Transcript Details

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Enhancing the Patient Colonoscopy Journey: Factors That Can Influence the Patient Experience

Announcer: This is ReachMD. Welcome to this medical industry feature titled Enhancing the Patient Colonoscopy Journey: Factors that Can Influence the Patient Experience" sponsored by Ferring Pharmaceuticals Inc. This program is intended for physicians.

Here's your host, Dr. Sophie Balzora.

Dr. Balzora: Since about one in four colonoscopies has an inadequate preparation [5], it's time we ask ourselves: what are we overlooking in our practices, and how can we better enhance the experience for our patients?

This is ReachMD and I'm Dr. Sophie Balzora. Joining me to talk about enhancing the patient journey and what that means for healthcare providers and their patients is Dr. Colleen Schmitt, gastroenterology expert from Chattanooga, Tennessee. Dr. Schmitt, welcome to the program.

Dr. Schmitt: Thank you, Dr. Balzora. I appreciate the opportunity to participate.

Dr. Balzora: So why don't we start from the beginning, Dr. Schmitt. How do you reflect on the patient

journey from initial consult to screening?

Dr. Schmitt: Well it all starts off with a referral. We have a process where our staff reaches out to patients for an interview, because it's important to understand the patient's medical history and other key information that helps us determine which colonoscopy bowel prep is appropriate for them. We then have multiple steps in place, even for open access patients, as it's important to have multiple touchpoints with patients to ensure they follow the process correctly. Every patient has different needs and requires educational information in order to help prepare them for their colonoscopy. So, whether the discussion is providing knowledge support for an ongoing problem, or for a first-time screening exam, this education is an important factor and it continues throughout the process. Failure to understand important parts of this information could reduce the effectiveness of screening.

Dr. Balzora: What elements of a patient's experience are important clinically, and which do patients and physicians consider most important?

Dr. Schmitt: Ultimately endoscopists want to hear our patients say, "It was no big deal." And without question, for all appropriate patients, a low volume prep is preferred. I've been in practice for over 25 years and sometimes see patients now for their 3rd time screening, and they say "[this was the best yet]". We don't want the prep to be The Thing that gets in the way of a patient returning for an examination. Today, there are three key factors that are essential for a good bowel preparation— a prep needs to be efficacious, it needs to be safe, and it needs to be palatable to the patient [4].

Dr. Balzora: And can you tell us about CLENPIQ (sodium picosulfate, magnesium oxide, and anhydrous citric acid) Oral Solution and the data that reflect a positive patient journey?

Dr. Schmitt: Sure. Well let's start with efficacy. CLENPIQ's FDA approval was based on clinical studies of another oral formulation of sodium picosulfate, magnesium oxide, and anhydrous citric acid.

In the split-dose trial, 84% of patients achieved excellent or good[1,2*] cleansing of the overall colon using the Aronchick scale, this assesses the colon before washing and suctioning. For the secondary endpoint, 90% of patients achieved successful cleansing of the ascending colon, which was defined as "excellent", "good", or "fair"[2*] using the Ottawa scale.

Additional data describing the efficacy and safety of CLENPIQ was recently published in Therapeutic Advances in Gastroenterology by Hookey, and colleagues. This randomized, assessor-blinded, multicenter, non-inferiority study compared split-dose, Clenpiq (the SPMC oral solution) to split-dose picosulfate magnesium oxide citric acid powder for reconstitution. Based on the Aronchick scale, which again assesses the colon prior to washing and suctioning, 88% of patients achieved successful

cleansing of the overall colon, the primary endpoint, [3]. In addition, 94% achieved successful cleansing of the ascending colon, 96% of the transverse colon, and 95% of the descending colon, which was the secondary endpoint.[3] For the secondary endpoint the investigators scored the colon using the Boston Bowel Prep Scale, which is conducted upon withdrawal and after all washing and suctioning is performed.

