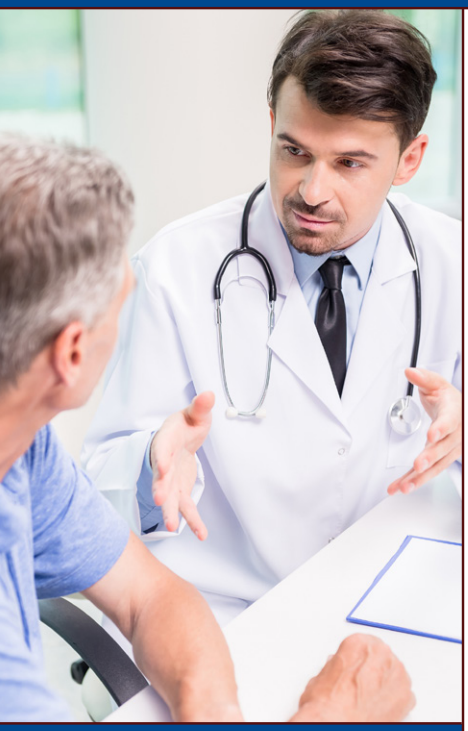
PCC Newsletter 2016

Preventing Colorectal Cancer News

Insights and Developments in the Fight Against CRC



Reflections from PCC Chair and Vice Chair

Dr. Steven Morris

Dr. Steven Morris

From its creation, the mission of PreventingColonCancer.org has centered on enabling patient access to colon care and preventative screenings. Over the past decade, PCC has identified barriers to access and has successfully removed or modified these barriers to achieve our goal of improving patient care and access.

A significant barrier identified by PCC early on was the lack of access to propofol anesthesia for patients undergoing screening colonoscopies. When we began our work with PCC, less than 25% of cases were done using MAC anesthesia. We challenged the prevailing sentiment and encouraged national organizations and insurers to adopt MAC anesthesia. By doing so, insurers could improve the experience for patients, remove the factor of any pain, and advance the performance of screening colonoscopy. Due

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Dr. Stanford Plavin

Dr. Stanford Plavin

As a founding member and vice chairman of PCC and National Coalition for Quality Colorectal Screening and Care, I am filled with a full range of emotions. Our journey started over nine years ago, initially in response to a policy change by an insurer, but has encompassed so much more!

We have seen our mission statement and agenda change and grow as the issues affecting our patients, their access to quality colorectal care and screenings, and the need for challenges and adjustments to both payor and public policy have evolved.

Our organization has achieved so much with the work of so few. It starts with the tremendous leadership of Dr. Steve Morris and our governmental affairs and consulting team headed by Garry Carneal and Randall Madry. It has continued with contributions by many physicians, practice administrators and executives, industry leaders and patient advocates. Our strength is our willingness to engage those that affect our mission and not be satisfied until the job is done.

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Dr. Stanford Plavin

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We made a difference that will continue long after our organization ceases to exist.

While looking back on our achievements, I would like to draw attention to a few of the initial encounters and issues that brought our organization into prominence and secured our legacy.

It began with our core group assisting the GA alliance in pushing back against Aetna's policy change in 2008. This policy interfered with the decision between physicians and their patients regarding anesthesia care for endoscopy procedures. After rebutting those attempts, our organization set our sights on the mission of improving access to quality screening and care while never losing touch of our central principles founded in patient care and choice.

We engaged pharma on a number of occasions by emphasizing and promoting patient safety. We were able to ensure that Fospropofol, which is a sedative hypnotic pro-drug of propofol, would only be administered by those qualified to do so! This was our first encounter with the FDA; part two occurred when we once again carried the torch of patient safety by ensuring that Ethicon-Endo, a Johnson & Johnson subsidiary, which had hoped to have a robotic-like device sedate patients with limited oversight, was rebuked. The device, called SEDASYS, was ultimately approved with a more stringent label and has subsequently been withdrawn from their portfolio.

More importantly, we have engaged in a number of initiatives with managed care organizations in many states when patient access to anesthesia and GI services was threatened. These fights were founded in patient care, safety, outcomes, access, and ensuring that the patient-physician relationship would not be compromised by financial decisions alone.

That being said, during our tenure the growth of anesthesia services and endoscopy, as well as the importance of access and improvements regarding screenings, has dramatically improved. Even CMS has considered the involvement of anesthesia services to be a key and valued component to patient screenings and care.

As our mission and our organization wind down, we remain steadfast in our commitment and take great pride in what a small group of motivated individuals has accomplished.

