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## **Editor's Letter**



# Disinformation

Columbia Retracts Cancer Research Studies

Remember the days when you felt like you knew what information to trust? Now, in an age when disinformation runs rampant, many people feel they don't know where to turn. Is the information we consume true, false, or worse yet, purposely false?

Disinformation is different than misinformation. Misinformation is a mistake (a good way to remember that is the "mis" in misinformation is like the "mis" in mistake). Disinformation, on the other hand, is false or misleading information shared with the intention of manipulation or to mislead, and it's being spread with reckless abandon. But we can at least trust medical studies from our nation's finest research institutions, right?

Um, yes. But note the "um." I offer apprehension because after recent news of unforgivable publication problems, perhaps we need more reservation than we used to have.

According to a recent New York Times article titled, "More Studies by Columbia Cancer Researchers Are Retracted," Columbia studies were pulled due to copied data. These cases indicate that some scientific publishers are slow to address serious errors such as data discrepancies and reuse of photos.

"Scientists in a prominent cancer lab at Columbia University have now had four studies retracted and a stern note added to a fifth accusing it of 'severe abuse of the scientific publishing system," the article reads.

In addition, the New York Times reported that "a medical journal in 2022 had quietly taken down a stomach cancer study by the researchers after an internal inquiry by the journal found ethics violations. Despite that study's removal, the researchers—Dr. Sam Yoon, chief of a cancer surgery division at Columbia University's medical center, and Changhwan Yoon, a more junior biologist there—continued publishing studies with suspicious data. Since 2008, the two scientists have collaborated with other researchers on 26 articles that have been publicly flagged for misrepresenting experiments' results."

Since then, medical journals pulled three other studies that described novel approaches for treating cancers of the stomach, head and neck. The studies had been cited dozens of times.

"For every one paper that is retracted, there are probably 10 that should be," said Dr. Ivan Oransky, cofounder of Retraction Watch, which keeps a database of 47,000-plus retracted studies.

Disconcerting, to say the least. We should trust most information from researchers and from universities, but clearly, we shouldn't trust it all. We can forgive mistakes, because we all make them. But intentionally misleading? No. This research situation is gross, and that's not disinformation.

Michelle Beaver

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# ENDOPRO All Stars

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## **Ascension St. Elizabeth Day Surgery Center** 'Together, We Can Do Something Wonderful'

By Shannon Rucynski, RN, CGRN, GI Service Line Coordinator

Our team is a true family (minus the dysfunction).

We work at Ascension St. Elizabeth Day Surgery Center in Menasha, Wisconsin, and get along very well on the clock and have fun outside of work, too. Our group consists of three board-certified gastroenterologists, nine registered nurses and five technicians. As most in our industry know, adenoma detection rate (ADR) is a quality measure for endoscopy facilities. ADR looks at the rate at which a physician finds precancerous polyps during a screening colonoscopy. A physician's ADR has become a gold standard for quality. The American Society of Gastrointestinal Endoscopy has determined that a minimal benchmark rate should be 25% average overall. Our three

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physicians have ADRs greater than 50% overall. We are all very proud of this and love bragging to patients about it.

We have a fairly large service line, including colonoscopies, gastroscopies, Barrett's abla-

tion, hemorrhoid ligation with the HET system, reflux services including Bravo and DigiTrapper, esophageal and anorectal manometry, endoscopic ultrasound (EUS), and endoscopic retrograde cholangiopancreatography. Additionally, one of our gastroenterologists recently became board certified in obesity medicine and is starting to

Every year we come up with a slogan to promote colon-cancer awareness, and the team gets together and dresses up for a photo shoot. We have done a superhero theme (saving lives), boxing (knocking out cancer), and plumber (flushing colon cancer down the toilet).

do Orbera intragastric weight-loss balloons, which we are super excited about!

Our pre-op and recovery nurses do a fantastic job teaching patients how to increase fiber in their diets, the importance of probiotics, when to best take their reflux medicine, and the importance of a repeat colonoscopy if polyps were found or if they have a family history of colon cancer. We also coordinate same-day CT scans for a newly diagnosed mass and any additional labs that need to be drawn, all while providing emotional support for the patient and their family.

One of our gastroenterologists, Dr. Sudeep Sodhi, M.D., gives a biannual talk (pre-COVID) called, "We Are What We Eat: A Gastroenterologist's Perspective." He opens his talk with a disclaimer, stating that if the audience members listen to him, it will be bad for his business. He—along with his partners—truly cares about the health of our community.

My colleague Sara Clark, RN, MSN, says, "The unique cohesiveness of our GI team is apparent in everything we do. Our goal is to ensure patients feel comfortable and well cared-for during their visit. From preadmission through discharge, our exceptional teamwork is evident every step of the way. We all understand the importance of one another and appreciate what each staff member brings to the table. The synergy is undeniable. Not a workday goes by that I don't hear a comment about our team's cheerfulness, love of our work, or exceptional care with a smile (which was even more obvious before we had to mask every day!). Work isn't work when you love what you do and those who surround you. I truly feel blessed to have such a remarkable work family."

Another team member, Vikas Khullar, M.D., says, "With three board-certified physicians who believe 'there is no I in TEAM' and work hard to provide high-quality, cost-effective and patient-centered care, I can say our GI team is the best. Be it day or night, we all enjoy getting up and taking care of patients, while at the same time having fun. Each member is treated as an integral part of the team, providing education and support, not only to patients, but also to each other. Outside of work, we get together to have Liver Rounds/ Happy Hour (it's Wisconsin, after all!) and various team activities. I am proud to be a part of this awesome team!"

We all believe that a team that plays together, stays together. Almost everything we do outside of work has a can-

> cer-awareness flair. We have done marathon relays wearing shirts that were specifically designed to promote screening colonoscopies. We ring bells for the Salvation Army at Christmastime, hand out pens with colon-cancer ribbons on them, and encourage patrons to come see us at work. We have pedaled around our downtown on a Pedal Pub, holding up signs

that read, "Clear liquids can be fun," and telling everyone we meet to make sure they get their screening when it is time.