CLENPIQ was also well tolerated. So, with regard to safety the most common adverse reactions observed in greater than 2% of patients were nausea in (3%), headache in (3%), and hypermagnesemia in (2%). [3]

Hypermagnesemia levels were transient and not associated with any clinically significant outcomes. Eight of the 9 patients with hypermagnesemia returned to baseline within 24 to 48 hours, and one patient returned to baseline by the 7-day follow-up visit. [1]

In addition, vomiting was observed in only 1% of patients.[3]

To reflect on the patient experience, the new CLENPIQ study evaluated patient compliance and tolerability using the Mayo Clinic Bowel Preparation questionnaire. The results show 99% of patients completed the majority of the CLENPIQ prep. 90% felt that the prep was "easy" or "acceptable" to take and 98% said they would be "mostly or somewhat willing" to take CLENPIQ again. [3] These results from the questionnaire demonstrate a favorable tolerability profile and a very positive willingness to use CLENPIQ in the future [3]

Dr. Balzora: Thanks for breaking all of that down for us, Dr. Schmitt, and before we wrap up, how do you shift the focus back to the patient experience and away from the caregiver to ensure satisfaction?

Dr. Schmitt: More and more, we are moving toward providing the optimal patient experience in health care, from the time the patient calls the office until after they are discharged from the endoscopy unit. This experience will include multiple touchpoints from our entire team and should be a significant part of our focus. For bowel preparation in particular, this experience *needs* to be easy to achieve the desired goal, this is to complete a high-quality colonoscopy for our patient in one visit.

Dr. Balzora: Well with that, I want to thank Dr. Colleen Schmitt, for joining me to discuss how we can improve compliance and tolerability in patients who are preparing to undergo a colonoscopy. Dr. Schmitt, it was great speaking with you today.

Dr. Schmitt: I enjoyed the opportunity. Thank you, Dr. Balzora.

Announcer: For those listening, CLENPIQ indication for use and important safety information follow.

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Indication

CLENPIQ oral solution is indicated for cleansing of the colon as a preparation for colonoscopy in adults.

Important Safety Information

CLENPIQ is contraindicated in the following conditions: patients with severe renal impairment (creatinine clearance less than 30mL/minute), gastrointestinal obstruction or ileus, bowel perforation, toxic colitis or toxic megacolon, gastric retention, or in patients with a known hypersensitivity to any of the ingredients in CLENPIQ.

Patients should be advised to hydrate adequately (before, during and after use of CLENPIQ), and post-colonoscopy lab tests should be considered if a patient develops significant vomiting or signs of dehydration, including orthostatic hypotension, after taking CLENPIQ. Patients with electrolyte abnormalities should have them corrected before treatment. Use caution when prescribing CLENPIQ for patients that have conditions or are using medications that increase the risk for fluid and electrolyte abnormalities.

Use caution in patients who have conditions, or are taking concomitant medications that increase the risk for seizures, such as those taking medications that lower the seizure threshold, patients withdrawing from alcohol or benzodiazepines or patients with known or suspected hyponatremia.

Use caution in patients with impaired renal function or taking medications that may affect renal function, as well as patients at increased risk of arrhythmias, including those patients with a history of prolonged QT, recent myocardial infarction, unstable angina, congestive heart failure, or cardiomyopathy.

Osmotic laxatives may produce colonic mucosal aphthous ulcerations and there have been reports of more serious cases of ischemic colitis requiring hospitalization. Concurrent use of additional stimulant laxatives with CLENPIQ may increase this risk.

Use caution in patients with severe active ulcerative colitis.

Use caution in patients with impaired gag reflex as they may be at risk for regurgitation or aspiration during administration of CLENPIQ.

The safety of CLENPIQ has been established from adequate well-controlled trials of another oral formulation of sodium picosulfate, magnesium oxide, and anhydrous citric acid. The most common adverse reactions in those trials were nausea, headache, and vomiting.

CLENPIQ can reduce the absorption of co-administered drugs. Do not take oral medications within one

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hour of starting CLENPIQ. Administer tetracycline and fluoroquinolone antibiotics, iron, digoxin, chlorpromazine and penicillamine, at least 2 hours before and not less than 6 hours after administration of CLENPIQ to avoid chelation with magnesium.

You are encouraged to report negative side effects of prescription drugs to FDA. Visit FDA.gov/medwatch, or call 800.FDA.1088. To see the Full Prescribing Information, visit Clenpiq.com

The preceding program was sponsored by Ferring Pharmaceuticals Inc. To listen to other programs in this series, please visit ReachMD.com/NextGenBowelPrep. This is ReachMD. Be Part of the Knowledge.

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