports, and clinic notes.

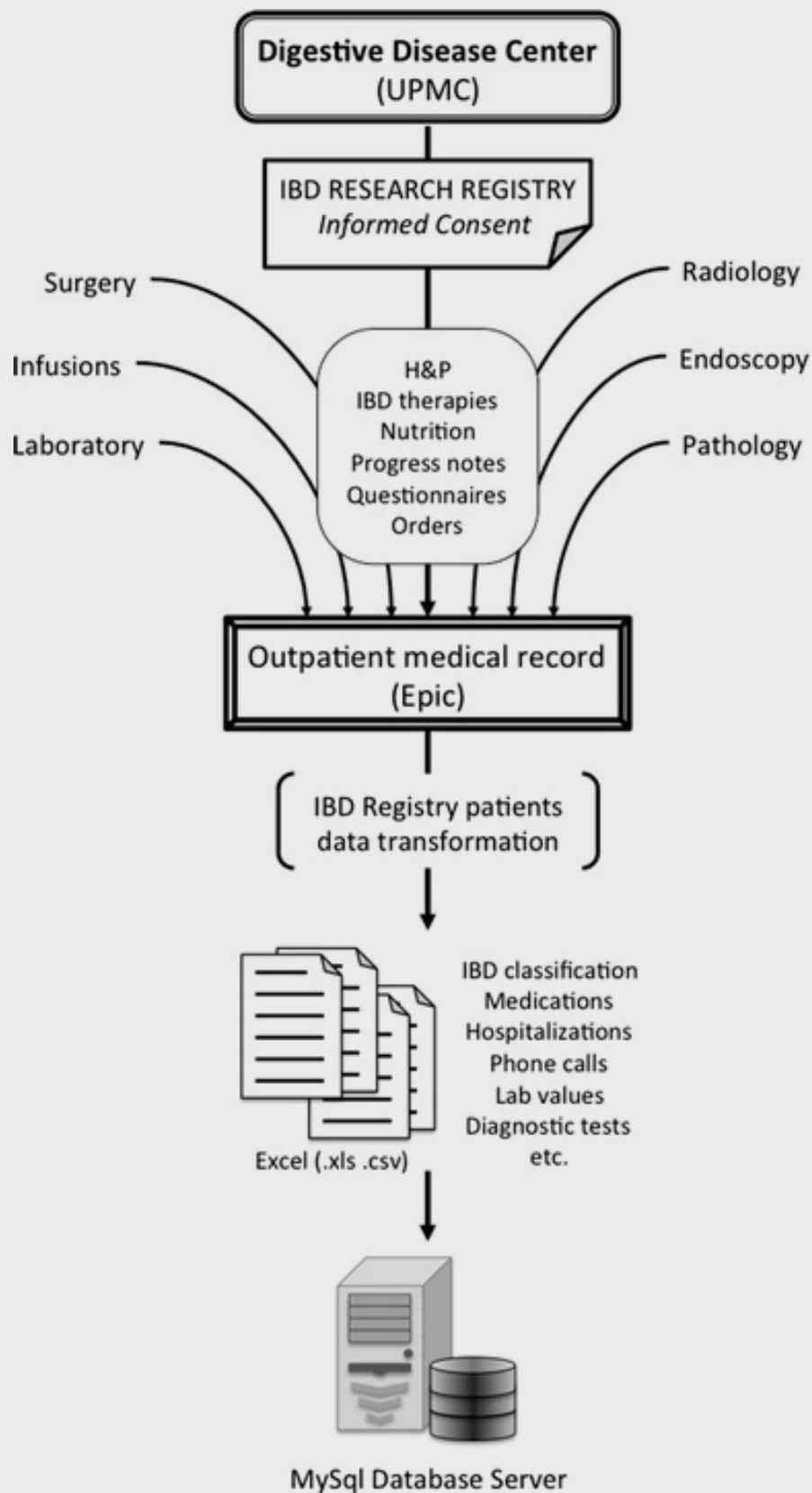
In developing resources to study IBD, we have taken a different approach to tissue and blood banking than that commonly used. We have cataloged every pathological specimen obtained during care and now have approximately 20,000 colonoscopy samples for easy study access. Additionally, we have well over 3 million time-stamped laboratory results from patients to capture the natural history of IBD. This totals over 3 terabytes of clinical data.