Every year we come up with a slogan to promote coloncancer awareness, and the team gets together and dresses up for a photo shoot. We have done a superhero theme (saving lives), boxing (knocking out cancer), and plumber (flushing colon cancer down the toilet). For a football theme (tackling), we all wore the #50 jerseys from our area high schools to signify the importance of screenings at age 50. Most recently, we featured a fire theme, because we want nothing more than to extinguish colorectal cancer. We also make our picture into a holiday card and send it to all our referring physicians in hopes they remember to send patients for their screening.

About five years ago, two of our three gastroenterologists quit on the same day, leaving just Dr. Sodhi. We were able to hire a locum gastroenterologist to help him, but for the most part he carried the load by himself, doing most of the daily colonoscopies and gastroscopies. He also performed all the EUS and ERCP cases. He did this for two years. We were all very thankful that he decided to keep going, even when the going got tough. One of his reasons for not leaving was the people of our community.

It wasn't easy finding someone who wanted to join a practice in small-town Wisconsin, but we were patient. Vikas Khullar, M.D., joined our team about three years ago, and he was definitely worth the wait. About a year ago, we hired Dr. Sankalp Dwivedi, M.D., to complete our team, and he has been a fantastic addition. All three of them bring something special to the table, and they all complement each other nicely. Besides being excellent endoscopists, these physicians have impeccable bedside manners and compassion, and treat staff with kindness and respect. We now have an All-Star team, and this challenging time of COVID has made us realize firsthand that every cloud has a silver lining.

If I had to sum up our team, I'd have to use the following Mother Teresa quote: "None of us, including me, ever do great things. But we can all do small things with great love, and together we can do something wonderful."

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## **Tech**Talk

## **One Direction** Endoscope-Reprocessing Workflow

By Roberta Harbison, MBA, CHL, CER, CRCST

Is your facility challenged by a less-than-ideal flow in the endoscope-reprocessing workspace? Never fear—we're here to help. This column will explore workflow, physical separation of spaces, equipment placement and efficient processes.

#### **Challenges with Endoscopy Reprocessing Areas**

Endoscopy reprocessing areas in an outpatient setting are often challenged by space (or lack thereof). Typically, the areas are retrofitted into an existing location that often has inadequate room for all the equipment necessary to clean and high-level disinfect scopes. When dealing with existing spaces, it's critical to reduce the risk for contaminating processed scopes.

Whenever possible, the endoscope-reprocessing areas should be separated. However, budgetary constraints, square footage of buildings, and the required areas for patient care often make this almost impossible. When separation of spaces is not possible, it's essential to understand what is required to ensure small spaces are meeting minimum standards to reduce the risk of contamination, transmissions, and infections to patients and employees, the environment, and community.

#### Workflow

An adequate area should have a unidirectional flow, with good distance between spaces used for the various stages in processing. There should be sufficient space for workflow patterns that start with a soiled holding area and end with a high-level disinfection area—and finally, storage. The area should be designed to reduce the risks of bloodborne pathogen exposure to employees and devices.

There should also be precautionary measures to prevent cross contamination of processed scopes and processing equipment. When reviewing the space, assess how to prevent employeerelated injuries (e.g., from having to lift or carry heavy items unnecessarily) and the possibility of microorganism growth in the reprocessing area.

Additional considerations include ensuring that all work surfaces, ceiling tiles and counters are nonporous; corners should be rounded off to prevent injuries; and all work areas should be height adjustable or positioned to meet the average height of most employees. While washing and decontaminating devices, technicians must stand for prolonged periods of time, so anti-fatigue mats should be used to help prevent worker injuries.

Personal protective equipment (PPE)—impervious gowns, face shields, masks, gloves, bouffant caps and shoe covers—should be located at the entrance to the area. Shelves or closed cabinets can be placed outside the entry door or as soon as one enters the area. If stored inside the processing area, PPE should be contained to prevent it from becoming contaminated. All equipment and supplies should be stationed and stored in such a way as to reduce the number of times the technician needs to move back and forth. Everything in the room should be set up to induce a single directional flow pattern when the technician enters.

#### **Physical Separation of Spaces**

In a one-room reprocessing area, sufficient space allows for all tasks to be performed with ease. Reprocessing functions should not be performed in the same room as procedures; the only disinfecting process that can be performed in the procedure room is point-of-use cleaning. Policies and procedures should outline how point-of-use pre-cleaning of endoscopes should be performed, how scope accessories are cleaned, and how endoscopic components are transported from the procedure room to the reprocessing area. Flexible endoscopes should not be stored in procedure rooms.

The processing area should be a restricted space that is limited to designated personnel only. A sign reading "Restricted Area, PPE Required" should be posted outside of the door (in the case of a one-room setup). Otherwise, a sign requiring PPE should be posted on the entry door to the scope-cleaning room. A unidirectional flow should be considered when transporting devices from the procedure room to the decontamination area. A hand-off process (delivering items from one point to the other) of the soiled device to the processing technician should be developed and written in the policy.

Although physical separation for each process is preferred, it is not always possible. Partitions or dividers may be needed to reduce potential splash between spaces. For example, a plexiglass partition at least four feet high and four feet wide can be installed next to the final rinsing sink in the decontamination space to separate the contaminated space from the clean space. *Story continues on p. 14.* 

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The clean space can continue as an inspection station, cleaning verification space, and staging area until the scope can proceed to high-level disinfection. Then there should be an adequate space for drying scopes with instrument air. Perform a risk assessment to verify that all process steps follow a unidirectional workflow pattern, fill potential gaps, and identify potential risks and exposed areas of opportunity that need immediate correction.

#### **Equipment Placement**

Daily tasks require specific tools and equipment that may take up counter space and limit how that area can be utilized. When considering the placement of equipment necessary for endoscope-device reprocessing, the person organizing the space should analyze intended use for each piece of equipment. Reading all operational manuals and manufacturer instructions will help identify the equipment specifications and space required to use the equipment properly.

For instance, when cleaning flexible endoscopes, the Association for the Advancement of Medical Instrumentation (AAMI) recommends a sink with a minimum of two wells – three wells are preferred. Each sink should be long and deep enough for technicians to place the endoscopes into the sink well, loosely coiled, without causing damage. Most flexible GI endoscopes need a sink at least 36 inches wide and about 8-10 inches deep (AAMI, 2017). Other processing equipment should be assessed for the required space and for service or repairs.