We thank the members of our board, our corporate partners and the individuals without whose support and spirit none of this would have been possible.

Warmest regards,

Stanford R. Plavin MD
PCC Vice-chair

Dr. Steven Morris

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in no small part to our efforts, gastroenterologists throughout the United States now have the freedom to decide what is in the best interest of their patients. Today, it is estimated that over 70% of all screenings are performed with MAC anesthesia.

In addition to our efforts to improve access to propofol anesthesia, PCC has also advocated for the use of ambulatory surgery centers (ASC) for routine cases. ASC facilities are less expensive and make colonoscopy more affordable for patients. Many providers now insist that routine colonoscopies be performed at ASCs. PCC took these efforts to Capitol Hill, along with other organizations such as the ACS, and successfully lobbied for the removal of the co-pay for screening colonoscopy. This fix was included in the Affordable Care Act. Our successes with propofol adoption, the use of ASCs, and the removal of co-pays are but a few examples of what a small, but motivated, team can achieve.

However, the landscape as we know it is in constant flux. Insurers are still trying to roll back the gains made in anesthesia, definitions of what constitutes screening versus surveillance threatens to increase patient co-pays, consolidation of hospitals and purchase of physicians practices can lead to removal of affordable choices in some communities for patients, and states still cling to politically motivated and costly certificate of need (CON) laws. We must be diligent that as medicine transitions from a fee-for-service model to a value based reimbursement scheme that we do not allow preventative measures to be victims of cost cutting. We encourage both patients and physicians to continue to lobby and advocate for colon care and preventive screenings championed by PCC over the past nine years.

Steven J. Morris MD FACP
PCC Chair

Then and Now: Let's take a look at some of the key issues PCC has addressed over the past nine years.

Retrospective 1: First printed Fall 2009, "Assessing the Impact of Health Care Reform on Cancer Prevention" by Steven J. Morris, MD, PCC Board Chair

Expanding strategies to prevent colorectal cancer must be a fundamental pillar of any health care reform program that is passed by Congress and implemented this year or in the future. However, consumers, providers, and others need to be vigilant to make sure that special interest groups do not compromise the accessibility, quality and cost of care—including any reforms that relate to the prevention and treatment of colorectal cancer. Improving the health care system and how we pay for it will continue to be a top priority. The physician community and patient advocates agree that change is needed, but the specific aspects of any new health care reform initiative will need to be worked out and tweaked over time. A key value that all physicians share is that we want our patients to have access to insurance without discrimination for pre-existing illness, no exorbitant deductibles or co-pays, no lifetime coverage caps, and to make insurance portable despite loss of job or change in location.

Colorectal cancer remains the second leading cause of cancer deaths. This year an estimated 147,000 Americans will be diagnosed with colorectal cancer and 56,500 will die from this disease. The larger tragedy is that colorectal cancer is one of the most treatable cancers if detected early. Colorectal cancer screening with colonoscopy, the gold standard, is an effective tool in the fight against this deadly disease.

Despite our efforts to promote quality patient care in cancer prevention and screening, colorectal cancer screening rates remain poor. Only 25-40% of adults over age 50 report receiving screening tests, depending on age and gender. Only 37% of cases are diagnosed when the disease is still localized. And, diagnosis at later disease stages results in substantially lower survival.

Based upon these trends and others, the mission of our organization is to educate the public and key stakeholders about the work we do as physicians, nurses and other caregivers and share the opportunities to reduce the incidence of colorectal cancer through maintaining screening and care options for patients.

In addition to payment and coverage issues, the current health care reform debates provide us an opportunity to discuss and promote enhanced evidence-based strategies related to better colorectal cancer screening and care. The Coalition provides a community and forum for all of us to develop better approaches or reinforce existing ones.

To view the entire newsletter go to *http://www.preventingcolorectalcancer.org/sites/default/files/fall2009newsletter.pdf*

Current statistics: There's good news in the fight against colorectal cancer. Since the preceding article was published in 2009, the rates for estimated new cases of colorectal cancer in 2016 is down by 9% to 134,490[1]. Screening rates have substantially increased to 59% for those over 50 or older[2].

Retrospective 2: First printed Fall 2011, "Consumer Advocate Section: Preventative Screening Covered Under the Affordable Care Act" by Randall H. H. Madry, PCC Executive Director

The Patient Protection and Affordable Care Act (PPACA) has become law, and under this reform initiative many are now covered for colorectal cancer preventive screenings without a copay or deductible. Unfortunately, not every health benefit plan is completely covered by the new law. Existing health benefit plans that are grandfathered in will not be covered by the initiative until 2014.