Identifying IBD Phenotypes

The IBD research registry offers a unique opportunity to investigate clinical research questions regarding the natural course of the disease, phenotype associations, effectiveness of treatments, and quality of care. Tracking the natural history of IBD using big data and this meta-platform have provided insight into subsets of IBD patients who likely have different disease endotypes, potentially enabling benefits from different treatments (Figure 2).

For example, to identify IBD subtypes using the meta-platform, we examined multiyear patterns of health care charges. IBD phenotypes that necessitate consistently high or consistently low levels of health care utilization were identified, taking multiple utilization measures (office visits, telephone calls, hospitalizations, ER visits, radiological procedures, endoscopic procedures, and surgeries) into account.²

Figure 1. Flow diagram of the UPMC inflammatory bowel disease research registry. IBD, inflammatory bowel disease; H&P, history and physical. (From Anderson AJ, et al. *Dig Dis Sci.* 2016;61(11):3236-3245.)



Biomarkers of IBD Severity

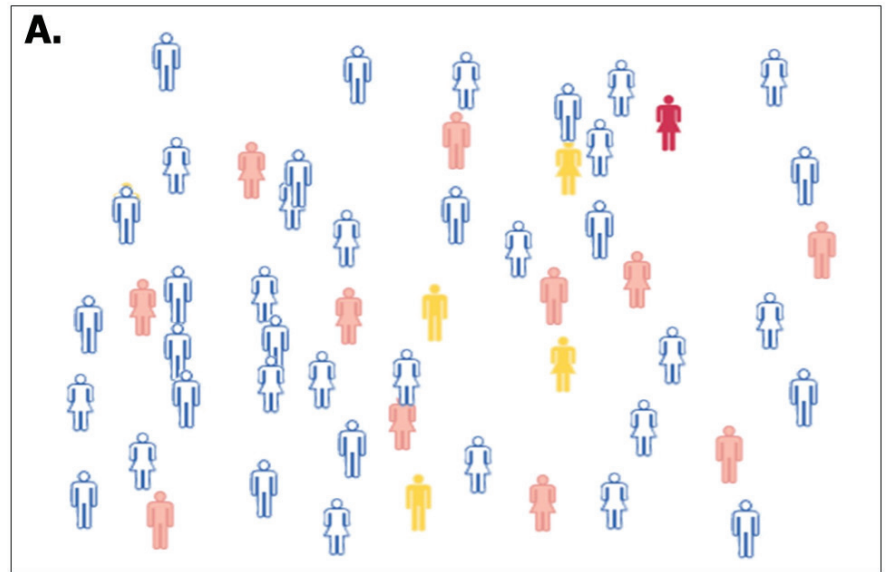
Biomarkers of IBD severity were another early research priority for this registry. We sought to identify markers obtained from laboratory data or pathology reports that would identify which individuals were at higher risk for health difficulties due to IBD as well as more rapid presentation of the health challenges associated with IBD. Peripheral blood eosinophilia (PBE) and elevated monocyte count are two biomarkers of IBD severity identified from routinely available lab results.

PBE is a defining feature of the type-2 immune response, is a well-characterized marker of asthma severity, and had been linked to IBD severity.³ Using the IBD registry, we demonstrated that laboratory findings of PBE are more common in patients with pediatric-onset IBD than in patients with adult-onset IBD. In adult patients with pediatric-onset IBD, PBE was associated with higher health care utilization, so the presence of PBE further stratified a subset of patients already at risk for severe IBD.⁴ This study provides insight into medications that may better support IBD management in patients with this profile.

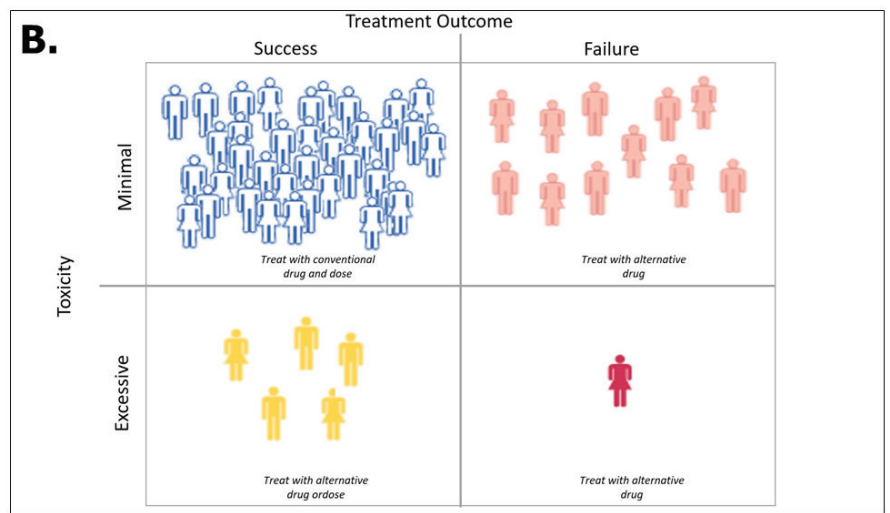
Similarly, using the registry, we found that approximately one-third of patients with IBD had an elevated monocyte count over a six-year observation period. Patients with IBD accompanied by monocytosis had an increased likelihood of hospitalization, IBD-related surgery, or emergency department use. Monocytosis was also predictive of an earlier need for this advanced care.⁵

