

# Gastroenterology & Endoscopy News

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## ENDOSCOPY SUITE

### ASGE Unveils New Training Facility

BY BRIGID DUFFY

As the global home of endoscopy, the American Society for Gastrointestinal Endoscopy (ASGE) was long in need of a training facility worthy of its stellar reputation. After nine years of planning, see [IT&T](#), page 28

### WEO Provides Global Training In Endoscopy

BY VICTORIA STERN

Early last year, the World Endoscopy Organization (WEO) organized the first Program for Endoscopic Teachers (PET). The aim of the two-day program, held in Hyderabad, India, was to provide see [PET](#), page 35

## NATIONAL COLORECTAL CANCER AWARENESS MONTH



### FOBT Shows 'Striking' Results for Long-Term Reduction in CRC Mortality

BY MONICA J. SMITH

SAN DIEGO—A randomized controlled trial (RCT) of fecal occult blood test (FOBT) screening for colorectal cancer (CRC) has demonstrated dramatic reductions in mortality. The results are highly durable and persistent, and also support the role of polypectomy.

Results of the Minnesota Colon Cancer Control Study, which included more than 46,000 participants, aged 50 to 80 years, who were randomized to receive annual or biennial CRC screening with FOBT, or no screening, showed a relative risk for CRC-related mortality of 0.68 in the annual screening arm and 0.78 in the biennial screening arm through 30 years of follow-up. This translated into risk reductions of 32% with annual screening and 22% with biennial screening.

The Minnesota study confirms the findings of two RCTs of biennial CRC screening with FOBT carried out in the United Kingdom and Denmark see [FOBT](#), page 18



## OPINION

### Colonoscopy—Facts *The New York Times* Omitted



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If you happened to come across *The New York Times* article "The \$2.7 Trillion Medical Bill: Colonoscopies Explain Why U.S. Leads The World in Health Expenditures" (by Elisabeth Rosenthal, June 2, 2013), you undoubtedly felt outraged by what you read, perhaps even betrayed. Outraged to

learn about the exorbitant cost of colonoscopy and the profit-mongering schemes of those who provide the service. Betrayed by the insight that the entire thing may have been a fraud: Your colonoscopy may not have even been medically necessary.

On the other hand, if you were a patient at any one of the 5,300 physician-owned and operated ambulatory surgery centers (ASCs) across the country, you may have felt perplexed, even confused. You could not easily dismiss the

see [Colonoscopy](#), page 6

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### EXPERT REVIEW

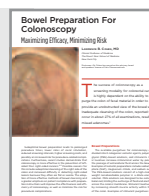
Postoperative Pain Management  
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### CLINICAL REVIEW

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**Bowel Preparation for Colonoscopy:  
Maximizing Efficacy, Minimizing Risks**  
By Lawrence B. Cohen, MD



### PRODUCT ANNOUNCEMENT

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**Medivators' Jet Prep  
Flushing Device**

for cleansing of GI mucosa  
during endoscopic procedures



### FROM THE BENCH TO THE BEDSIDE

see pages 10-11

**Solesta for the Treatment of Fecal  
Incontinence**

Mitchell A. Bernstein, MD, FACS, FASCRS





## PET

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a framework for endoscopy training programs around the globe.

“The idea was to create a program on how to teach safe and high-quality endoscopy and improve the quality of endoscopic services, which could be brought to many institutions around the world, particularly the developing world,” said Douglas Faigel, MD, PET program director and professor of medicine at Mayo Clinic, Scottsdale, Ariz.

In 2009, Jerome D. Waye, MD, president of WEO, devised the idea for PET after recognizing a major flaw in endoscopy education. "There are no programs aimed at teaching endoscopists how to teach," said Dr. Waye, clinical professor in the Department of Gastroenterology at Mount Sinai Medical Center, New York City. "When I first became president of WEO, I thought that I would like to have a special program to educate

endoscopists in the art of teaching endoscopy, and establish guidelines."

D. Nageshwar Reddy, MD, chairman and chief of gastroenterology, Asian Institute of Gastroenterology, in Hyderabad, volunteered to host the first meeting and invited the major trainers of endoscopy in India and from surrounding countries. Approximately 65 experts attended. The faculty included experienced instructors from the United States, India, China,

Chile, Egypt and Singapore, and guests were hand-selected based on their interest and willingness to teach endoscopic skills in their respective countries. Representatives from industry, including Olympus, Boston Scientific and Cook Medical, helped fund the program and were in attendance as well.