When starting the decontamination process, there should be space to perform leak testing of the scopes. Space is also needed so technicians can visually inspect the flexible endoscopes under 10x lighted magnification. When counter space is limited, installing shelves or brackets can help free space where a leak tester and magnifying glass can be stationed.

Automated device flushing systems often require a significant amount of space. When considering purchasing, it's very important to know how much total space is required and to assess where the flushing unit can be placed so that it does not take vital space needed for staging scopes and other supplies.

For clean workspaces, create a designated area to store supplies, manufacturers' instructions for use (IFU), operational manuals, detergent, safety-data sheets and chemicals.

Most facilities are no longer manually high-level disinfecting their scopes; however, facilities that use manual soaking stations for high-level disinfection (HLD) of medical devices should have a designated area near a plumbing drain where technicians can pour and empty chemicals without creating splash or having to lift and carry heavy soaking and rinsing pans to a sink or drain. Placing the manual soaking station near a drain can prevent work injuries and chemical-exposure hazards.

When manual soaking stations cannot be located near a drain,

it's a good idea to use small lakeside carts with wheels so that the technician can slide the chemical- or water-filled pans onto the cart and push the cart to the drain and empty them safely. For employee safety, emergency eyewash stations and handwashing sinks should be in a designated clean area of the room, preferably by the exit. Eyewash stations should never be installed on the decontamination sink as this is considered contaminated. Employees should never flush their eyes or perform hand hygiene in a decontamination sink.

Automatic endoscope reprocessors (AER) that perform HLD are considered a clean activity, and so should never be placed next to or side by side with the decontamination space. At least four feet of distance is recommended. Although not ideal in areas where separation is not possible, partitioned walls can be installed to separate the decontamination space from the clean space. AAMI provides guidance and recommendations on how to properly separate one-room reprocessing areas. Storage cabinets should be placed and positioned in clean areas. Each scope in inventory should have enough storage space to prevent potential damage to the scope. Nothing else should be stored in the scope storage cabinet unless validated by the scope storage manufacturer.

#### **Efficient Process**

Dealing with existing spaces can be quite challenging. The most efficient process is mapped out in a way that allows technicians to be efficient, with all the needed equipment and supplies in the correct order, and all tools and resources readily available. Additional improvements can be made by utilizing color-coding systems to identify various brushes or supplies for specific pieces of equipment. Labeling and identifying each storage container and setting up par levels to keep inventory and supplies controlled will help technicians be more efficient as well.

All logbooks, manuals, safety-data sheets and paper materials should be stored in covered cabinets but identified with water-resistant labels (i.e., P-touch labels). Wipeable charts for cleaning processes, and information on how to start AER cycles and use the leak tester or flushing device, can be posted on walls or in a binder for quick reference.

Creating a highly functional space in the smallest areas can reduce the risk of hazard, make the area more user-friendly and provide safe and effective ways to reprocess flexible endoscopes properly. Patient and employee safety can be greatly reduced when proper assessments, planning, reviewing and organization of space is performed.

Roberta Harbison, MBA, CHL, CER, CRCST, is the president and CEO of RLH Consultants, LLC, located in southern New Jersey. The company was founded in 2021 and provides SPD and GI consultations, quality-assurance assessments, competency assessments, design of sterile processing areas (in hospitals, surgery centers, dental practices, FQHC healthcare facilities, and endoscopy processing areas), on-site training, virtual training, and certification-preparation education and training.

## **Learning to Let Go** Losing Love by Bits and Pieces

By Patricia Raymond, M.D., FACG (retired)



I wasn't trained for this.

All of us in medicine were taught to battle death to the final breath. We would debate euthanasia practices of foreign climes and those of our veterinarian colleagues with occasional envy and confusion on how one might know when the time was right to let go. We all heard of our hospice nurses who pointedly cautioned their terminal, in-pain patients on how much narcotic not to take.

I have a history of holding on too long. Starting in medical school with fur-babies to whom I administered daily subcutaneous saline, insulin and home-produced renal diets, or debated diagnostic laparotomies to determine feline Crohn's versus lymphoma (the latter more likely), I acknowledge that I frequently held on too long to my loves for my own selfish needs.

My granddad (we called him GrandDOM, for dirty old manhe wasn't, but did share a love of pull-my-finger humor and "break glass in case of emergency" corncob bathroom decor) died after a six-month battle with metastatic pancreatic cancer while I was in my first year of GI fellowship. My mother practically needed to pry him from the hospital, as they wouldn't release him with an indwelling biliary catheter and a fever of unknown origin; they wanted to continue rotating antibiotics and consider chemotherapy in a deeply jaundiced 86-year-old. Thank goodness mom was brave and bold, and kept GrandDOM in comfort in their home for his final months. I agreed that further hospitalization was futile, but I was frightened and heartbroken that my beloved gastroenterology could not make him more comfortable or buy him extra time.

I lost my dad to disease related to his tobacco use; despite his own father succumbing to mouth cancer, Dad simply couldn't quit smoking. He had a quadruple bypass and still didn't quit, smoking on the down-low while attending his modeltrain club. Laryngeal cancer? I'm afraid that he continued his burning cancer sticks, even via his laryngeal stoma - I wince at the mental image. I'm afraid he couldn't see the point of nicotine withdrawal — he later said that he fully expected to die as early as his father had from "tobacco-use disorder" (a pretty sanitized name for a difficult-to-break, nasty addiction) and was woefully surprised to last about seven more years after his laryngectomy.

I was alerted by a phone call from Mom that Dad had visited the ED the previous day — an unheard of occurrence for my stoic pop — for weakness and shortness of breath, and he was found to be profoundly anemic. He refused hospitalization or transfusion. I hopped an evening flight from Virginia to Florida to fix this apparent GI issue; after all, who better than a gastroenterologist to manage anemia?

We took my pallid and weakened Dad, who didn't make his usual objections, back to the ED, where they confirmed his profound anemia and admitted him to the floor. He had just arrived to the room and had yet to be checked in by the staff when he suffered a respiratory arrest, and as the sole person in the room who knew the relevant medical history, I found myself presiding over the code. Dad was intubated and moved to the ICU — precisely where and how he had told me he wished never to be.

