



Drug Shortages and the Impact on Clinical Care

Stanford R. Plavin, PCC Vice Chair

As a practicing anesthesiologist, I have been trained to manage all types of clinical situations and make fundamentally sound and safe decisions about the care of my patients.



Stanford Plavin, MD

In recent years, another variable has surfaced in our clinical community—that of drug shortages and the subsequent lack of having what we need to provide the best possible care and choice to our patients.

Preventing Colorectal Cancer’s (PCC) mission is to encourage key stakeholders, most importantly patients, to get the colorectal cancer screenings, treatment options and care that they richly deserve and need. More than two years ago, propofol, which is administered by trained anesthesia providers like myself during colonoscopy procedures, was in short supply. Many patients ended up receiving the “old” standard of care, which includes a narcotic and benzodiazepine. Like any industry, shortages

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Issue Brief Series: Colonoscopies Prevent Colon Cancer

PCC is publishing a series of issue briefs for consumers, physicians and other interested parties in an effort to promote colorectal cancer screenings and prevention. Key topics include the importance of colon cancer screenings and prevention, industry standards and current legislation impacting the industry and ultimately patients. The briefs will also address such issues as the appropriate time for people to get screened and how the industry can increase polyp detection rates.

A nonprofit organization, PCC encourages public policy makers to support colonoscopy as the gold-standard colorectal cancer screening method. Beginning at age 50 (age 45 for African Americans), both men and women are at average risk for developing colorectal cancer and should be receiving preventative screenings.

The Issue

The majority of colorectal cancers emerge from precancerous growths in the colon called polyps. Detecting and removing polyp growths through a screening colonoscopy with polypectomy (also known as a colonoscopic polypectomy) has been proven to reduce colorectal cancer deaths.¹

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PCC Names Champions of Colon Cancer Prevention

PCC has awarded the prestigious 2012 *PCC Champion Award of Colon Cancer Prevention* to three medical practices: Manhattan's Physician Group; Staten Island Physician Practice P.C.; and the Queens Long Island Medical Group. The annual award was launched in 2011 to recognize individuals, groups and companies that provide either exceptionally high standards of care or who most effectively advocate for the prevention and early detection of colorectal cancer.

"On behalf of PCC, we are extremely pleased to honor these organizations that are such an asset to the preventing colorectal cancer community," says Dr. Steven J. Morris, MD FACP, PCC board chair and president, Atlanta Gastroenterology Associates. "Their continuous efforts to educate communities that are traditionally underserved in terms of colon cancer screening make them worthy recipients of the *Champion Award*."

About the 2012 PCC Champion Award recipients:

- **Manhattan's Physician Group (MPG):** MPG's medical offices serve a diverse community with approximately 25% of its population comprised of African American members and 20% Americans of Latin decent.

In 2010, MPG's colon cancer screening program resulted in 68.89% of Medicare members getting screened. While 2011 figures are not yet finalized, the screening level is expected to increase to 71%.

MPG achieved the 90th percentile nationally through an aggressive program comprised of educational materials for patients, follow-up reminder phone calls and fecal immunochemical tests (FIT) kits to members who have not received screenings.

- **Staten Island Physician Practice (SIPP):** SIPP, one of the largest medical groups on Staten Island, serves an area that has some of the highest medical condition severity rates in the country.

With the goal of becoming a center of excellence for colon cancer screening within a community of great need, SIPP communicates weekly with members to promote information regarding preventative screenings.

The group has consistently demonstrated high CRC screening rates over the last several years by implementing a series of interventions aimed at educating providers and staff, and by proactively identifying members in need of screening and providing outreach assistance to complete screenings.

- **Queens Long Island Medical Group (QLIMG):** QLIMG services a diverse community with approximately 36% of its populations comprised of African American members and 13% Americans of Latin decent. CRC is the second leading cause of cancer death in these populations. QLIMG has achieved a screening rate of 71% of its members for three years in a row, placing it in the 90th percentile and the Medicare Stars five-star range, both of which are the highest levels that can be achieved.

This group works consistently to achieve results on par with the highest national benchmarks. It has improved colon cancer screening rates each year over the last four years by implementing a series of interventions aimed at educating providers, staff and the community.

All three winning organizations use the National Committee on Quality Accreditation benchmarks and measure specifications for colon cancer screening to monitor their performance.

"The selection committee felt these three facilities have gone above and beyond to promote colorectal cancer screenings," says Stanford R. Plavin, MD, PCC vice chair and president and managing partner, Ambulatory Anesthesia of Atlanta. "Colorectal cancer is the second leading cause of cancer deaths in minority populations, and this year's winners have achieved results consistent with the highest national benchmarks while serving a very large community that traditionally experiences disparities in colon cancer screening." •



DRUG SHORTAGES

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can occur for many reasons. In the case of propofol, generic medications have driven down the interest of many pharmaceutical companies due to the lack of reimbursements.