The IBD registry offers a better understanding of which patients may benefit from more aggressive surgical and surveillance approaches. When patients with Crohn's disease undergo ileocecal resection for strictures caused by cumulative damage from IBD, epithelioid granuloma (a type of immunological scar) is found in 20%-30% of resected specimens in routine pathological analysis. When the registry was utilized to examine the prognostic value of granuloma detection, the presence of a granuloma was associated with higher rates of steroid and narcotic use, higher health care utilization, and the need for repeat surgery

Figure 2. Toward precision medicine.



A. Variability in patients with IBD remains underappreciated.



B. Our goal is to leverage what we learn about individuals to make personalized decisions, such as the correct drug and dose, to improve the health of the overall population.

during a six-year observation period. In fact, this histologic data was a better predictor of the need for further surgical intervention over an 11-year observation period than colonoscopy findings after surgery.^{6,7}

Toward Individualized Treatment of IBD

Treatment of IBD cannot be a one-size-fits-all endeavor. We currently have tools and medications that may change the clinical trajectory of some patients, but we need to know which patients will benefit,

because stronger and more aggressive treatments often have side effects or clinical trade-offs affecting quality of life (Figure 2).

Studies leveraging the registry may also improve recognition of which patients with IBD are most likely to benefit from dietary modifications. Recently, we studied the influence of the consumption of sugar-sweetened beverages, such as non-diet soda, juice drinks, sports drinks, and energy drinks, on the long-term clinical trajectory of patients with IBD.

High consumption of sugar-sweetened beverages was linked with increased time to hospitalization and quicker time to a first emergency department visit in patients without active disease at the time of study enrollment. High consumption of sugar-sweetened beverages was also associated with elevated markers of disease severity (anemia, monocytosis, and eosinophilia) and elevated inflammatory biomarkers.⁸ Additionally, the metadata platform has been used to identify subsets of patients with IBD, those with positive celiac serology without histopathologic findings of celiac disease. These patients may benefit from a gluten-free diet, since a gluten-free diet was correlated with a reduction in the burden of inflammation in these patients.⁹

Many potential therapies for IBD have shown only modest effects in clinical trials, with <40% of participants responding to treatment in many trials. We believe this can be attributed to the heterogeneity of patients with IBD and the existence of different disease endotypes. This metadata platform will greatly facilitate the development of treatments for patients with IBD, because it can complement ongoing and completed clinical trials and inform future trials leading to clinical breakthroughs. By identifying the biomarkers that define IBD disease subtypes, we may be able to revisit the results of completed clinical trials to examine if the percentage of respondents to therapies with a particular IBD subtype is higher than that assessed in the whole study cohort. Identifying IBD endotypes can also inform new clinical trial design, such that different subgroups of patients with IBD are targeted.

Moreover, when evaluating response to therapy, patients with IBD need to be tracked for three to five years. Clinical trials often do not include this length of follow up, as a one-year follow-up is typically required by the United States Food and Drug Administration (FDA). As a result, post-FDA-approval studies of therapies are needed to truly evaluate the efficacy of many therapies in patients with IBD. Our meta-platform should greatly facilitate this type of analysis,

which is crucial to the management of a lifelong disease.

The longevity of the UPMC EMR was not the only benefit of establishing this registry within the UPMC health care system. The registry contains participants from the entire UPMC network — 40 hospitals and >600 outpatient clinics — and is supported by robust computer informatics expertise at both UPMC and the University of Pittsburgh. Thus, the UPMC network allows us to assess differences in care and clinical trajectories between the tertiary referral and community settings.