With conversation with the intensivist and Dad's internist, and looking at his profound acidosis, the three of us decided we would give Dad one hour on the ventilator to reverse the acidosis and hopefully benefit from deep suctioning. If there was no improvement, we would discontinue the ventilator — a bit belatedly but in accord with Dad's wishes — and allow him to go.

The repeat blood gas showed no improvement, so Dad's laryngeal stoma was extubated, and the family received liberal bedside privileges in the ICU. We gathered at bedside and shared stories of growing up with our complex and brilliant father. And his death lingered.

Several times I was approached by the intensivist warning me that if he remained alive by morning he would be moved to a step-down floor, and consideration for transfer to a nursing home under hospice would begin. The nurses, being supportive, would murmur in my ear that if I would like, they could give a dose of IV morphine to help with "anxiety from air hunger." I simply couldn't give the order. Dad appeared comfortable, the outcome was a forgone conclusion, but I simply couldn't give the okay to euthanize him. He died about 0200, directly after my younger brother Michael had left the hospital to get my mom home.

I am faced with loss again. My mom is a healthy 90 years old but is beginning to "slip a bit," mentally. Her internist says it's not dementia, but rather, normal aging. Mom insists this summer she wants to return to her summer home in the in the mountains of North Carolina, with its twisty-turny roads, despite a recent diagnosis of wet macular degeneration in her one remaining good eye, requiring intraocular, anti-vascular shots monthly. Her friends have all died or moved down to the flatlands. At her Florida condo, her friends have died or moved on. We, her children, have carefully started to discuss a retirement home close to my brothers in Orlando, with inhouse activities, transportation and nearness to the family (and to the great-granddaughter with a second in the oven). But it's difficult; I believe her resistance is concern over loss of autonomy and change.

I just returned home from a major blessing: the opportunity to travel with my mom on a 14-day river cruise of the Netherlands and Belgium. It was wonderful to travel with Mom, my older brother, Robert, and my sister-in-law, but because we were outside of Mom's normal venues, her confusion was more obvious. If I didn't keep her in reach on our walking tours, she would head off in a random direction. She became trapped in two travel bathrooms (one airline, one tram station), unable to unlock the door and needing assistance to exit. I mislaid her for fifteen endless minutes in the crowded Keukenhof flower gardens when she was swept away in a different tour group.

The others on our tour were kind with her, gently tapping her shoulder to direct her and waving her ahead to board buses and boats. On our return home, both she and Robert contracted COVID-19; Mom's case was moderate, and she became confused and disoriented in her illness, although not hypoxic or in need of hospitalization. My younger brother, Michael, drove to Daytona to help assess her, participate in an urgent telehealth appointment, and bring her to his Orlando home for close watch. She has since recovered, although she has a persistent and concerning hacking cough. She will delay her return to North Carolina, but instead plans to come stay with me in Virginia for a bit until she is better before proceeding to what I believe will be her final summer in the mountains.

So I'm faced with an upcoming inevitable loss of love — akin to a slow-moving freight train approaching where our family sits, stuck on the tracks. However, my own age seems to have birthed some degree of wisdom; I can permit feeling sorrow without erecting a wall of science between me and the upcoming loss. I have learned to embrace the sadness and not buffer it.

I am learning to let go.

Patricia Raymond, M.D., FACG, is a retired gastroenterologist and educator savoring the third third of her life in coastal Virginia. She completed her gastroenterology fellowship at the Medical College of Virginia oh, so long ago. After a 30-year GI practice in southeastern Virginia and thriving professional-speaking and broadcast career, she is a popular provider of second opinions in gastroenterology for 2nd MD, now educating people one by one. You will likely find her in her greenhouse or gardens, either propagating fig trees or growing much of her vegan diet organically with donated rabbit poo.

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## **Researchers Find Weight-Related Differences in Small-Intestine Microbes**

Cedars-Sinai investigators have identified that significant variations in the microbes of the small bowel (small intestine) are strongly associated with various body weights — from a normal body mass index, or BMI, to having obesity.

News

The gut microbiome includes the bacteria, fungi and viruses that inhabit the human gastrointestinal tract. Imbalances in these microbial populations have previously been observed in the stool samples of patients with obesity-related diseases. This is the first study to fully examine the small-bowel microbiome in patients who are of normal weight, overweight and obese, according to investigators.

"Using specialized techniques, we did a deeper dive into the microbial universe and found the small bowel was significantly, and specifically, altered in participants who were overweight or had obesity, when compared to those of normal weight. Some of these changes were progressive, moving from normal weight to overweight to having obesity," said endocrinologist Ruchi Mathur, M.D., a professor of medicine at Cedars-Sinai and corresponding author of the study.

The paper is published in the American Journal of Gastroenterology.

"Many functions related to food metabolism and nutrient absorption converge in the small bowel, as do many endocrine and immune functions that may influence weight gain. We think that changes in the balances of small-bowel microbial populations may have a greater impact on weight gain and the development of obesity than previously understood," said Mathur, who is also the director of the Diabetes Outpatient Teaching Education Center.

Using specimens obtained from esophagogastroduodenoscopies, blood samples and patient questionnaires, investigators examined the small-bowel microbiomes of 214 patients stratified by BMI. Study participants were classified according to the Centers for Disease Control and Prevention (CDC) guidelines: Patients with normal weight have a BMI of 18.5-24.9, overweight individuals have a BMI of 25-29.9, and those classified as having obesity with a BMI of 30 or higher.

The microbial populations of the duodenum, the first part of the small bowel where nutrition absorption begins, were analyzed in all three groups. Shotgun metagenomic sequencing was used to obtain a comprehensive evaluation of all the organisms present.

"A key finding was that one bacterial population, Lactobacillus, in the duodenum exhibited differing and highly species-specific associations in subjects classified as overweight or having obesity. These microbiome changes related to weight gain may be of particular importance, because many people regularly consume Lactobacillus-containing products, including dairy-based foods, probiotics and certain vegan cuisine such as fermented tempeh," said Gabriela Leite, PhD, the lead author of the study and lead project scientist for Cedars-Sinai's Medically Associated Science and Technology (MAST) Program.