## PET Design

"The PET was designed to provide experienced endoscopists, working in countries that do not have an adequate number of trained endoscopists, with greater knowledge of the techniques and methods for teaching endoscopic skills," said Lawrence Cohen, MD, gastroenterologist and clinical professor of medicine at the Icahn School of Medicine at Mount Sinai in New York City, who taught courses at the meeting.

**DISCUSSION**

Interactions with Antimetabolite Therapy. Concurrent use of atazanavir and zalcitabine with PPIs is not recommended. Concomitant use of atazanavir with PPIs is expected to substantially decrease atazanavir plasma concentrations and may result in a loss of therapeutic effect and the development of drug resistance. Concomitant use of atazanavir with PPIs is expected to increase zalcitabine concentrations, which may increase toxicity and require dose reduction. Conversely, if atazanavir is used in combination, but is not expected to interact with some antiretroviral drugs. The clinical importance, and the mechanism behind these interactions are not always known. Increased gastric pH leading to decreased treatment drug efficacy, the absorption of some antiretroviral drugs. Other possible interactions mechanisms are via CYP3A4. Reduced concentrations of atazanavir and zalcitabine. For some antiretroviral drugs, such as stavudine, zalcitabine, zalcitabine, decreased serum levels have been reported when given together with atazanavir. Following multiple doses of zalcitabine (1250 mg, twice daily) and atazanavir (400 mg daily), AUC was decreased by 35% and 50%, C<sub>max</sub> by 35% and 50% and C<sub>min</sub> by 50% and 75%, respectively for zalcitabine and AUC. Following multiple doses of atazanavir (400 mg daily) and zalcitabine (400 mg daily, 2 to 4 hours after atazanavir), AUC was decreased by 94%, C<sub>max</sub> by 90%, and C<sub>min</sub> by 94%. Concurrent administration with atazanavir and drugs such as stavudine and zalcitabine is therefore not recommended. Decrease concentrations of zalcitabine. For other antiretroviral drugs, such as zalcitabine, elevated serum levels have been reported, with an increase in AUC by 62%, C<sub>max</sub> by 70%, and C<sub>min</sub> by 70%. Following multiple dosing of zalcitabine (1250 mg, twice daily) and atazanavir for 10 days with zalcitabine (400 mg daily) concomitant dosing, 11 to 15. Clinical and laboratory monitoring for zalcitabine toxicity is recommended during concurrent use with atazanavir. Dose reduction of zalcitabine should be considered from the safety perspective for both adult patients.

**Drugs for Which Gastric pH Can Affect Bioavailability:** Esomeprazole inhibits gastric acid secretion. Therefore, esomeprazole may interact with the absorption of drugs whose gastric pH is an important determinant of bioavailability (e.g., lefampridine, docusate, iron salts, and ceftriaxone can decrease, while the absorption of drugs such as alginic acid can increase their potential bioavailability). Concomitant treatment with esomeprazole (20 mg daily) and alginic acid in healthy subjects increased the bioavailability of digoxin by 17% (20% in two subjects). Esomeprazole is an enhancer of esomeprazole. Combination of alginic acid with esomeprazole is expected to increase the systemic exposure of alginic acid. Patients may need to be monitored when digoxin is taken concomitantly with esomeprazole.