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[1] Cancer.Net. (June 2016). Colorectal Cancer: Statistics. Retrieved from *http://www.cancer.net/cancer-types/colorectal-cancer/statistics.*

[2] American Cancer Society. (2014). Colorectal Cancer Facts & Figures. Retrieved from *http://www.cancer.net/cancer-types/colorectal-cancer/statistics*

Then and Now

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From a colorectal cancer screening and care perspective, one of the most important elements of PPACA is found in Section 2713. This section states, "A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for-(1) evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force."

Colorectal cancer is the second leading cause of cancer deaths; it is also one of the most treatable cancers if detected early. Colonoscopy is recognized on the United States Preventive Services Task Force (USPSTF) list of evidence-based services, and received an 'A' rating. With this rating in place, if a person is covered by a health benefit plan that is subject to Section 2713 of PPACA, and is of the appropriate age, they can sign up for a potentially life-saving colorectal cancer colonoscopy and will not be charged a copay or deductible.

However, if a health benefit plan is grandfathered in or has been granted a waiver by the Obama Administration, there still may be a copay or deductible associated with the procedure. Health insurance carriers are required to advise customers if the plan is grandfathered at the time of renewal. If a person has individual coverage, they can contact their broker or call their health benefit carrier, or, if they are covered under a group plan, they can contact their employer's health benefits representative.

Time ultimately will cure this problem. The waivers and grandfather provision only last until 2014, at which time all plans will have to comply with Section 2713.

Some payors are only defining the colorectal cancer screening colonoscopy as a preventive service with no out-of-pocket costs as long as the procedure does not identify and remove a polyp. Once the procedure finds and removes a polyp, the payor then defines it as a non-screening procedure with applicable deductibles and co-pays. We at PCC take strong exception to this action on the part of payors. Because of that action, many patients who undergo what was billed as a no out of pocket cost screening colonoscopy are given a potentially hefty bill with a hefty for undergoing a procedure that has the potential of saving the payor the cost of eventually treating a very expensive colorectal cancer patient. That is simply unacceptable. We are actively supporting efforts in Congress to make that practice illegal.

However it is important for individuals to understand that whatever the out-of-pocket costs for a colorectal cancer screening colonoscopy may be, it can't be as significant as the opportunity for a colorectal cancer screening colonoscopy to detect and remove pre-cancerous polyps. You can't put a price on health and well-being, and compared to the cost of becoming a colorectal cancer patient, the out-of-pocket expense of a colonoscopy is relatively insignificant.

To view the entire newsletter go to *http://www.preventingcolorectalcancer.org/Newsletter/PCCFall2011/ConsumerAdvocateSection.htm*

Current: The issue of cost sharing if a polyp was removed during a colonoscopy screening was clarified to state "….the plan or issuer may not impose cost-sharing with respect to a polyp removal during a colonoscopy performed as a screening procedure[3]."

In addition, CMS stated, "The definition of colorectal screening tests has been revised to include anesthesia furnished in conjunction with screening colonoscopies effective January 1, 2015. In order to encourage beneficiaries to seek colorectal cancer screening services, the coinsurance and deductibles will be waived for anesthesia or sedation services furnished in conjunction with screening colonoscopies[4]."

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[3] The Center for Consumer Information & Insurance Oversight. Centers for Medicare & Medicaid Services. Affordable Care Act Implementation FAQs-Set 12: Coverage of Preventive Services. Retrieved from *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-10-31-7.html?DLPage=1&DLEntries=10&DLFilter=policy%20and%20p&DLSort=0&DLSortDir=descending*

[4] Centers for Medicare & Medicaid Services. (October 2014). Policy and payment changes to the Medicare Physician Fee Schedule for 2015. Retrieved from *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-10-31-7.html?DLPage=1&DLEntries=10&DLFilter=policy%20and%20p&DLSort=0&DLSortDir=descending*

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Retrospective 3: First printed in May, 2012, "Preventing Colon Cancer: The Benefit of Propofol".

The Issue: Medical procedures such as colonoscopy provoke concern and anxiety for most patients. In fact, patients tend to avoid experiences out of fear of pain and the potential outcome of the test. Patients who have uncomfortable or painful colonoscopies are likely to be more reluctant to return for their next colonoscopy. Also, friends and family who hear about a patient's uncomfortable or painful experience will become more hesitant to schedule a colonoscopy—a potentially lifesaving procedure. Since colorectal cancer is the second leading cause of cancer deaths in the United States, killing more than 50,000 Americans annually, encouraging colonoscopy screenings is vital.