An estimated 182 million adults in the U.S. are overweight or have obesity, according to the CDC. The global number exceeds 1 billion. The causes are multifactorial and associated with serious health problems, including cardiovascular disease, metabolic syndrome and Type 2 diabetes. Genetics, epigenetics, gut hormones and gut microbiomes are involved in the pathophysiology of obesity, which can also be influenced by socioeconomic and psychosocial factors.

Investigators believe understanding the influences and activity of the microbes that populate our small bowel microbiome may offer an important path to improving the health and lives of millions of people.

"Identifying changes in the populations, and activity, of small-bowel microbial species associated with overweight or having obesity is part of a key initiative to develop new therapeutic targets and to personalize medicine," said gastroenterologist and study co-author Mark Pimentel, M.D., executive director of Cedars-Sinai's MAST Program.

"More research will be needed to identify the cause-and-effect relationships between the changes we observed, but the goal is to develop treatments and interventions that help people lower their risk for obesity-related disease and improve their overall health," Pimentel said.

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# Polypectomy During Insertion Advances and Best Practices

By Lisa Hewitt, MA

Polypectomy is an obvious reason for colonoscopy: finding the little devils that can morph into something cancerous and cutting them out before they begin their deadly invasion. Standard operating procedure for many endoscopy pros is to mark polyps on the way to the cecum and then remove them on the way out. Traditionally, that's how it's been done. There's just one problem: Polyps can hide.

Finding a previously noted polyp during scope removal is often easier said than done. Precious minutes can be wasted doing a search, or the polyp may not be found at all. Reasons include small polyp size and cold-snare removal, according to Komeda, et al., who wrote, "It was difficult to retrieve small, sessile, and proximal colon polyps."

Teramoto, et al., performed a multicenter randomized controlled trial (also known as the PRESECT study). They discovered that performing polypectomy during insertion "significantly shortens the total procedure time and eliminates all missed polyps without experiencing any disadvantages."

In another randomized controlled trial, Wildi, et al., evaluated polypectomy on insertion and withdrawal for 301 patients. While all polyps detected on insertion and withdrawal were easily removed at the time they were found, 7.3% of polyps slated to be removed on withdrawal only were subsequently not found. The authors wrote, "Removal of polyps  $\leq$  10 mm during withdrawal only is associated with a considerable polyp miss rate. We therefore recommend that these polyps are removed during both insertion and withdrawal."

Conversely, a 2021 systematic review and meta-analysis concluded that there were "no obvious advantages" to polypectomy during both insertion and withdrawal phases. And Moons, et al., stated that "maneuvers can be applied during insertion and withdrawal of the colonoscope to optimize mucosal visualization and decrease the number of missed polyps."

Gweon, et al., conducted a randomized trial at three university hospitals. "For patients in the study group," they wrote, "polypectomy was performed together with careful inspection during both colonoscope insertion and withdrawal. In the control group, polyps were inspected and removed only during colonoscope withdrawal. The primary endpoint was the ADR [adenoma detection rate], which was defined as the percentage of patients with  $\geq 1$  adenoma." What they found was that the ADR was similar in both groups, with a polyp miss rate of 2.1 percent in the control group.

Their conclusion? Paying attention pays off. "Polypectomy and careful inspection during both colonoscope insertion and withdrawal did not improve the overall ADR compared with standard colonoscopy."

Bleeding is often a factor during polypectomy. Janik found that cold-snare polypectomy (CSP) results in less bleeding than hot-snare polypectomy (cautery), making CSP safer. Katagiri, et al., conducted a single-center, prospective, randomized controlled trial, examining whether epinephrine-added saline could influence resection time. What they found was that out of 261 lesions, epinephrine "shortened the time for resection by shortening the time to cessation of immediate bleeding compared with conventional CSP in colorectal polyps  $\leq$  10 mm."

Another factor in accurate polypectomy is the utilization

of water and/or gas-generally carbon dioxide-to expand the colon so clinicians can more readily analyze the mucosa during withdrawal. Unusual anatomical structures can present problems in this regard: redundant colons, which present with excessive looping, and colons with severe angulation, generally on the left side, can make examination challenging.

Commonly used techniques to cope with this challenge include water immersion (WI) and water exchange (WE). In both techniques, water is infused into the colon while inserting the colonoscope to the cecum. During WE, the water is aspirated during insertion, while during WI the water is aspirated during removal. Both are effective when paired with gas.

Joseph Anderson outlined a third technique, total underwater colonoscopy, that can be especially helpful in colonoscopy for those with anatomical challenges. "Water can distend the colon so that it is actually narrower and shorter than when gas insufflation is used," he wrote. "In addition, water has the advantage of weighing down the sigmoid, especially in the left lateral decubitus position, allowing for a straighter and less redundant sigmoid."

Anderson added that he uses this technique when he encounters "frequent looping that does not respond to abdominal pressure, colonoscope stiffening, or change in position." Shutting off the air and infusing water allows him to complete the insertion.

Water acts as a lubricant, Anderson wrote, and has the added benefit of not causing spasms as air does. When working with a patient who has a severely angulated sigmoid colon, a clinician might be tempted to pump air into the lumen to help facilitate visualization. Anderson wrote that "water can distend the colon, allowing for visualization of the lumen without maximally distending the lumen similar to air, which can exacerbate the angulation." Another benefit to water is it can help prevent baro-trauma to the cecum.

A side benefit to water, Anderson noted, is that it helps patient comfort. "Meta-analyses have shown that patients who have unsedated or minimally sedated examinations with water experienced less pain, required less sedation, and were more likely to have examinations that were complete than those who had the colonoscopies performed with air."

When he's performing unsedated or minimally sedated exams, he observed, "I routinely use water immersion beginning at insertion with the air valve turned off. I find this particularly useful in older, thinner patients, especially women. In addition, in patients with multiple comorbidities, cecal intubation often can be achieved safely with minimal sedation."