The Promise of Precision Medicine for IBD

Establishing the UPMC Natural History Registry and the ability to extract and securely store its metadata was a foundational step to understand the complexity of IBD. We have established the infrastructure necessary to examine the disease course of different IBD endotypes and the effectiveness of treatments in a real-world setting. We hope to soon reap the benefits of this investment of time, money, and effort. Through the application of big-data analytics and the clarification of the natural course of IBD subtypes, we are on the brink of implementing precision medicine for IBD.

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News and Updates

The Division of Gastroenterology, Hepatology and Nutrition Is Pleased to Welcome Scott Biggins, MD, MAS, and Kiran Bambha, MD, MSc, to UPMC Liver Care.



Dr. Biggins has joined our faculty as chief of Hepatology and UPMC Liver Care, as well as medical director of Liver Transplant and co-director of Clinical Research for the Starzl Transplant Institute. He received his medical degree at the University of Southern California and completed an Internal Medicine residency at the

Oregon Health & Science University. He then completed his Gastroenterology fellowship and a Masters Degree in Clinical Research at the University of California in San Francisco (UCSF). Dr. Biggins has held numerous leadership positions as an attending and researcher at UCSF, the University of Colorado, and the University of Washington. Nationally, he leads and develops organ allocation health policy as a chief of the UNOS/OPTN Liver and Intestinal Organ Transplantation Committee. Notable research includes his work to create and implement the MELD-Na score as the tool for prioritizing patients for liver transplant in the United States and, more recently, the MELD 3.0 score that reduced long standing disparities for women. His current research includes the development of continuous distribution models for organ allocation and a NIH funded multi-center project assessing immunosuppressive protocols to protect renal function after liver transplantation.



Dr. Bambha will join UPMC as the medical director for Hepatology and as the director of operations and quality for Liver Care and Liver Transplantation. She received her medical degree at Tulane University, followed by her internship and residency at the Mayo Clinic in Rochester, Minnesota. Dr. Bambha stayed at the Mayo Clinic for

her gastroenterology and hepatology fellowship, which included T32 research training, followed by a targeted transplant hepatology fellowship at UCSF. She served as an attending at the Mayo Clinic, UCSF, University of Colorado, and the University of Washington. Dr. Bambha's practice is centered on Living Donor Liver Transplant (LDLT) and Metabolic Dysfunction-associated Steatotic Liver Disease (MASLD). She is also interested in epidemiologic surveys to assess factors that impact decisions for organ donation and potential wait list removal, as well as Diversity, Equity, and Inclusion (DEI) projects.

Thank You to David Whitcomb, MD, PhD



With fond gratitude, we acknowledge the retirement of pancreatology thought leader David Whitcomb, MD, PhD. He served as a tenured professor of Medicine, Cell Biology and Physiology, and Human Genetics, as the Giant Eagle Foundation Professor of Cancer Genetics, and led the Division of Gastroenterology, Hepatology and Nutrition

as chief for 13 years. Dr. Whitcomb continues to be part of the division in an emeritus capacity.

Dr. Whitcomb's research and discoveries resulted in a major paradigm shift in our understanding of inflammatory disease of the pancreas. He published more than 200 peer-reviewed manuscripts and edited 10 books on pancreatic disease. His laboratory is renowned for its discovery of the gene variants that cause hereditary pancreatitis, familial pancreatic cancer, and primary genetic risks for alcoholic chronic pancreatitis, as well as a new CFTR-associated syndrome.

He held leadership positions with virtually all of the major pancreatology associations and was a co-founder of the Midwest Multicenter Pancreatic Study Group, the North American Pancreatic Study Group, and the Collaborative Alliance for Pancreatic Education and Research. He also founded and co-directed the annual PancreasFest translational research conference. In retirement, Dr. Whitcomb will focus on his grandchildren and Ariel Precision Medicine, his biotechnology company focusing on complex trait genetics and precision medicine.

Readers are encouraged to read his publication in *Pancreatology*, reflecting on his George E. Palade Medal Award Lecture, "Innovation and Hard Work," presented in Shanghai, China, in 2015. This medal is the highest honor awarded by the International Association of Pancreatology.

UPMC Total Care-IBD: Accepting Referrals

As the nation's first patient-centered, multidisciplinary program for people with IBD, UPMC Total Care-IBD provides UPMC Health Plan members with enhanced access to an IBD gastroenterologist, specialized health care professionals (including a dietitian, behavioral health counselor, etc.), and a full spectrum of support services to develop personalized treatment plans. Patients who prefer to remain with their existing gastroenterologist can still enroll and take advantage of the program's offerings.