**Effects on Hepatic Metabolism/Excretion:** P-450 Pathways: Enzyme: is extensively metabolized in the liver by CYP2C9 and CYP3A4, it should be one studies have shown that enoxaparin is not likely to inhibit CYPs 1A2, 2A4, 2D6, 2E1, and 3A4. No clinically relevant interaction with drugs metabolized by these CYP enzymes would be expected. Drug interaction studies have shown that enoxaparin does not have any clinically significant interaction with phenytoin, quinine, chlofazimine, or cimetidine. Although drug interaction studies have not shown that enoxaparin is a clinically significant interaction with warfarin, post-marketing reports of changes in prothrombin measures have been received among patients on enoxaparin sodium and warfarin therapy. Increases in INR-enoxaparin time may lead to abnormal bleeding/over-anticoagulation. Patients treated with P450s are enoxaparin consistently may need to be monitored for increases in INR on enoxaparin time. Enoxaparin may potentially interfere with CYP2C9, the major enoxaparin metabolizing enzyme. Combination of enoxaparin 30 mg and clozapine, a CYP2C9 substrate, resulted in a 40% decrease in clearance of clozapine. Dipyridol is metabolized to its active metabolite is just by CYP2C9. Concurrent use of enoxaparin 40 mg results in reduced plasma concentrations of the active metabolite of dipyridol and a reduction in platelet inhibition. Avoid concurrent administration of enoxaparin sodium with dipyridol. When using enoxaparin sodium, consider use of alternative and platelet therapy. Enoxaparin acts as an inhibitor of CYP2C9. Enoxaparin, given in doses of 40 mg daily for one week in 20 healthy subjects in a cross-over study, increased C<sub>max</sub> and AUC of clindamycin by 35% and 26% respectively. C<sub>max</sub> and AUC of one of its active metabolites, 3,4-dihydroclindamycin, which has 4-7 times the activity of clindamycin, were increased by 2.4- and 3.8% respectively. Combination of clindamycin with enoxaparin is expected to increase concentrations of clindamycin and its active metabolite. A dose reduction of clindamycin from 140 mg twice daily to 80 mg twice daily should be considered. Concurrent administration of enoxaparin and a combined inhibitor of CYP2C9 and CYP3A4, such as voriconazole, may result in more than doubling of the enoxaparin exposure. Dose adjustment of enoxaparin is not routinely applied. However, in patients with Zollinger-Ellison's Syndrome, who may require higher dosages to 200 mg daily, dose adjustment may be considered. Drugs known to induce CYP2C9 or CYP3A4 or both (such as rifampin) may lead to decreased enoxaparin serum levels. Enoxaparin, of which enoxaparin is less sensitive, has been reported to interact with St. John's Wort, an inducer of CYP3A4. In a cross-over study in 12 healthy male subjects, St. John's Wort (90 mg three times daily for 14 days) significantly decreased the systemic exposure of enoxaparin to CYP2C9 poor metabolizers (C<sub>max</sub> and AUC decreased by 32.5% and 37.5%, respectively) and extensive metabolizers (C<sub>max</sub> and AUC decreased by 68.8 % and 45.9%, respectively). Avoid concurrent use of St. John's Wort or rifampin with enoxaparin sodium.

**Interactions in Investigations of Rheumatoid Arthritis** (Long-induced disease is genetic; acutely results in extraosseous effects; not hyperplastic and increased Chondrocyte loss, which may interfere with investigation of osteoarthritis).  
 Furthermore, treatment administration of corticosteroids and analgesics may increase the acute levels of inflammation.

cholinergic, and succinyls has resulted in increases in the plasma levels of succinyls and 14-hydroxydichloroquine. Concurrent administration of dichloroquine with other drugs can lead to serious adverse reactions due to drug interactions [see WARNINGS and PRECAUTIONS in prescribing information for dichloroquine]. Because of these drug interactions, dichloroquine is contraindicated for concomitant administration with certain drugs [see CONTRAINDICATIONS in prescribing information for dichloroquine].

**Metabolism:** Case reports, published population pharmacokinetic studies, and retrospective analyses suggest that concurrent administration of PPIs and metformin (primarily at high dose; see metformin: prescribing information) may decrease and prolong some levels of metformin: *in vitro* to metabolic: hydroxyphenylacetic acid. However, no formal pharmacokinetic studies of metformin: *in vitro* to metabolic: hydroxyphenylacetic acid have been conducted.

**STAND FILL**

**Pregnancy Category C:** There are no adequate and well-controlled studies of cospasane situations during pregnancy; exposures in pregnant women. Experimentally was not observed an embryofetal developmental study in rats with cospasane situations or cospasane suspension at 0.5 mg/kg and doses up to 250 mg cospasane/kg/day (about 87 times the daily maximum recommended human dose: 250 mg) of 48 mg in a body surface area basis. When administered on either the duration or suspension only, changes in bone morphology and physical properties were observed in pre- and postnatal developmental toxicity studies in rats at doses equal to or greater than 135 mg cospasane/kg/day (approximately 33.6 times the daily MMRD) of 48 mg in a body surface area basis. Because of the observed effect at the high doses of cospasane situations on developing bone in rat studies, cospasane situations should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Swiss Medicines Limited published data indicate that cefuroxime and stavudine are present in human milk. Because of the effect of cefuroxime, stavudine observed at high doses on developing bone in rat studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Problems thus limit the study and effectiveness of emergency situations delayed release capsules have not been established in pediatric patients. Therefore, whenever capsules are indicated for intraluminal absorption and is incorporated into form, the in pediatric patients is not recommended because adequate safety studies have not been performed. Caution thus limit the overall effectiveness in safety and efficacy were observed between the elderly and younger individuals, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater variability of some elderly individuals cannot be ruled out.

Due to PatientWatch Band limitations the design effectiveness necessary in patients with mild to moderate renal impairment. The pharmacokinetics and safety of sitagliptin in patients with severe renal impairment has not been studied and, therefore, use in this patient population is not recommended.