Another benefit is that water can help aid in adenoma detection, although some clinicians may argue the point. "Because water does not fully distend the lumen, flat polyps may be easier to detect because they may not completely flatten as compared to the use of gas for insufflation," Anderson wrote.

Where water could become a real asset is in endoscopic mucosal resection (EMR). Because polyps have more of a

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tendency to float in water, they may be easier to see. They also tend to "float into the snare," according to Anderson. "Polyps also are more likely to appear protruding underwater, as opposed to flat with gas insufflation. Because water has a magnifying property, UEMR may allow for easier delineation of the polyp's border, also facilitating complete removal. Underwater may be safer than traditional EMR using air because the lumen may not be as distended and therefore the colonic wall may not be as thin as when gas is used."

But underwater colonoscopy isn't all perfection. The use of water can lengthen the procedure time—particularly on insertion. And while water can (obviously) improve bowel prep, it can cause a whitish mucus that's difficult to remove. There's some question as to the physiological effects of a large amount of water introduced into the colon, but Anderson cited two studies indicating no safety issues with the process. "Water infusion does not appear to alter serum electrolytes or vital signs."

#### **Polypectomy Best Practices**

According to the American Gastroenterological Association, the AGA "Clinical Practice Update on Appropriate and Tailored Polypectomy: Expert Review" was published to give "timely guidance on a topic of high clinical importance to the AGA membership." Its best-practices recommendations start simply: "A structured visual assessment using high-definition white light and/or electronic chromoendoscopy and with photodocumentation should be conducted for all polyps found during routine colonoscopy." And of course, polyps should be inspected closely for evidence of submucosal cancer.

The next recommendation is to use cold-snare polypectomy for small polyps (less than 10 millimeters in size). If polyps are truly tiny (1–3 millimeters), cold-forceps polypectomy is an acceptable alternative. The authors do not recommend using hot-forceps polypectomy.

For intermediate-sized polyps, AGA authors expect that clinicians are "familiar with various techniques, such as cold- and hot-snare polypectomy and endoscopic mucosal resection, to ensure effective, safe, and optimal resection." In addition, they advise using lifting agents or underwater endoscopic mucosal resection (EMR) to remove intermediate sessile polyps.

Serrated polyps need cold-resection techniques, and for polyps with difficult margins, submucosal injection is recommended.

The authors recommend hot-snare polypectomy for pedunculated lesions larger than 10 millimeters. Practitioners should have a full understanding of "the endoscopy suite's electrosurgical generator settings appropriate for polypectomy or postpolypectomy thermal techniques." The AGA advises against using clips to close holes for polyp sites smaller than 20 millimeters. And if the polyp is 20 millimeters or larger, is recurrent at the site, or has a challenging location for polypectomy, refer to an endoscopy center.

Lesions such as these that may require referral should be tattooed for future placement. "Tattoos should be placed in a location that will not

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interfere with subsequent attempts at endoscopic resection," they wrote.

And if you're seeing clear evidence of submucosally invasive cancer in a nonpedunculated polyp, the AGA recommends an immediate referral for surgical evaluation.

#### Make a Hole

Endoscopic mucosal resection, or EMR, has become an effective tool for removing larger colonic polyps, obviating the need for traditional surgery. EMR is popular because of its higher efficacy and patient-satisfaction rates, quicker recovery, lower costs and complication rates, and "the ability to preserve normal gut function," according to the Mayo Clinic.

But removing large polyps is challenging at best. Practitioners often inject a 0.9% sodium chloride solution, enhanced with dye, to help elevate the polyp and make removal easier by creating a cushion between the mucosal layer and muscular layer. This helps prevent thermal injury and lowers perforation risk. But saline is rapidly absorbed into the body, which means practitioners often must inject more solution to finish the procedure.

To deal with this challenge, GI professionals have long come up with other "homemade" solutions to help elevate polyps. Ultimately this led to the development of FDAapproved gels and other submucosal injection agents. One of the most popular, SIC-8000, was approved in 2015 as a Class 2 medical device, and other gels quickly followed notably, without much clinical data—and hit the market. ORISE was particularly well received as it was a darker color than SIC-8000—especially beneficial during EMR.

However, problems quickly arose with its use.

Esnakula, et al., wrote in a case report, "ORISE Gel may potentially hinder the histologic evaluation of mucinpredominant lesions such as mucinous adenocarcinoma or adenocarcinoma with mucinous component. Hence, the gastroenterologist needs to report the use of ORISE Gel on the requisition form or endoscopic report. In addition, pathologists must be aware of the histologic appearance of ORISE and be prepared to use additional stains to prevent overinterpretation of such findings in the ER specimen."

It gets worse. Mendelson, et al., examined how lifting agents can present as a colonic mass that mimics cancer. "Lifting agent granulomas have become a routine endoscopic technique to help achieve full resection of flat/sessile colorectal polyps and early-stage cancers," they wrote. "This report confirms that these granulomas exhibit colonic transmural involvement. Sub-serosal blood vessel involvement is reported for the first time. It is important to recognize the unique characteristics of these new synthetic lifting agents. Their propensity to develop a mass-forming granulomatous reaction has the potential to mimic invasive adenocarcinoma clinically, radiologically and pathologically. This can significantly impact patient care and management both clinically and surgically."



And in a 2023 editorial, Rex and Lahr detailed numerous clinically significant adverse issues with ORISE. They wrote, "ORISE appeared to persist in the tissue, and biopsies from specimens taken at a later date showed an eosinophilic material accompanied by a multi-nucleated giant cell reaction."

"Purported advantages of submucosal injection before resection have sparse evidential backing," Nett and Binmoeller wrote. "Poorly performed submucosal injection can make EMR more challenging and may increase the risk of certain complications."

But EMR is where underwater colonoscopy can really shine. "Compared with reported outcomes of conventional EMR, underwater EMR achieves high rates of en-bloc resection and low rates of lesion recurrence," they wrote.

Anderson cited a randomized trial showing the effectiveness of underwater EMR for smaller polyps. "Applying the technique to smaller lesions may be a good starting point for endoscopists who want to try UEMR," he wrote.

#### **Closing the Hole**

Clinicians have several tools in the kit when it comes to fixing the gap created by a polypectomy. In an ideal world, the gap would close itself and everyone would go home happy. But in the real world, practitioners often use clips, sutures or staples to bring the edges together again.