- To schedule an appointment, call **412-647-2183**.
- To request an in-person or virtual educational Grand Rounds or a discussion with our team, email joj2@pitt.edu.

EVENTS

New Paradigms in Gastrointestinal Surgery and Medicine

Reception: Friday Nov. 8, 2024

5:30 to 7:30 p.m.

Conference: Saturday, Nov. 9, 2024

7:30 a.m. to 3 p.m.

Omni William Penn Hotel

520 William Penn Place

Pittsburgh, PA 15230



UPMC Pittsburgh Gut Club

Treatment Advancements: Alcoholic Hepatitis

Presented by Philippe Mathurin, MD, PhD

Tuesday, Nov. 12, 2024

5:30 to 8 p.m. ET

To learn more about the UPMC Division of Gastroenterology, Hepatology and Nutrition, please visit

UPMCPhysicianResources.com/GI.

Milestones

Shari Rogal, MD, received a \$6.5 million PCORI grant with co-PI **Andrew Gawron, MD, PhD**, to study “Comparing Effectiveness of Implementation Strategies to Improve Cancer Screening for Veterans.”

Rocky Schoen, MD, MPH, and **Dhiraj Yadav, MD, MPH**, received two of the total eleven American Gastroenterological Association (AGA) Institute Council Research Mentor Awards at Digestive Disease Week 2024. Dr. Schoen was honored for his mentorship contributions in clinical practice, and Dr. Yadav was recognized for his mentorship among pancreatic disorders colleagues.

Jaideep Behari, MD, PhD, was named an Associate Director for the Pittsburgh Liver Research Center (PLRC), which is led by **Paul Monga, MD**. **Gavin Arteel, PhD**, co-leads the PLRC’s Pilot and Feasibility Program. Dr. Behari also received the UPMC Award for Commitment and Excellence in Service (ACES) in 2024. Each year, fewer than 1 percent of UPMC staff from across the health system receive this honor.

Dhiraj Yadav, MD, MPH, received the Senior Mentor Award from the Collaborative Alliance for Pancreatic Education and Research at the PancreasFest 2023 conference.

David Binion, MD, received the Top UPMC Physician by Specialty Award for Gastroenterology in 2023. Dr. Binion was among only 48 awardees, selected from 5,000+ UPMC physicians.

The UPMC Pancreas Team was recognized at the October 2023 National Pancreas Foundation Courage for the Cure Gala at PNC Park. **Dhiraj Yadav, MD, MPH**, and **Amer Zureikat, MD**, received the Courage Award in Pancreatitis and Pancreatic Cancer. **David Whitcomb, MD, PhD**, received the NPF Legacy Award, and **Anna Evans Phillips, MD, MS**, received the Rising Star Award.

Clinical Name Updates:

- The Digestive Disorders Center (DDC) has been renamed to UPMC Digestive Health Care (DHC).
- The Center for Liver Diseases has been renamed to UPMC Liver Care.

Both name changes prioritize attention to patient health.

The UPMC Division of Colon and Rectal Surgery earned a three-year accreditation from the National Accreditation Program for Rectal Cancer (NAPRC), a quality program of the American College of Surgeons.

UPMC Division of Gastroenterology, Hepatology and Nutrition

EDITORS

Janet R. Harrison, MD
Joy Jenko Merusi, MA

ADDRESS CORRESPONDENCE TO:

Joy Jenko Merusi
joj2@pitt.edu

For consults and referrals, please call UPMC’s 24-hour physician OnDemand service at **1-866-884-8579**.

To learn more about the UPMC Division of Gastroenterology, Hepatology and Nutrition, please visit [UPMCPHYSICIANRESOURCES.COM/GI](https://www.upmc.com/physicianresources).

UPMC
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About UPMC

UPMC is a world-renowned, nonprofit health care provider and insurer committed to delivering exceptional, people-centered care and community services. Headquartered in Pittsburgh and affiliated with the University of Pittsburgh Schools of the Health Sciences, UPMC is shaping the future of health through clinical and technological innovation, research, and education. Dedicated to advancing the well-being of our diverse communities, we provide more than \$1 billion every year in community benefits, more than any other health system in Pennsylvania. Our 100,000 employees — including more than 5,000 physicians — care for patients across 40 hospitals and 800 doctors’ offices and outpatient sites in Pennsylvania, New York, and Maryland, as well as overseas. UPMC Insurance Services covers more than 4 million members with a focus on providing the highest-quality care at the most affordable price. To learn more, visit [UPMC.com](https://www.upmc.com).