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A single-blind study of intracranial at 3300 mg/day (about 1183 doses for humans dose on a body surface area basis), was failed to rate. The major signs of acute toxicity were reduced motor activity, changes in respiratory frequency, tremor, ataxia, and incoordination. Chronic conditions: The symptoms described in humans with idiopathic intracranial pressure: limited exposure of doses in excess of 2880 mg/day) are transient. Single doses of 3300 mg of intracranial were successful. Reports of chronic toxicity with intracranial in humans may also be relevant. Doses ranged up to 2,400 mg (1233 doses for usual recommended clinical dose). Manifestations were variable, but included confusion, drowsiness, blurred vision, headache, nausea, diplopia, flushing, bradycardia, dry mouth, and other adverse reactions similar to those seen in usual clinical exposure (see intracranial package insert - AMPHIS PERMANENT). No specific antidote for intracranial in humans. Since intracranial is extremely potent, it is not expected to be absorbed by adipose. In the event of overdose, treatment should be symptomatic and supportive. As with the management of any overdose, the possibility of multiple drug ingestion should be considered. For consultation on treatment of any drug overdose contact a Poison Control Center at 1-800-222-1222.

Please use postage stamp to fill remaining information.

More detailed information is available upon request.  
For more information about emergency detection contact  
Animal Fluorocarbon at 1-877-826-5472.  
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**‘The idea was to create a program on how to teach safe and high-quality endoscopy and improve the quality of endoscopic services, which could be brought to many institutions around the world, particularly the developing world.’**

—*Douglas Faigel, MD*

To this end, the program delineated a set of strategies and rules on how to teach endoscopy using educational lectures, videos of mock training sessions and hands-on training with simulators. The lectures outlined criteria that make good teachers and students, and provided tactics for teaching technical and cognitive skills to trainees of all skill levels. For example, when teaching cognitive skills, instructors need to define a core curriculum in endoscopy and be able to tailor training to incorporate local practice and customs; risk management; pre- and postprocedure evaluation; and communication skills, as well as trainee assessment and mentoring. The trainer also should vary the educational format, supplementing textbook and lecture-based learning with videos and interactive approaches that include simulators and other training tools.

In a session entitled “Teacher and Student,” presenter Ibrahim Mustafa, MD, see [PET](#), page 36





## PET

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from Egypt, said that a teacher must regularly monitor how well trainees are acquiring necessary skills by documenting their experience with procedures and determining how well they have met specific performance standards. The teacher should not only evaluate students, but also allow trainees to provide feedback and personalize the curriculum as needed.

In the same session, Dr. Wayne explained that when teaching technical skills, instructors should be patient and encouraging as students learn the ropes,

while also providing clear directions on what to do and how to do it. After a student has observed several procedures, possibly practiced on a simulator and aided a senior fellow during an actual procedure, the trainee should then handle the scope alone while the instructor watches closely and provides feedback throughout. Importantly, however, trainees should only be evaluated on their competence after completing a requisite number of procedures (Table).

see [PET](#), page 38

**Table. Threshold Numbers of Endoscopic Procedures Before Competency Can Be Assessed by Direct Observation or Other Objective Measures, as Required in Different Countries or Regions**

Procedure	United States <sup>a</sup>	Australia <sup>b</sup>	Canada	Poland	India	Europe <sup>c</sup>
Colonoscopy	140	100 to cecum	150	500	120	150
EGD	130	200	150	500	190	200
ERCP	200	200	200	200	140	150
EUS	150	200				150
Sigmoidoscopy	30		30			50

**EGD**, esophagogastroduodenoscopy; **ERCP**, endoscopic retrograde cholangiopancreatography; **EUS**, endoscopic ultrasonography

<sup>a</sup> American Society for Gastrointestinal Endoscopy guideline.

<sup>b</sup> Colonoscopy: cecal intubation in >90% of the last 50 logged procedures; ERCP: unassisted, with intact papilla, to include 80 sphincterotomies and 60 stent placements.

<sup>c</sup> European Board of Gastroenterology: Colonoscopy numbers include polypectomy and assume competency in EGD.