But what happens when the polyp is irregular, the hole large,

or the spot in question difficult to reach?

A novel through-the-scope suturing system was put through its paces in a 2021 multicenter study. Eight medical centers located in the United States examined the system's feasibility and safety, as well as secondary considerations such as "assessment of need for additional closure devices, prolonged procedure time, and technical feasibility of performing the procedure with an alternative device(s)."

The authors concluded that the device was safe, efficient and worked as intended to close large and irregular defects that were difficult or impossible with established devices.

A multicohort retrospective study by Bi, et al., examined the rate of delayed bleeding with a through-the-scope suturing device (TTSS). The authors found that "TTSS alone or with TTSCs was effective in achieving complete closure of all post-EMR defects, despite a large lesion size. After TTSS closure with or without adjunctive devices, delayed bleeding was seen in 3.2% of cases."

While polyps and their malignant offspring continue to present challenges to GI professionals, innovation and substantive research help make the job easier and more rewarding, improving the surgical experience and patient care.

Lisa Hewitt, MA, senior editor at EndoPro Magazine, has had a long career as an editor, writer and designer, with an emphasis on medical content.



# **Asset Utilization** Right-Sizing Equipment Inventory

By Matt Ofenloch, BS, CSPDT, and Amy Williams, DNP, RN, CPAN, CSPDT, CSPM

How often do you experience stress or anxiety the day before a busy procedural schedule? Have you ever wondered if you have enough colonoscopes or if any devices have been sent out for service? If so, has loaner equipment arrived? Is the department efficiently staffed to manage the patients, doctors and equipment?

How often do you think about the number of assets in your department? Assets are all the endoscopes needed to provide safe patient care. How do you know you have enough assets to support the procedures on your schedule? If endoscopy professionals across the country were asked if their department has enough equipment, many would say they do not. GI procedures are increasing, and according to Paone (2024), the leading causes of higher volumes are a backlog of patients who delayed procedures during the pandemic, a new recommendation for colorectal cancer screening to begin at the age of 45, and an aging population.

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## Get in the game. Become a part of the team.



Subscribe today! www.endopromag.com/subscribe How does a department get ahead and ensure enough equipment is available to accommodate procedural volume? Before we get to the "how," let's review why it is important to have sufficient inventory.

#### Form and Function

The Centers for Medicare & Medicaid Services (CMS) requires hospitals to ensure supplies and equipment are maintained to an acceptable level of safety and quality for patient use (Centers for Medicare & Medicaid Services, Department of Health and Human Services, 2017). These guidelines are based on a federal statute called the Code of Federal Regulation (CFR), which governs areas in healthcare that pertain to patient care. CMS and other accrediting



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agencies conduct surveys to ensure healthcare facilities effectively meet required standards and regulations.

The CFR spells out standards and expectations for how facilities should function to keep patients safe, stating that hospitals have three responsibilities: 1) Facilities should have enough supplies on hand to meet day-to-day needs as well as what would likely be needed in the event of an emergency; 2) Facilities should have adequate provisions to support and maintain supplies; 3) Facilities should ensure supplies are stored in a manner to protect them from theft, contamination, damage and deterioration. This responsibility applies to equipment too (Centers for Medicare & Medicaid Services. Department of Health and Human Services, 2017).

When we think about how to ensure equipment is safe for patient use, it is good to think about it from a quality-management perspective. Quality management is an ongoing process a series of actions or steps taken in order to achieve a particular end (Seelbach & Brannan, 2023). Understanding how equipment is used is known as asset utilization, and it's part of a quality-management process. Understanding and implementing the quality-management process is important in the perioperative space because things change very frequently. For example, priorities shift, procedure volumes increase and decrease, and employees come and go. Using a quality-management approach can provide insight into needed changes to your inventory that will positively impact your department and facility. Hopefully, by using a quality-management strategy, the frequency and severity of asset damage will change as well.

There are various types of flexible endoscope models that are used in the perioperative space. Specific situations, such as opening a new department or upgrading to a new generation of equipment, require assessment of how much inventory is needed. Over time, that initial amount can change. Perhaps you started with enough, but how do you determine when to add more?

One approach is to consider how long it takes to clean, inspect, disinfect or sterilize, and dry items, along with the types of reprocessing equipment and specific cycle times being used. Another approach is to evaluate the physical size of your department. Do you have enough space to manage all flexible endoscopes in your inventory? Is the layout and flow conducive and efficient? A third approach is to determine the number of staff needed to manage inventory. How many people are needed to turn around flexible endoscopes safely in a timely manner? Many times, these factors are used to determine the amount of inventory needed initially but may not be used to determine if inventory is sufficient on an ongoing basis.

How many assets do you really need? According to Philip Doyle, Olympus executive director of marketing, "Olympus recommends that each scope only get around 300 uses per scope per year." (TechNation, 2023). Without the right number and mix of equipment, procedural turnover times can decrease, which can impact efficiency and other factors such as staff overtime. Understanding not only how much inventory is needed overall but how much of each type of flexible endoscope model is needed can be challenging.

Determining environment-of-care requirements in departments such as sterile processing and endoscopy is important. One of the biggest challenges facilities may have is inventory storage. Having adequate space is vital. As procedural volumes increase, it is important to evaluate space in the department to ensure there is enough room to store an increase in inventory. It is also important to evaluate the types of containers needed to transport and cabinets to store – flexible endoscopes. For example, are transport containers designed to support flexible endoscopes from shifting and being damaged? Do you have the right type of cabinets to properly isolate and secure flexible endoscopes? Is storage space organized and easy to navigate?

Evaluating workspace is another factor to consider. Having an adequate setup in the decontamination and reprocessing area is critical to ensure efficient and effective cleaning. Some flexible endoscopes may require extended cleaning or soak time, which can tie up a sink and create a backlog. When space is limited, it can be easy to stack flexible endoscopes on top of each other, but this can potentially damage the endoscopes and create the need for replacements.