Safety and comfort seem to be the major concerns of those who haven't received a screening colonoscopy. PCC strongly endorses monitored anesthesia care with the use of propofol for all endoscopic procedures. Over the last six to 12 months, many sedatives such as midazolam and fentanyl have become scarce due to shortages,

resulting in more patients able to receive monitored anesthesia care with propofol sedation. Unlike the previous shortage of propofol, this drug shortage has given patients a better treatment option than the antiquated approach of conscious sedation.

The drug shortages are not only affecting sedation options, but also chemotherapeutic choices,

Over 140,000 patients are diagnosed with colorectal cancer each year, and 80,000 are expected to rely on typical treatments such as fluorouracil or leucovorin, both of which are in short supply.

Join PCC

What are the members of Preventing Colorectal Cancer doing?

- Bringing awareness to insurance companies about cost-savings associated with early diagnoses
- Contributing to grass root advocacy efforts on behalf of patients and doctors by taking their concerns to Capitol Hill
- Representing patient safety and doctor concerns to the FDA and other regulatory agencies when questions need to be asked and answered
- Accurately representing the concerns of physicians and facility managers on issues such as sedation, reimbursements, and ambulatory surgical centers

The benefits of becoming an organizational member include receiving the newsletter via email and printed format, invitation to participate in PCC committees and advocacy activities, policy briefings, and prominent positioning of your logo in the newsletter and on the PCC website. For more information, please call the office at (866) 333-6815. •

antibiotic regimens, and life-saving treatments. A recent American Hospital Association survey of 820 hospitals found that more than 80% of hospitals indicate delaying treatment and more than half could not provide patients with the recommended drug for their disease. Sixty-nine percent of patients had to settle for a less effective treatment.

Over 140,000 patients are diagnosed with colorectal cancer each year, and 80,000 are expected to rely on typical treatments such as fluorouracil or leucovorin, both of which are in short supply.

A number of task forces and solutions are being sought. FDA is more aggressively working with the pharmaceutical industry and its suppliers to encourage tracking of drug supplies as well as exploring alternative treatment options to avert these shortages.

At PCC we are constantly looking for ways to ensure your voice is heard. That being said, please do not hesitate to become part of an organization that strives for your safety and security. Join PCC today! •

Dr. Plavin is president and managing partner of Ambulatory Anesthesia of Atlanta.



CRC Guidelines: Often Misunderstood or Forgotten

David A. Johnson, MD, FACG, FASGE

Colon cancer remains a significant health care issue with nearly 145,000 new cases per year and 48,000 related deaths in the U.S. annually. Everyone is at risk—even without a family history. In the U.S., the average risk patient at age 85 has a 5.6% chance of having colorectal cancer (CRC).



David A. Johnson, MD, FACG, FASGE

This risk increases with age, family history, smoking, and obesity (see below discussion).

Although there is clear evidence that colon cancer screening saves lives and can effectively (in most patients) prevent the development of colon cancer, the rates for colon cancer screening remain far less than other very effective programs such as breast cancer or cervical cancer (PAP smears).

In 2009, new guidelines were released by the American College of Gastroenterology (ACG) that highlighted some important issues for patients—particularly African Americans and those with a family history of CRC.

Colonoscopy is the preferred colorectal cancer prevention test: Colonoscopy every 10 years beginning at age 50 remains the preferred strategy for colorectal cancer screening. This test remains the best and most cost effective test for prevention of colon cancer.

Stool tests for occult blood: The 2009 guidelines suggest that the older tests (hemoccult) be replaced with another stool test that more effectively detects human blood and is much more specific for blood. The dietary restrictions during the hemoccult test (e.g. avoidance of red meats, leafy vegetables) are not needed with the newer fecal immunohistochemical tests (FIT).

Virtual colonoscopy: CT Colonography (also known as “virtual” colonoscopy) done every 5 years is endorsed in the updated ACG guideline as an alternative to colonoscopy every 10 years for patients who decline colonoscopy.

Screening for African Americans should begin earlier: The updated guideline includes a new recommendation for African Americans to begin colorectal cancer screening earlier, at age 45, because of the high incidence of colorectal cancer and a greater prevalence of right-sided (higher up in the colon) polyps and cancerous lesions in this population.

Family history of colon cancer: Changes were made as to when to begin screening in family members. Age 60 is a key factor for determining when screening should be moved up to an earlier age or when to screen more frequently.

1. Single first degree relative (mother, father, brother, sister) with colorectal cancer or advanced precancerous adenoma (based on the size and histology of the polyp) diagnosed at age < 60 years. Begin at age 40 or ten years earlier than the age of the patient when they developed colon cancer. These patients should be followed with colonoscopy every five years.
2. Single first degree relative (mother, father, brother, sister) with colorectal cancer or advanced precancerous adenoma (based on the size and histology of the polyp) diagnosed at age \geq 60 years. Recommended screening: Same as average risk (colonoscopy every 10 years beginning at age 50).
3. Single first degree with colorectal cancer or advanced adenoma diagnosed at age < 60 years or two first degree relatives with colorectal cancer or advanced adenomas. Recommended screening: colonoscopy every five years beginning at age 40 or 10 years younger than age at diagnosis of the youngest affected relative.