The Opportunity: By promoting a painless approach to colonoscopy, more Americans will get screened, which will increase the early detection of pre-cancerous polyps and thus save thousands of lives. When anesthesiologists or Certified Registered Nurse Anesthetists (CRNAs) administer propofol for monitored anesthesia care during a colonoscopy, patients are deeply sedated and have a faster recovery profile than when sedated with synthetic opioids. Therefore, the use of propofol will improve clinical outcomes and eventually decrease health care system costs by reducing the incidence of colon cancer.

Higher Polyp Detection Rate: The administration of propofol in the endoscopy suites, hospitals and ambulatory surgical centers improves the sedation experience for the patient, allowing the gastroenterologist to focus exclusively on the procedure and less on concerns about the patient's vital signs and comfort when teamed up with an MD anesthesiologist or CRNA trained to manage all types of clinical situations and make fundamentally sound and safe decisions about the care of patients. The administration of propofol during a colonoscopy screening has been linked to increased rates of polyp detection during the exams, higher colon completion (cecal intubation) rates, as well as improved patient satisfaction.

According to a study by Dr. Katherine Hoda of the Oregon Health and Sciences University, more pre-cancerous polyps are found in colonoscopies performed with deep sedation primarily using propofol than with milder sedation in which patients remained conscious. The retrospective review of nearly 105,000 procedures shows that physicians found polyps larger than 9mm or suspected colorectal tumors at a 25% higher rate in patients under deep sedation than those under moderate sedation.

This research further bolsters the findings of two studies completed by the University of Pennsylvania and State University of New York. These studies tracked results from facilities that switched from having the gastroenterologist performing both the colonoscopy procedure and supervising/delivering the conscious sedation, to having the gastroenterologist perform the colonoscopy with a CRNA or anesthesiologist who administered propofol. The findings revealed that polyp detection improved up to 43% when the medical team included an anesthesiologist or CRNA. In light of these studies, GI-only directed sedation with propofol could represent a step backwards in terms of emerging standards of care.

Patient Safety First: Patient safety should be the top priority in all discussions related to colon cancer screening. In fact, many experts agree propofol should be administered only by persons trained in the administration of general anesthesia, airway management and life support techniques and should not be involved in the actual diagnostic/surgical procedure.

While very safe when administered by properly trained and experienced clinicians, propofol takes effect quickly and can move rapidly from light sedation to a state of general anesthesia, and is potentially dangerous when administered by personnel who lack extensive training. The U.S. Food and Drug Administration recognizes this and has placed a black box warning on propofol that states, "For general anesthesia or

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monitored anesthesia care (MAC) sedation, Propofol Injectable Emulsion should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure…."

For example, monitoring patient blood oxygen saturation levels while a patient is sedated is one of the key elements to avoid any adverse consequences. Anesthesiologists and CRNAs are the most appropriate professionals to oversee patient sedation, and the deployment and use of these trained professionals should be considered as a best practice.

The Question of Cost: There has been much written about the use of anesthesia professionals administering propofol and the additional cost this adds to the procedure. As Dr. Morris pointed out in the April/May 2010 issue of AGA Perspectives, the cost of outpatient screening colonoscopy has dramatically dropped over the past several decades. The use of propofol with the assistance of an anesthesia professional adds very little and has been the harbinger of dramatic improvement in procedure quality, patient acceptance and ability to increase patient access. The high cost of colonoscopy in hospitals, academic centers and out of network facilities remains a problem and can often result in cost that is dramatically more expensive. The next Issue Brief in our series will highlight this aspect of screening.

Conclusion: Patients undergoing a colorectal cancer screening should be provided with optimal options for a safe, comfortable and clinically superior colonoscopy—in most cases, that means a patient who is anesthetized with propofol administered by an anesthesiologist or CRNA. It is the recognized standard of care in most areas of the country, and is continuing to become so in areas that have been clinging to the older practices. Patients deserve nothing less than the highest quality of care.

To view the Issue Brief go to *http://www.preventingcolorectalcancer.org/IssueBrief/PCCIssueBrief2/PccIssueBrief2.html*

Current: Propofol is now considered the gold standard and is offered in most areas of the country[5]. There are still pockets of the U.S. where the use of propofol during a colonoscopy screening is not offered; this continues to be an issue of concern.

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[5] Preventing Colorectal Cancer. (March 2016). The Importance of Offering Propofol during a Colonoscopy Procedure. Retrieved from *http://preventingcolorectalcancer.org/IssueBrief/PCCIssueBrief13/Pcc-Issue-Brief-13.html*