Routinely evaluating departmental environment provides insight into continuous improvement measures. When procedural volume is high, more time is needed to sufficiently clean everything. Evaluating the specific types of cleaning cycles being used can be very insightful when determining whether inventory is sufficient. Leak testing, manual cleaning, inspection, HLD/sterilization and drying all take time. The longer the reprocessing time, the more inventory you may need to support procedural volume. Always refer to the manufacturer's instructions for use (IFU) for cleaning requirements for each flexible endoscope model to determine what cleaning steps should be used. Part of implementing quality-management processes requires evaluating inventory. It can be beneficial to consider the impact of insufficient inventory on individual departments, the facility as a whole, and the patients being cared for. It can be challenging to turn equipment over quickly. This type of pressure can increase staff stress and potentially lead to missing an important step - or worse, cutting corners. Increased wear and tear on inventory from repetitive use and reprocessing can result in increased damage and repairs and result in equipment not being patient-ready when needed. Ultimately, lack of sufficient inventory can lead to the need for bringing in outside equipment (referred to as loaners). Loaner equipment is not an immediate solution. For example, if you have a flexible endoscope that is sent out for repair and a loaner device is needed, most likely you will not receive that device until the next day at the earliest. Once received, the loaner item should be fully reprocessed before it is used, which also takes time.

#### **Nurses Count**

Many facilities experience staffing challenges. McKinsey & Company (2022) predicts a potential shortfall of 200,000 to 450,000 registered nurses available for direct patient care by 2025. Staff are crucial to the success of a facility and play a critical role in on-time procedural starts and positive patient outcomes. Once staff are hired, training and education are needed to set teams up for success. Initial training, competency validations and ongoing education are all part of the process. Ensuring departments have the right number of staff to manage inventory for procedural volumes is important.

The last two years have seen updates to guidelines set forth by the AORN and the Association for the Advancement of Medical Instrumentation (AAMI) regarding reprocessing of flexible endoscopes. These updates include a heightened emphasis on visual inspection, cleaning verification, leak testing, drying, and the need for delayed reprocessing.

Visual inspection should be completed for all flexible endoscopes to ensure they are clean, free of damage and functioning as intended (Klacik, 2022; Kyle, 2022). Having enough inventory on hand reduces the need for quick instrument turnover and the potential for missing something during reprocessing. Effective and efficient reprocessing could be impacted because visual inspection, cleaning verification, lengthened leak testing, and drying time all increase the amount of time it takes to reprocess devices.

Without the right number and mix of flexible endoscopes, efficiency of the reprocessing cycle could decrease, resulting in slower procedural turnover times and increases in staff overtime hours. It's important to evaluate the mix of models in your inventory to ensure you have enough for the different types of procedures being performed. For example, perhaps a doctor prefers to use a pediatric colonoscope for all patients, versus using an adult colonoscope. In that situation, how is inventory impacted? If only pediatric colonoscopes are being used, adult colonoscopes are being used less. This can increase staff stress from needing to turn the pediatric scope over quickly and could potentially result in delayed availability throughout the day. Even if you have a mix of models, preferences such as this can lead to overutilizing certain models and increased repairs. The challenge is that inventory and volume are not apples-to-apples. Inventory does not always meet procedural volume needs.

#### **A Systematic Approach**

An VVV-tracking system can provide insight into how often equipment is being used. Tracking systems may be used to evaluate department productivity, cleaning and assembly times, and the total time needed to complete all reprocessing steps from patient use to patient use. Scanning items into or out of high-level disinfection (HLD) or sterilization can provide insight into procedure volumes. Each time an item goes through HLD or is sterilized, it can be aligned with each time it was used. Year-over-year analysis helps determine overall increases in inventory use and can help determine how to best plan for spikes in procedural volume at specific points in time. For example, some institutions may do more procedures in November and December than other months of the year.

Another approach would be to identify a specific model of flexible endoscope and evaluate its usage month by month. A higher number of procedures performed in a particular month using that specific model may warrant adding more of that type of model to accommodate for higher volume months.

See bar graph below for an example.

Reviewing average uses per day in one month will provide insight into daily average use. Evaluating how many times a specific model was used in the month, the number of that model in inventory, the number of operating days in the month, and the average use per day in that month can tell a story. For example, when evaluating a pediatric colonoscope model, you may determine that two or more uses per day justifies adding another model to your inventory. When considering the length of the procedure, total reprocessing time, and dry time, adding one or two more of this type of model may be necessary to ensure enough inventory is available.

Every facility will be different. The busiest days are typically when stress is higher and turnover times need to be quicker. It may also be beneficial to drill down further and look at the day or days of the month when more procedures are being done or when a specific doctor works on a specific day. When evaluating asset utilization in this manner, it may be beneficial to have additional equipment to meet the needs of those specific high-volume days. When you analyze usage, you have insight into what items are in demand and what items are needed, which helps prioritize items for budgeting purposes.

See pie chart below for an example.



Routinely evaluating usage can help identify which models you need more of and help you achieve an apples-to-apples comparison between inventory and procedural volume. Right-sizing inventory may not happen quickly, but having data that clearly identifies usage can help support the need for adding inventory and enable you to plan ahead. For example, if procedural volumes are trending upward by



10%, you may consider adding 10% more inventory. Having data to justify the need and to support acquisition drives value for departments, the facility, and the patients served.

Let's circle back to the quality-management process. Look at the department environment and consider whether it supports the volume and type of equipment being reprocessed, whether you have the right number of staff and can provide needed training and education, and whether you are experiencing inventory-related challenges in one area more than another. Identify, track and trend key performance indicators (KPI) to obtain inventory specific data. For example, KPIs might include reducing the number of HLD or sterilizations for specific models month by month, reducing repair frequency by 20%, or improving on-time procedure starts by 90%.

As you assess your inventory, set measurable indicators to determine if the strategies implemented are successful. Using data analysis to evaluate inventory usage can be beneficial. Increased usage should lead to adding inventory. Make reviewing inventory a routine task and be aware of factors that could lead to needing more equipment, such as adding a new doctor or opening a new room, which leads to increases in volume. Routine evaluation drives changes that will enable you to plan ahead.

Understanding asset utilization can help justify the need to

supplement inventory to adequately support increases in procedural volume and help ensure safe patient care.

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