Colon cancer screening should be a top priority. This disease is treatable, beatable and preventable! Hopefully this brief update will be helpful in putting the new information and recommendations in perspective for health care providers and their patients. With well-informed patients asking good questions to their health care providers, together we can make a meaningful difference in this deadly disease! •

Dr. Johnson is professor of medicine, chief of gastroenterology, Eastern VA Medical School, and affiliated with Digestive and Liver Disease Specialists/Gastrointestinal and Liver Disease Specialists of Tidewater PLLC, Norfolk, VA.

ON THE HILL

Colorectal Cancer Legislative Roundup

Randall Madry, PCC Executive Director

Several interesting colorectal cancer bills are circulating in our nation's capital, some of which could have a significant impact on consumers and physicians. Here's an overview:

Affordable Screenings

H.R. 4120, The Removing Barriers to Colorectal Cancer Screening Act of 2012

H.R. 4120 would amend title XVIII of the Social Security Act to waive coinsurance under Medicare for colorectal cancer screening tests, regardless of whether therapeutic intervention is required during the screening.

Why is this important? Many health insurance companies comply with federal rules that mandate that they provide colorectal cancer screening colonoscopies at no cost, but as soon as a polyp is detected and removed, the procedure becomes a surgical procedure and full copays and deductibles are applied. The patient is unaware of the cost until the procedure is completed and they receive the bill.

H.R. 912, The Colorectal Cancer Prevention, Early Detection, and Treatment Act

H.R. 912 would amend the Public Health Service Act to establish a national screening program at the Centers for Disease Control and Prevention and to amend title XIX of the Social Security Act to provide States the option to increase screening in the United States population for the prevention, early detection, and timely treatment of colorectal cancer.

And its companion bill:

S.494, The Colorectal Cancer Prevention, Early Detection, and Treatment Act

We urgently recommend you contact your congressmen to share your views on these important legislative initiatives. •

IN THE NEWS

CDC: Room for Improvement in Cancer Screening Rates

According to the Centers for Disease Control and Prevention (CDC) screening rates for breast, cervical and colorectal cancer are below target levels in the United States, and are particularly low among Asians and Hispanics.

To view the full CDC release, visit www.cdc.gov/media/releases. •

Colonoscopy Cuts CRC Death Risk in Half

Recent studies published in the *New England Journal of Medicine* show that preventative screenings using colonoscopies cut the death risk from colon cancer in half. The exam helps doctors detect precancerous growths, and remove polyps before they develop CRC.

To read the entire article, go to www.prnewswire.com. •

Colonoscopy Screenings Down During Recession

A study published in *Clinical Gastroenterology and Hepatology* using data for 106 health plans showed that monthly rates of screening colonoscopies on patients ages 50-64 decreased by 68.9 colonoscopies per one million individuals per month during the recession.

For more information, visit www.beckersasc.com. •

Eat Fish and Fight Off Cancer

A new study published in the *American Journal of Clinical Nutrition* found that the omega-3s found in fish can help protect women from colorectal cancer. Women who ate fish at least three times a week were 33% less likely to have polyps, which are usually considered to be precursors to colon cancer.

Visit www.prevention.com/health. •

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The Opportunity

A cancer prevented is better than a cancer cured. The opportunity to remove polyps before they become cancerous exists when patients receive the “gold standard” screening, colonoscopy. Other screening options find polyps after they’ve become cancerous or identify polyps without simultaneously removing them.

Both the ‘pill cam’ and CT colonography are new screening options for patients. Both require the same cleansing prep process as a colonoscopy and have a lower sensitivity/polyp detection rate. CT colonography identifies polyps of 5.0–9.9mm with only 66.9% sensitivity.² The ‘pill cam’ is not yet approved in the United States but will likely move forward as an option for diagnostic exams as it provides direct visualization of the colon.³ Neither of these procedures will remove a polyp. Once these procedures identify a polyp, a colonoscopy must then be performed to remove the polyp.

The Bottom Line

A colonoscopy is the only screening procedure that is both diagnostic and therapeutic. To ensure this high standard is maintained, efforts to improve the colonoscopy procedure are ongoing. In fact, new colonoscopic imaging methods are in development to enhance evaluation of surface patterns of the lining of the intestine. And equipment innovations—such as backward viewing capability—have also enhanced the colonoscopy procedure.

To be included on the issue brief distribution list, please send an email to info@preventingcolorectal.org.

¹ Zauber, A., Winawer, S.J., O’Brien, M., Lansdorf-Vogelaar, I., van Ballegooijen, M., Hankey, B., Shi, W., Bond, J., Schapiro, M., Panish, J., Stewart, E., Waye, J. (2012) Colonoscopic Polypectomy and Long-Term Prevention of Colorectal-Cancer Deaths. *New England Journal of Medicine*. 2012; 366:687-696

² Yee, J. Akerkar, G., Hung, R., Steinauer-Gebauer, A., Wall, S., McQuaid, K. (2001) *Radiology* 219,p.685-692.

³ <http://www.givenimaging.com/en-us/AboutGivenImaging/InvestorRelations/Pages/PressReleases.aspx>

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