## An Organized Program for Global Training in Endoscopy



### Jerome D. Wayne, MD

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Past President,

American Society for Gastrointestinal Endoscopy

Past President, American College of Gastroenterology

Past President, World Endoscopy Organization

I have just stepped down from four years as president of the World Endoscopy Organization (WEO). This is an organization that oversees gastrointestinal endoscopy throughout the world. The major thrust is, of course, pointed at underserved areas where endoscopy is needed, but is a scarce commodity. During 2013, WEO organized a course called Program for Endoscopic Teachers, referred to as the PET program. When I began my presidency four years ago, I realized that this was a topic that had been completely overlooked by endoscopists throughout the world. There was no organized program for how endoscopy should be taught, who the instructors should be, what the curriculum should be for endoscopic teaching, what teaching material could be found on the Internet and how to best teach novices the techniques of the procedure. Additionally, there was no data to inform more advanced endoscopists how to perform more complex procedures.

The first PET meeting was held in Hyderabad, India, under the direction of Douglas Faigel, MD, of Mayo Clinic, Scottsdale, Ariz., and hosted by Nageshwar Reddy, MD, who famously helped initiate natural orifice transluminal endoscopic surgery by passing an endoscope through the stomach into the abdominal cavity. The first meeting brought together a cadre of known experts in endoscopic teaching and 40 endoscopic teachers from throughout India and Asia. The meeting was a resounding success, and so far this year, three countries have requested that the PET program be brought to their areas because of the important material, which even now is in a state of rapid evolution. This is an exciting area and will undoubtedly affect the way endoscopy is taught.



D. Nageshwar Reddy, MD, chairman and chief of gastroenterology at the Asian Institute of Gastroenterology, in Hyderabad, India, volunteered to host the World Endoscopy Organization's first Program for Endoscopic Teachers (PET) meeting. The aim of the two-day PET program, held in January 2013, was to provide a framework for endoscopy training programs around the globe.





## PET

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### Reflections on PET

Overall, Drs. Faigel and Waye agreed that the pilot program went well. “We had excellent attendance and interaction among experts and the feedback was very positive,” said Dr. Faigel. “We’re moving toward milestones and standardized training, and this program was a good first step to see how we could do so in India.”

**‘We have to be cognizant of local training facilities and local training venues for us to continue our success. We also want teachers to be able to adapt to different training situations and to be comfortable with using and teaching a variety of techniques and technologies.’**

**—Jerome D. Waye, MD**

Reflecting on the success of the program, Dr. Cohen noted, “the attendees were enthusiastic and seemed committed to taking their experience back to their respective country and attempting to implement some of the techniques and concepts discussed at the course.” For instance, two attendees from Myanmar (formerly Burma) expressed their desire to use the PET educational model to train more endoscopists in their country, Dr. Cohen said. Myanmar currently has four endoscopists serving a population of more than 30 million.

One attendee, C. Ganesh Pai, MD, professor and head of the Department of Gastroenterology and Hepatology, Kasturba Medical College, Manipal, India, agreed that PET was a “successful and informative” program that “brought together expertise from different parts of the world and exposed trainers to what is happening elsewhere.”

When asked how PET could be improved, Dr. Pai suggested “fewer lectures and more workshop-like situations, hands-on training and small-group interactive sessions, [that would involve] identifying problems in endoscopy training and solving them.”

Dr. Faigel concurred and, in the next meeting, plans to incorporate more breakout sessions and subgroup discussions, as well as to create specific sessions tailored to local issues. As for increasing



Approximately 65 experts attended the first Program for Endoscopic Teachers (PET) meeting in Hyderabad, India. Faculty included experienced instructors from the United States, India, China, Chile, Egypt and Singapore, and guests were hand-selected based on their interest and willingness to teach endoscopic skills in their respective countries. Representatives from industry, including Olympus, Boston Scientific and Cook Medical, helped fund the program and were in attendance as well.



hands-on training, Dr. Faigel noted that employing such features in local teaching facilities is expensive and may not be feasible everywhere, especially in parts of the world where resources and funds may be more limited. “We want a modular course so we can train with local faculty from all over the world and make implementation achievable for everyone involved.”

To this point, Dr. Waye said that, “We have to be cognizant of local training facilities and local training venues for us to continue our success.” But, Dr. Waye added, “We also want teachers to be able to adapt to different training situations and to be comfortable with using and teaching a variety of techniques and technologies.”

Going forward, the PET organizers plan to conduct at least one program a year and are currently planning other meetings. Three meetings are scheduled for 2014: July 11-12 in Moscow, Aug. 22-23 in Cairo and Dec. 5-6 in Rio. The PET meeting in Rio will be sponsored by Pentax, and the Moscow meeting will be sponsored by Boston Scientific. Planning is under way for a meeting in China in 2015.



## what is your opinion?

*Gastroenterology & Endoscopy News* is now accepting opinion pieces. Send your thoughts to the editor at:

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